**Tuesday, March 18, 2025 at 13:34:45 Eastern Daylight Time**

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**Subject:** RE: Am. Oversight v. HHS/FDA 20-cv-947 Final Draft Vaughn Segments
**Date:** Thursday, March 13, 2025 at 3:29:30 PM Eastern Daylight Time
**From:** Holland, Liam C. (CIV)
**To:** Emma Lewis
**CC:** FOIA, AO Records
**Attachments:** image001.jpg

Good Afternoon Emma,

I just sent a link to a box.com file sharing folder to you, FOIA@americanoversight.org, and records@americanoversight.org. That folder includes a complete production set for FDA records in this case as well as revised Vaughn segments from many of the earlier segments FDA had produced. This should conclude FDA's draft *Vaughn* production.

Let me know if you have any questions.

Best,
Liam

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**From:** Holland, Liam C. (CIV)
**Sent:** Wednesday, March 5, 2025 11:43 AM
**To:** Emma Lewis <emma.lewis@americanoversight.org>
**Subject:** Am. Oversight v. HHS/FDA 20-cv-947 Final Draft Vaughn Segments

Good Morning Emma,

Please see attached for the final two draft *Vaughn* segments from FDA in this matter. The JSR indicated that the agency anticipated these would be produced by 2/28. The delay is my fault—I misunderstood a communication from FDA.

FDA is going to get you a complete bates-stamped production set in the next couple of weeks—they're also re-reviewing some of the initial draft *Vaughn* segments, which may have a handful of pagination issues and other minor errors.

Thanks,
Liam

---

**From:** Emma Lewis <emma.lewis@americanoversight.org>
**Sent:** Friday, January 17, 2025 4:03 PM
**To:** Holland, Liam C. (CIV) <Liam.C.Holland@usdoj.gov>
**Subject:** [EXTERNAL] Re: JSR Due Today--Am. Oversight v. HHS/FDA 20-cv-947

Thanks Liam. I have no edits to the draft, and you have my permission to file.

AMERICAN OVERSIGHT

**From:** "Holland, Liam C. (CIV)" <Liam.C.Holland@usdoj.gov>
**Date:** Friday, January 17, 2025 at 1:29 PM
**To:** Emma Lewis <emma.lewis@americanoversight.org>
**Subject:** JSR Due Today--Am. Oversight v. HHS/FDA 20-cv-947

Good Afternoon Emma,

I hope all is well with you. We have a JSR due today in this matter. Please see attached for a draft. Let me know if this is acceptable to file with your signature, or if you have any edits or comments.

Thanks,
Liam

**Liam Holland**
Trial Attorney | United States Department of Justice
Civil Division | Federal Programs Branch
Tel: (202) 514-4964

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AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/11/2020 12:26:57 PM
**To**: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
**CC**: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
**Subject**: RE: URGENT 1pm deadline for : CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine
**Attachments**: ASPR News Release 2019-nCoV vaccine1_v7RB for HHS clearance.docxFDA.docx

Megan,

Liz had some excellent points. Attached please find an updated version with nuances on the diagnostics.

Uwe

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 11:52 AM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
**Subject:** RE: URGENT 1pm deadline for : CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine

A few comments in the attached. Thanks.

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 11:14 AM
**To:** CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Choe, Lena <Lena.Choe@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Subject:** URGENT 1pm deadline for : CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine
**Importance:** High

AMERICAN OVERSIGHT

Hi all – please see the attached PR from ASPR. Asking for concurrent clearance given the short turnaround and the reference to multiple products – vaccines, diagnostics, and therapeutics. CDRH -copying Heather Agler through the IMG, as well as Uwe and Kim since this references the EUA. Also, ccing Jennifer Ross from OCET and Toby Lowe (CDRH) given reference to EUA.

**Comments are now due today @ 1:00 p.m.**

V/R,

Naweed Lemar
U.S. Department of Health and Human Services
Direct: (b) (6)
Mobile: (b) (6)
Email: naweed.lemar@hhs.gov

---

**From:** OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>
**Sent:** Tuesday, February 11, 2020 9:02 AM
**To:** OS - ASPA - Clearance <OS.ASPA-Clearance@hhs.gov>; OS - ASPA - Public Health Clearance <OS.ASPA-PublicHealthClearance@hhs.gov>
**Cc:** Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>; Walz, Christopher (OS/ASPR/OEA) <Christopher.Walz@hhs.gov>
**Subject:** CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine

**Close-Hold**

**Agency/Office**: ASPR

**Subject (or headline)**: 2019-nCoV vaccine development

**Materials**: Press release

**Deadline for comments**: Today @ 3:00 p.m.

**Planned release date**: Wednesday, February 12

**Driving Event**: Other Transaction Authority agreement expansion signed; company news release timed for stock market opening

V/R,

Naweed Lemar
U.S. Department of Health and Human Services
Direct: (b) (6)
Mobile: (b) (6)
Email: naweed.lemar@hhs.gov

AMERICAN OVERSIGHT

(b) (5) Draft

AMERICAN OVERSIGHT

(b) (5) Draft

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 10:05:40 PM
**To**: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: White House Request-Due 0900 tomorrow (Wednesday)

Michael, this will work, since we only provide the number and not information on the individual companies. So we are good.

Uwe

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 10:00 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: White House Request-Due 0900 tomorrow (Wednesday)

Can we add this? Or is it confidential?

<< File: CoV Diagnostics USG Interagency One-pager v6_FDA.docx >>

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 9:36 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: White House Request-Due 0900 tomorrow (Wednesday)

Michael, Rosemary,

Diagnostics look good, no comments. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 8:21 PM
**To:** Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** FW: White House Request-Due 0900 tomorrow (Wednesday)
**Importance:** High

Hi – please take a look and send me any comments before the deadline if possible thx -m

Understanding is that this is a briefing for the White House Task Force – currently scheduled to meet at 4pm on Thursday. After that brief, a subset will go in to brief POTUS. Drs. Fauci (and likely Kadlec) will be doing the briefing for the *Task Force*.

---

**From:** Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>
**Sent:** Tuesday, February 4, 2020 7:31 PM
**To:** Embry, Alan C (NIH) (b) (6) @niaid.nih.gov>; Jennifer Kishimori <jennifer.m.kishimori.mil@mail.mil>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Biggins, Julia (MIL) <julia.e.biggins.ctr@mail.mil>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>
**Cc:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Armstrong, Kimberly (OS) <Kimberly.Armstrong@hhs.gov>; Tse, Brian (OS) <Brian.Tse@hhs.gov>; Donabedian, Armen (OS) <armen.donabedian@hhs.gov>; Donis, Ruben (OS) <Ruben.Donis@hhs.gov>
**Subject:** RE: White House Request-Due 0900 tomorrow (Wednesday)

All,

Thanks for your patience as we worked through a number of rapid-fire tasks today. I've attached the following documents for your review:

1)Therapeutics one pager
2)Vaccines one pager
3)Diagnostics one pager
4)Two overview slides: talking points and graphic

Please add information that is missing and return the documents by 0900 tomorrow (Wednesday). I'll adjudicate comments and make edits once I receive input from each Agency. I understand that all need to go through ASPR and NIAID clearance tomorrow.

Thanks again for your input and your patience as we polished these documents as much as possible today.

Best,
Christy

AMERICAN OVERSIGHT
<< File: CoV Diagnostics USG Interagency One-pager v6.docx >> << File: 2019_nCoV_Tx_One_Pager_v4 02042020.docx >> << File: Vaccines-1-pager v1ad.docx >> << File: ASPR-WH Slide Deck_v5.pptx >>

--
Christy L. Ventura, Ph.D.
Tunnell Government Services
Executive Secretary, 2019-nCoV Medical Countermeasures Task Force
Project Manager, CBRN/BARDA/ASPR/HHS
O'Neill 23L05
Office: (b) (6)
Cell: (b) (6)

---

**From:** Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
**Sent:** Monday, February 3, 2020 10:24 PM
**To:** Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Tse, Brian (OS/ASPR/BARDA) <Brian.Tse@hhs.gov>; Donabedian, Armen (OS/ASPR/BARDA) <armen.donabedian@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>
**Cc:** Marston, Hilary (NIH/NIAID) [E] <(b) (6) @nih.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>; Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>
**Subject:** White House Request-Due COB tomorrow (Tuesday)

All,

We have received a request from the White House Task Force. We need to provide the S1 with three one-pagers, one each for diagnostics, vaccines, and therapeutics. ASPR also wants a single slide showing product development for all three, close collaboration between agencies, etc. we will also put together a slightly longer deck with more detail around the one-pagers.

I've asked Rosemary to coordinate the diagnostic one-pager.

BARDA will take the pen on the one pager, but we are going to have pieces coming in from DoD and NIAID. The attached word document is a very rough outline. Below is what we are thinking in terms of specifics:

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

I recognize the challenge in this approach, but just do not see a better approach with the time we have. I need the first draft of the one pagers by about noon tomorrow, so we can start dropping in pieces and working on the flow. I've copied Hilary so she can weigh in with any thoughts.

(b) (5)

For all of these, we're going for bullet format, lots of white space.

We can chat tomorrow a.m., but I wanted to get this out to you tonight in case some of you had time/wanted to get a jump.

Thanks.

Robert

**Robert Johnson, Ph.D.**
Director, Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research and Development Authority
**BARDA**
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
Office: (b) (6)
Cell: (b) (6)
email: Robert.Johnson@HHS.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 3:38:28 PM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Attachments**: SIGNED_CDC_2019_nCoV_EUA_Ltr.pdf

Dear Julie, Steve, and Steve,

CONGRATULATIONS! Your EUA has just been authorized by FDA! Please see attached the signed letter!

This is an incredible accomplishment! You can be extremely proud of your accomplishments and contributions to public health.

It has been an absolute pleasure to work with you.

Very kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 4, 2020 2:32 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

The pdf of the updated instructions for use.

AMERICAN OVERSIGHT

THANK YOU!

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:40 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

This works thank Julie

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:37 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

We added this to footnote 2: Calculations only include positive results.

Are you OK with that addition?

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:33 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH)

AMERICAN OVERSIGHT

<Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Sounds good can you just add a(b) (5) .
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:28 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

(b) (5)

Does this help?

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:25 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

AMERICAN OVERSIGHT

**Dear Julie and Steve**

**Li has these numbers - please just check**

**Thanks**
**Kim**

**Table 4. Limit of Detection Confirmation of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with QIAGEN EZ1 DSP**

| Targets | 2019-nCoV_N1 | 2019-nCoV_N2 | (b) (4), (b) (5) |
|---|---|---|---|
| RNA Concentration[1] | (b) (4), (b) (5) | | |
| Positives/Total | | | |
| Mean Ct[2] | | | |
| Standard Deviation (Ct) | | | |

[1] Concentration is presented in RNA copies/µL
[2] Mean Ct reported for dilutions that are ≥95% positive
NA not applicable

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

AMERICAN OVERSIGHT

Fantastic – thank you! We will accept the edits and will send a clean version with doc and rev numbers.
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:14 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

We concur

Thank you all

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Hi Kim,

We have made a few edits to the table and have found a few numbers that we've highlighted that we'd like you to double check. Happy to discuss again if needed.

Thanks,
Julie

AMERICAN OVERSIGHT

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 11:34 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Julie,

Please find attached our suggested edits – let us know if you concur ASAP.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov






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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 9:34 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

Hi Kim,

Attached are our edits to the instructions for use. We appreciate the edits on the other documents, but unfortunately those documents have been printed and are with the kits at ATCC. We will update the typos in future versions and will send to you for approval. Please let me know if you have any questions.

Thanks,
Julie

AMERICAN OVERSIGHT

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 8:53 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Julie,

Please find attached some minor edits to the verification requirements, PIS and IFU,

Please let us know if you have any questions

Please send revised ASAP

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov






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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Monday, February 03, 2020 10:42 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

Hi Uwe,

AMERICAN OVERSIGHT

Attached are the following for the CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission:

- CDC 2019 Novel Coronavirus Real-Time RT-PCR Diagnostic Panel EUA Request Letter
- EUA Template CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Executive Summary
- Appendix A_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers
- Appendix B_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Patients
- Appendix C_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Vial_Control Vial_Package Labeling_Final
- Appendix D_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Product Information Sheet
- Appendix E_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Instructions for Use
- Appendix F_CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Verification Requirements
- Appendix G_CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Analytical Performance Data
- Appendix H_ CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Sequence Alignment and In Silico Analysis
- Appendix I_ CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Clinical Performance Data

We cannot thank you enough for all of your assistance with this. We cannot do our jobs without you.

Best regards,
Julie

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/5/2020 8:54:07 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Arsenault, Sam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f4304f5e82a4bb88d9210e1aa7ecc5b-Samuel.Arse]; Zablan Jr., Russell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=214878514387409eaa619c1e0b2b6886-RZABLAN]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]
**CC**: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
**Subject**: RE: For FDA review by 1:00pm today : CLEARANCE_0110: CMS - Information for Healthcare Facilities Concerning Coronavirus Illness

Looks good, no comments. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, February 5, 2020 8:47 AM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Arsenault, Sam <Samuel.Arsenault@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
**Subject:** RE: For FDA review by 1:00pm today : CLEARANCE_0110: CMS - Information for Healthcare Facilities Concerning Coronavirus Illness

Looks good to me

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Wednesday, February 05, 2020 8:38 AM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Arsenault, Sam <Samuel.Arsenault@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
**Subject:** RE: For FDA review by 1:00pm today : CLEARANCE_0110: CMS - Information for Healthcare Facilities Concerning Coronavirus Illness

AMERICAN OVERSIGHT

Nothing from me thx

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Wednesday, February 5, 2020 8:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Arsenault, Sam <Samuel.Arsenault@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
**Subject:** For FDA review by 1:00pm today : CLEARANCE_0110: CMS - Information for Healthcare Facilities Concerning Coronavirus Illness
**Importance:** High

Hi all – please see below and attached. I have made some minor tweaks already in the attached. Thank you!
**EXPEDITED REVIEW. Comments due TODAY at 1:00PM Feb. 5, 2020 (apologies for the tight turnaround)**

**All: For your review and input.**

**Title:** Information for Healthcare Facilities Concerning Coronavirus Illness

**Agency/Office:** CMS

**Subject/Description:** The Centers for Medicare & Medicaid Services (CMS) is committed to the protection of patients and residents from the spread of infectious disease. Every Medicare participating facility in the Nation's health care system must adhere to standards for infection prevention and control in order to provide safe, high quality care. As concerns arise with the emerging Coronavirus threat, CMS encourages all healthcare facilities to carefully review the information provided by our partners at The Centers for Disease Control and Prevention.

**COMMs Materials for Rollout:**

- Information Bulletin

**Deadline for comments: 1:00PM Today, February 5, 2020**

Simone Myrie, MPS
Public Affairs Specialist
Office of the Assistant Secretary for Public Affairs
US Department of Health & Human Services
(b) (6) o)
c)

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/6/2020 9:25:59 AM
**To:** McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: REUPPING And sharing new deadline of 9:45am today re: - CLEARANCE_0115: CMS Healthcare Facilities and Surveyors Coronavirus Press Release
**Attachments:** 2020.02.05 Coronavirus Release FINAL.docxFDA.docx; QSO 20-10-CLIA_EUA_2019_nCoV.v4.docxFDA020520 (OCC).docxfda.DCLIQ FINAL CLEAN.docx

Megan,

Attached only minor edits to consider. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Thursday, February 6, 2020 8:35 AM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
**Subject:** REUPPING And sharing new deadline of 9:45am today re: - CLEARANCE_0115: CMS Healthcare Facilities and Surveyors Coronavirus Press Release

Hi all – reupping the attached documents for review and sharing that CMS has just now moved up deadline – please send any edits by 9:45 am today. Thank you!
***
Hi all – please see the attached for clearance. (b) (5)

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As we will need to consolidate all edits and send back to HHS by 11 am – we are requesting that you **please send any edits and comments by 10:15am tomorrow.** Thank you!
**EXPEDITED REVIEW. Comments due tomorrow, Thursday, February 6 at 11 am (apologies for the tight turnaround)**

**All: For your review and input.**

(b) (5)

**Deadline for comments: Thursday, February 6th at 11AM**

Thank you,
Tasha

Tasha Bradley
U.S. Department of Health & Human Services
(b) (6) Direct
(b) (6) Mobile
Tasha.bradley@hhs.gov

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(b) (5)

(b) (5) Draft

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(b) (5) Draft

For more information about the CMS's efforts to help facilities prepare for Coronavirus, visit:
LINK TO MEMO

For more information about how CLIA-approved laboratories can test for Coronavirus, visit:
LINK TO MEMO

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

**Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group**

**Ref: QSO 20-10-CLIA**

**DATE:** **February 5, 2020**

**TO:** State Survey Agency Directors

**FROM:** Director
Quality, Safety & Oversight Group

**SUBJECT:** Notification to Surveyors of the Authorization for Emergency Use of the **CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel** Assay and Guidance for Authorized Laboratories

**Memorandum Summary**

- The Centers for Medicare & Medicaid Services (CMS) is providing guidance to surveyors in regards to the authorization for emergency use of the Centers for Disease Control (CDC)'s 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel assay and the deployment into CDC qualified, and, certified laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity tests).
- Assays that have been issued an Emergency Use Authorization (EUA) by the United States Food and Drug Administration (FDA) remain subject CLIA regulations.
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay and the corresponding protocols have been developed by the CDC for use by CDC qualified laboratories and the assay has been issued an EUA from the FDA.
- Upon receipt of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay and corresponding Manufacturer's Instructions (MI), CDC qualified laboratories will verify assay performance specifications in their laboratory per the manufacturer's instructions.
- CMS is also providing guidance for surveyors to notify their CMS Location if they discover a laboratory using an assay without an EUA that is testing for the same agent for which the emergency has been declared, or a modified EUA assay. The CMS Location will notify CMS Baltimore.

## Background

The FDA Emergency Use Authorization (EUA) of Medical Products and Related Authorities Guidance for Industry and Other Stakeholders document describes key legal authorities to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents,

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including emerging infectious disease threats. The rapid development and deployment of emergency assays is afforded through the EUA authority under Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3). This permits the FDA Commissioner to authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances, if certain criteria are met, after there is a determination and the Secretary of Health and Human Services (HHS) issues a declaration that circumstances exist justifying the authorization of emergency use of the medical product. The EUA remains in effect until the emergency declaration is terminated or until the FDA revokes the authorization. The emergency use of an assay under an EUA must be consistent with the terms of the Letter of Authorization, including the Scope and Conditions of Authorization.

As of December 31, 2019, active 2019-Novel Coronavirus (2019-nCoV) transmission has occurred in Wuhan City, Hubei Province, China. At that time, there were no FDA approved/cleared tests available that could detect and/or diagnose 2019-nCoV in clinical specimens in the United States. CDC recently developed a test for the detection of 2019-nCoV infections in humans and was authorized for emergency under an EUA by FDA on February 4, 2020.

**Discussion**

The CDC 2019-nCoV Real-Time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR) assay is a molecular in vitro diagnostic test that aids in the detection of 2019-nCoV and is based on widely used nucleic acid amplification technology. The product contains oligonucleotide primers and dual-labeled hydrolysis probes and control material used in rRT-PCR for the in vitro presumptive qualitative detection of 2019-nCoV RNA in upper and lower respiratory specimens.

CMS has coordinated with the CDC to ensure the establishment of performance verification specifications for assays developed and tested by CDC. Subsequent assay performance verification on site at each CDC qualified laboratory is required. Inclusion as a CDC qualified laboratory, as defined in the assay's Manufacturer's Instructions (MI) for use, is not automatic, and members must demonstrate certain capabilities and capacities, and meet established agent-specific performance standards. The CDC assay's manufacturer instructions requires at least one set of assay verification results from each laboratory. CMS encourages laboratories to further evaluate assay performance while testing continues and more patient samples with known results become available.

Assays that have been authorized for emergency use by the FDA remain subject to the CLIA regulations.

Laboratories must follow any and all manufacturer's instructions.

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**Verification of Performance Specifications**

Upon receipt of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel and corresponding Manufacturer's Instructions for Use (MI), CDC qualified laboratories will verify the assay performance specifications as per the Manufacturer's Instructions.

**Resources**

For guidance regarding the verification of performance specifications for EUA assays, please refer to [ HYPERLINK "%20https:/www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/QSO18-19-CLIA.html?DLPage=2&DLEntries=10&DLSort=3&DLSortDir=descending" ].

For a complete list of all assays authorized for use under EUA, please refer to the FDA link [ HYPERLINK "https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations" ]

**Laboratory Use of Assays Without FDA Emergency Use Authorization**

Surveyors should determine if the laboratory is using an assay that has been authorized for emergency use by the FDA. Surveyors should notify their CMS Location if they discover a laboratory using an assay without an EUA that is testing for the same agent for which an emergency has been declared, or a modified EUA assay. The CMS Location will notify CMS Baltimore.

**Contact:** Questions related to this policy memorandum may be submitted to: [ HYPERLINK "mailto:LabExcellence@cms.hhs.gov" ].

**Effective Date:** Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/CMS Locations training coordinators within 30 days of this memorandum.

/s/
David R.
Wright Director

cc: Survey & Certifications Group Management

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/7/2020 7:00:08 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: Intended use wording

Kim, LI, Tamara,

3 PM can work for me for the call with CDC. Let's get together at 11 to discuss their proposal. Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Thursday, February 6, 2020 7:53 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** RE: Intended use wording

Hi Kim,

We are only a few days out from our initial authorization, but we are ready to discuss study design for amendments. We are currently working on the virus LoD studies as discussed, but we'd like to discuss plans to demonstrate equivalency with nucleic acid extraction platforms. We are proposing the following:

1. Extraction Platform Limit of Detection Equivalency

The LOD performance equivalency between Qiagen EZ1 Advanced XL and the Roche MagNA Pure 96 and Roche MagNA Pure 24 instruments will be demonstrated. Perform testing of 3-fold dilution serial dilutions of 2019 novel coronavirus in lysis buffer containing Human Specimen Control using an authorized extraction and the new extraction method(s) in parallel. Each dilution will be tested in a minimum of 5 extraction replicates. The extracted samples will be tested with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. The acceptance criteria for LOD equivalency should be defined as demonstrating 100% positivity (5 out of 5 replicates) for each primer/probe set at either the same endpoint LOD concentration or within a 3-fold dilution of each other.

2. Extraction Platform Clinical Specimen Equivalency

Clinical specimens (10 positive, 10 negative) will be extracted with the MagNA Pure 24 and MagNA Pure 96 and tested with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. The acceptance criteria for equivalency should be defined as generating 100% concurrent results with those generated with the Qiagen EZ1 Advanced XL.

Do you have time either at 9:30am or after 3pm tomorrow to discuss?

Thank you again,
Julie

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 8:45 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>
**Subject:** RE: Intended use wording

Dear Julie, Steve and Steve,

We just wanted to follow-up on some of the outstanding items/questions from yesterday's Telcon:

**For Current EUA Package:**

1) (b) (5) [redacted]

**For Future EUA Amendments:**

1) Condition of authorization – (b) (5) [redacted]

2) (b) (5) [redacted]

3) (b) (5) [redacted] (b) (5) [redacted]

If we missed anything let us know. FYI, the Fact sheets had some edits from OCET and OCC so we are working through those and hope to have them to you tomorrow (sorry for the delay) – we will also update based on out intended use discussion today. Authorization letter and contact fact sheet are also being worked on and we hope to share them with you ASAP.

Any questions, let us know

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)
CDRH | Food and Drug Administration

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White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 29, 2020 5:52 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** [WARNING : MESSAGE ENCRYPTED] RE: Intended use wording

Hi Kim and Li,

I am attaching the clinical line item data sheet, password protected. I'll send a separate email with that. We will actually more data to add to this tomorrow. I've arranged the data by case but removed names. I've identified the positive cases by location. As Julie explained, the additional N gene assays (N4 and N5 in the file) were initially run with all specimen testing, but eventually the testing only included the N1 through N3 assays that we're including in the EUA request.

Also attached are the LoD and Exclusivity testing performed for the CLIA validation with the N1, N2, N3 assays. I've included the results for the additional N gene assays N4 and N5. In these summaries.

Regards,
Steve

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Wednesday, January 29, 2020 11:49 AM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** RE: Intended use wording

Hi Kim,

We agree with the proposed change below. Thank you for proposing it. Would you mind sending all of the intended use language so we can be sure we are using the correct version in our documents?

Thank you all again,
Julie

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 11:08 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** Intended use wording

Julie as discussed on the call:

Current:
(b) (4)

Potential:

(b) (4)

I am going to draft the contact fact sheet (b) (4)

If in the future that were to change and we need and/or we could update the factsheets accordingly via amendment.

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 9:36:12 PM
**To**: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Styrt, Barbara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=458d7290e25347c2801b8214b89d81fa-STYRTB]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: White House Request-Due 0900 tomorrow (Wednesday)

Michael, Rosemary,

Diagnostics look good, no comments. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 8:21 PM
**To:** Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** FW: White House Request-Due 0900 tomorrow (Wednesday)
**Importance:** High

Hi – please take a look and send me any comments before the deadline if possible thx -m

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Understanding is that this is a briefing for the White House Task Force – currently scheduled to meet at 4pm on Thursday. After that brief, a subset will go in to brief POTUS. Drs. Fauci (and likely Kadlec) will be doing the briefing for the *Task Force*.

---

**From:** Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>
**Sent:** Tuesday, February 4, 2020 7:31 PM
**To:** Embry, Alan C (NIH) (b) (6) @niaid.nih.gov>; Jennifer Kishimori <jennifer.m.kishimori.mil@mail.mil>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Biggins, Julia (MIL) <julia.e.biggins.ctr@mail.mil>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>
**Cc:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Armstrong, Kimberly (OS) <Kimberly.Armstrong@hhs.gov>; Tse, Brian (OS) <Brian.Tse@hhs.gov>; Donabedian, Armen (OS) <armen.donabedian@hhs.gov>; Donis, Ruben (OS) <Ruben.Donis@hhs.gov>
**Subject:** RE: White House Request-Due 0900 tomorrow (Wednesday)

All,

Thanks for your patience as we worked through a number of rapid-fire tasks today. I've attached the following documents for your review:

1) Therapeutics one pager
2) Vaccines one pager
3) Diagnostics one pager
4) Two overview slides: talking points and graphic

Please add information that is missing and return the documents by 0900 tomorrow (Wednesday). I'll adjudicate comments and make edits once I receive input from each Agency. I understand that all need to go through ASPR and NIAID clearance tomorrow.

Thanks again for your input and your patience as we polished these documents as much as possible today.

Best,
Christy
<< File: CoV Diagnostics USG Interagency One-pager v6.docx >> << File: 2019_nCoV_Tx_One_Pager_v4 02042020.docx >> << File: Vaccines-1-pager v1ad.docx >> << File: ASPR-WH Slide Deck_v5.pptx >>
--
Christy L. Ventura, Ph.D.
Tunnell Government Services
Executive Secretary, 2019-nCoV Medical Countermeasures Task Force
Project Manager, CBRN/BARDA/ASPR/HHS
O'Neill 23L05
Office: (b) (6)
Cell: (b) (6)

---

**From:** Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
**Sent:** Monday, February 3, 2020 10:24 PM
**To:** Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Tse, Brian (OS/ASPR/BARDA) <Brian.Tse@hhs.gov>; Donabedian, Armen (OS/ASPR/BARDA) <armen.donabedian@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>
**Cc:** Marston, Hilary (NIH/NIAID) [E] (b) (6) @nih.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>; Ventura, Christy

AMERICAN OVERSIGHT

(OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>
**Subject:** White House Request-Due COB tomorrow (Tuesday)

All,

We have received a request from the White House Task Force. We need to provide the S1 with three one-pagers, one each for diagnostics, vaccines, and therapeutics. ASPR also wants a single slide showing product development for all three, close collaboration between agencies, etc. we will also put together a slightly longer deck with more detail around the one-pagers.

I've asked Rosemary to coordinate the diagnostic one-pager.

BARDA will take the pen on the one pager, but we are going to have pieces coming in from DoD and NIAID. The attached word document is a very rough outline. Below is what we are thinking in terms of specifics:

(b) (5)

I recognize the challenge in this approach, but just do not see a better approach with the time we have. I need the first draft of the one pagers by about noon tomorrow, so we can start dropping in pieces and working on the flow. I've copied Hilary so she can weigh in with any thoughts.

(b) (5)

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For all of these, we're going for bullet format, lots of white space.

We can chat tomorrow a.m., but I wanted to get this out to you tonight in case some of you had time/wanted to get a jump.

Thanks.

Robert

**Robert Johnson, Ph.D.**
Director, Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research and Development Authority
**BARDA**
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/13/2020 10:26:29 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject**: RE: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel - kit rework instructions DRAFT

Agree, I let Julie know. Uwe

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 10:22 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel - kit rework instructions DRAFT

Looks good to me also

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 10:19 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel - kit rework instructions DRAFT
**Importance:** High

Hi all,
I don't have any comment to the CDC draft instructions for the replacement N3 assay component of the RT-PCR panel. It looks clear to me.

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Thanks,
Li

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Thursday, February 13, 2020 10:10 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Zale, Amy (CMS) <Amy.Zale@cms.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Rager, Stacy (CDC) <vmk4@cdc.gov>; Murray, Janna' R (CDC) <hko3@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Subject:** CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel - kit rework instructions DRAFT
**Importance:** High

Hello everyone,

We would greatly appreciate your feedback on this draft package insert for our newly manufactured N3 primer/probe set. Thank you for your attention to this urgent matter.

Thanks,
Julie

Julie Villanueva, Ph.D.
Chief, Laboratory Preparedness and Response Branch
Division of Preparedness and Emerging Infections, NCEZID, CDC
404-639-3851

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/3/2020 10:26:16 PM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Limit of detection study data

Julie,

Thank you so much, please put Feb 4 on the EUA template. Regarding the instructions for use, yes please send a version in tonight and we can update it tomorrow morning. Do not worry about the hard copies.

This is great. Your team and you can be VERY proud!!!

Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Monday, February 3, 2020 10:23 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Limit of detection study data

Fantastic! Thank you all so much.

A few questions/issues:

- Should I put February 4 on the EUA template for the declaration?
- We will need to put a document number and revision number on the instructions for use. I will send a version tonight but will send a final word document tomorrow morning with those numbers.
- Hard copies and a CDC will be sent tomorrow morning.

I'll be putting this together right now so feel free to call or email for anything else 404-579-7398

Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 10:14 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH)

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<Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Limit of detection study data

Julie,

Thanks, this looks all good, no discussion needed. We are ready to receive the whole package.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Monday, February 3, 2020 9:54 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Limit of detection study data
**Importance:** High

Hi all,

Attached are the data from the limit of detection experiment incorporated into the EUA template. Please let us know if you would like to discuss. We are still in the office, of course.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 10:43 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC qualified laboratories

Dear Julie,

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Please find attached DMD edits to the documents you sent last night.

1) Appendix E Instructions for use: We went through the Instructions for Use with OCET, OCC and DMD this morning and had some minor edits that are highlighted in green.
2) Cover Letter: minor suggestion for CDC consideration
3) EUA template: minor edits – tracked changes – some to match edits made in the instructions for use
4) HCP Fact Sheet: Edits acceptable with the exception of including (b) (4), (b) (5)

I also have FDA responses to CDC comments in the Letter of Authorization – does CDC want to see them?

Let us know if you need a call to discuss – hope the LoD study data is going okay.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 02, 2020 9:52 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: CDC qualified laboratories

Hi Kim,

Thank you for the recommendation. I incorporated the statement below into our instructions for use. I did not add it elsewhere in other documents at this time which I think is fine.

Our CDC colleagues had a few comments on our documents. I've attached four documents with tracked changes. Please let us know if you accept these changes.

We plan to share the remaining data tomorrow. Thank you for your patience. Again I cannot thank you all enough for your comradery and collaboration!

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Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 9:15 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: CDC qualified laboratories

Dear Julie,

Thanks for the attaching the CDC comments in the LOA – we are discussing them internally with OCET and OCC tomorrow AM.

We discussed internally your question about defining "qualified laboratory" and think it is best to include similar wording to what you proposed somewhere in the instructions for use. One thought would be in:

## Summary and Explanation

An outbreak of pneumonia of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019. Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis 2019-nCoV and is based on widely used nucleic acid amplification technology. The product contains oligonucleotide primers and dual-labeled hydrolysis probes (TaqMan®) and control material used in rRT-PCR for the *in vitro* qualitative detection of 2019-nCoV RNA in respiratory specimens.

The term "qualified laboratories" refers to laboratories in which all users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

If CDC agree just let us know. Also we thought (b) (4), (b) (5) .

In addition, please note that there may be additional comments from OCET/OCC on the Instructions for Use – and I still need to double check that the Conditions of Authorization for Laboratories Section in the IFU matches the Letter of Authorization wording once I finalize with OCET/OCC tomorrow.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 02, 2020 6:47 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Subject:** CDC qualified laboratories
**Importance:** High

Hi all,

We are getting a lot of questions regarding what the term "qualified laboratory" means. We do not want to change the intended use but recommend that we put some additional language in our documents to clarify. The Influenza Division uses language such as this: All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

My question is: how can we edit the language above to include in our EUA and in which documents should include this language?

I'm also attaching feedback from our Office of General Counsel on the authorization letter. We haven't been through full clearance yet here but thought we should share this now in case there are any issues.

Thanks,
Julie

Julie Villanueva, Ph.D.
Chief, Laboratory Preparedness and Response Branch
Division of Preparedness and Emerging Infections, NCEZID, CDC
404-639-3851

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/15/2020 5:42:17 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Request for enforcement discretion

Jeff,

No, they have not send anything yet. I spoke with Steve Lindstrom at 4 PM again, they are discussing their internal data before they send it to us.

(b) (5)

We will need to have a conference call with CDC to come to an agreement which will realistically happen tomorrow. I will you keep you posted at every step.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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uwe.scherf@fda.hhs.gov
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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 5:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion

Thank you. Have you received the email from CDC with the request for a new cut off?

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 5:29 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen

AMERICAN OVERSIGHT

<Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion
**Importance:** High

Dear Dr. Kuhnert-Tallman,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

On February 15, 2020, CDC submitted to FDA a request for enforcement discretion from FDA for the testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Asymptomatic individuals do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC has stated that testing will be conducted at CDC's headquarters in Atlanta, GA. Specimens are expected to arrive at CDC for testing during this holiday weekend.

Our understanding of the facts and the public health concerns at issue here are that there is currently no other test available to respond to this emergency, significant public health concerns are presented by the infectious disease, and the proposed testing may help to prevent the spread of the infectious disease. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the following conditions: that the testing will be conducted only at CDC's headquarters in Atlanta, GA, that CDC will submit data to FDA on the number of asymptomatic cases identified as being positive during the testing, and that CDC will act promptly to submit an application for a new EUA or a request to modify its existing EUA to include testing of asymptomatic individuals at CDC's headquarters in Atlanta, GA.

Regards,

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 15, 2020 12:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Request for enforcement discretion

Good afternoon Dr. Scherf,

CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC respectfully requests (b) (5)

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(b) (5)

Laura Rose, Regulatory Affairs Activity Lead for OLSS, is the primary point of contact at CDC to facilitate communications about this request. She may be reached at 404-639-1084 or LERose@cdc.gov.

Warm regards,
Wendi

Wendi Kuhnert-Tallman
ADIM
Mobile – 678-576-2121
CDC IMS LAB TF
2019 nCoV Response
eocevent177@cdc.gov

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/12/2020 9:45:49 AM
**To:** McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
**Subject:** RE: Flagging - tight turnaround - CMSCLEARANCE_0137: CMS Coronavirus News Alert

Megan,

I cannot not make this, will be on a call now until 11. Sorry, Uwe

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 9:37 AM
**To:** 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
**Subject:** Flagging - tight turnaround - CMSCLEARANCE_0137: CMS Coronavirus News Alert

Hi all – apologies for the tight turnaround. Does the IMG have any comments on the attached? While the deadline has passed – I will ask HHS to give us until 10:15 am. Thank you! Megan

**EXPEDITED REVIEW—Comments due by 9:30AM Wednesday, February 12, 2020 (apologies for the tight turnaround)**

**All: For your review and input. Concurrent HHS/CMS review.**

**Title:** Coronavirus News Alert

**Agency/Office:** CMS

**Subject/Description:**
CMS is alerting providers that a HCPCS code for the 2019 Novel Coronavirus Real Time RT-PCR Diagnostic test panel has been created.

**COMMs Materials for Rollout:**

- News Alert

**Deadline for comments: 9:30AM Wednesday, February 12, 2020**

**Release date: Wednesday, February 12.**

Simone Myrie, MPS
Public Affairs Specialist
Office of the Assistant Secretary for Public Affairs
US Department of Health & Human Services
(b) (6) (o)
(b) (6) (c)

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

February 3, 2020
Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
CDRH Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

**New Request for Emergency Use Authorization:**
**CDC 2019 Novel Coronavirus (nCoV) Real-Time RT-PCR Diagnostic Panel**

Dear Dr. Hahn,

Please find enclosed the Centers for Disease Control and Prevention's (CDC) formal request for Emergency Use Authorization (EUA) regarding the distribution and use of the CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel for detection of the 2019 Novel Coronavirus. Due to the exigent nature of this request, an electronic copy of the official submission of this EUA request is also being concurrently provided to Dr. Uwe Scherf, Director, Division of Microbiology Devices, Center for Devices and Radiological Health (CDRH) via e-mail on February 3, 2020.

CDC is closely monitoring the outbreak of respiratory illness caused by 2019-nCoV that was first detected in Wuhan City, Hubei Province, China and which continues to expand. As of January 31, 2020, there were 9,817 cases of confirmed 2019-nCoV in 22 locations with six confirmed cases of 2019-nCoV in the United States, including one confirmed instance of person-to-person transmission. On January 31, 2020, Health and Human Services Secretary Alex M. Azar II declared a public health emergency for the United States to aid the nation's healthcare community in responding to 2019-nCoV. As CDC continues to investigate this outbreak and work with state, local, and territorial health departments to support investigation of suspect cases, the use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in qualified laboratories designated by CDC within the United States is imperative.

At this time, there are no adequate, approved (cleared), and available alternative diagnostic tools that can detect the 2019-nCoV during the acute phase of infection in the United States. Therefore, CDC requests this EUA to allow use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel to expand testing capabilities within the U.S. public health system by providing a rapid diagnostic tool to qualified laboratories for the detection of RNA from 2019-nCoV in clinical specimens during the public health emergency. Deployment of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel meets an unmet need of providing qualified laboratories a rapid diagnostic tool for evaluation of specimens from patients in the acute phase of infection during this public health emergency.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use on an Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument, in conjunction with clinical and

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epidemiological information. The assay will be used for the qualitative detection of 2019 Novel Coronavirus RNA only by qualified laboratories.

Please find enclosed an Executive Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Patients, the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel package insert and manufacturer's labeling.

If you have any questions regarding this submission, please contact:

Julie Villanueva, Ph.D.
Laboratory Preparedness and Response Branch Chief
Division of Preparedness and Emerging Infections
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
jfv3@cdc.gov
(404) 639-3851

Technical questions may be directed to:

Stephen Lindstrom, Ph.D.
Respiratory Virus Team Lead
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
sql5@cdc.gov
(404) 639-1587

Sincerely,



Anne Schuchat, MD (RADM, USPHS, RET)
Principal Deputy Director
Centers for Disease Control and Prevention

Enclosures: 10

- EUA Template CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Executive Summary
- Appendix A_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers
- Appendix B_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Patients
- Appendix C_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Vial_Control Vial_Package Labeling_Final

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- Appendix D_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Product Information Sheet
- Appendix E_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Instructions for Use
- Appendix F_CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Verification Requirements
- Appendix G_CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Analytical Performance Data
- Appendix H_ CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Sequence Alignment and In Silico Analysis
- Appendix I_ CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Clinical Performance Data

cc: Dr. Uwe Scherf, CDRH/FDA
Joseph Foster, OD/CDC

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# FACT SHEET FOR HEALTHCARE PROVIDERS

**CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel** **February x, 2020**

**2019 Novel Coronavirus (2019-nCoV)**

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Centers for Disease Control and Prevention (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Testing is to be conducted on specimens from people who meet CDC criteria for 2019-nCoV testing, available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section). The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel should be ordered only to presumptively detect 2019-nCoV infection. If outside the U.S., testing should follow appropriate public health authority consultation and/or guidance for the diagnosis and reporting of 2019-nCoV infection. All information and guidance, including for 2019-nCoV laboratory testing, may change as more data is gathered on this virus. Please check the CDC's 2019 Novel Coronavirus, webpage (see links provided in "Where can I go for updates and more information" section) regularly for the most current information.

**All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel**

**What are the symptoms of 2019-nCoV?**
Most patients with confirmed 2019-nCoV infection have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with 2019-nCoV infection. Based on what is known about MERS-CoV and SARS-CoV, signs and symptoms may appear any time from 2 to 14 days after exposure to 2019-nCoV virus. The median incubation period is unknown at this time.

Public health officials have identified cases of 2019-nCoV infection in the United States, which may pose risks for public health. To date most reported cases of 2019-nCoV infection outside of China have been directly or indirectly linked through residence in or travel to Wuhan City, China. There also are reports of human to human transmission through close contact with an individual confirmed to be ill with 2019-nCoV in countries outside China. Please check the CDC webpage for the most up to date information.

**This test is to be performed only using respiratory specimens collected from individuals who meet CDC criteria for 2019-nCoV testing.**

**What do I need to know about 2019-nCoV testing?**
Current information on 2019-nCoV infection for healthcare providers, including case definitions and infection control, is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel can be used to test upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, bronchoalveolar lavage, sputum, lower respiratory tract aspirate, nasopharyngeal wash/aspirate or nasal aspirate).
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel should be ordered for the presumptive detection of 2019-nCoV in individuals who meet CDC criteria for 2019-nCoV testing.
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized for use in laboratories designated by CDC as qualified, and in the U.S., certified under CLIA to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions following CDC *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007).*

Use appropriate personal protective equipment when collecting and handling specimens from individuals

**Report Adverse events,** including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 ([ HYPERLINK "https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home" ]~~https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home~~) or by calling **1-800-FDA-1088**

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suspected of being infected with 2019-nCoV as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV)*. These specimens are only shipped for analysis to laboratories designated by CDC as qualified for analysis. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV) (*see links provided in "Where can I go for updates and more information" section).

**What does it mean if the specimen tests positive for 2019-nCoV?**
A positive test result for 2019-nCoV indicates that RNA from 2019-nCoV was detected, and the patient is presumptively infected with 2019-nCoV and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially 2019-nCoV infected patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

**What does it mean if the specimen tests negative for 2019-nCoV?**
A negative test result for this test means that 2019-nCoV RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out 2019-nCoV infection and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of 2019-nCoV infection.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with 2019-nCoV infection. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that 2019-nCoV infection is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If 2019-nCoV infection is still suspected based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities.

Risks to a patient of a false negative include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of 2019-nCoV within the community, or other unintended adverse events.

**What is an EUA?**
The United States (U.S.) FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of in vitro diagnostics (IVDs) under EUA for the detection and/or diagnosis of 2019-nCoV.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. However, based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of 2019-nCoV.

The EUA for this test is in effect for the duration of the 2019-nCoV emergency, unless terminated or revoked (after which the test may no longer be used). An FDA



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approved or cleared IVD should be used instead of an IVD under EUA, when applicable and available.

## Where can I go for updates and more information?

### CDC webpages:

**General:** https://www.cdc.gov/nCoV
**Healthcare Professionals:** https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
**Information for Laboratories:** https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
**Laboratory Biosafety:** https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
**Isolation Precautions in Healthcare Settings:** https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html#a4
**Specimen Collection:** https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html

### FDA webpages:

**General:** www.fda.gov/novelcoronavirus
**EUAs:**(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

### Manufacturer: CDC

CDC Emergency Operations Center (EOC)
1600 Clifton Road
Atlanta, Georgia, USA, 30329
Phone: **CDC EOC (770-488-7100)**



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# FACT SHEET FOR PATIENTS

## CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Febuary x, 202

2019 Novel Coronavirus (2019-nCoV)

You are being given this Fact Sheet because your sample(s) were tested for the 2019 novel coronavirus (2019-nCoV) using the Centers for Disease Control and Prevention (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Testing was done because you meet CDC criteria for 2019-nCoV testing.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of 2019-nCoV infection. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on 2019-nCoV please visit the CDC 2019 Novel Coronavirus webpage:**

- [ HYPERLINK "https://www.cdc.gov/nCoV" ]

**What is 2019-nCoV Infection?**
2019-nCoV infection is caused by the 2019-nCoV. The 2019-nCoV infection can cause mild to severe respiratory illness in humans and was recently idenitifed in Wuhan, China. Limited information is available to characterize the spectrum of clinical illness associated with 2019-nCoV. 2019-nCoV likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, sneezing, difficulty breathing, etc.).

**What is the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel?**
The test is designed to detect 2019-nCoV in respiratory specimens, for example nasal or oral swabs.

**Why was my sample tested?**
Your sample(s) were tested because your healthcare provider believes you may have been exposed to 2019-nCoV based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and because:

- You live in or have recently traveled to a place where transmission of 2019-nCoV is known to occur, and/or
- Because you have been in close contact with an individual suspected of or confirmed to have 2019-nCoV infection.

The sample(s) collected from you were tested to help find out whether you may be infected with 2019-nCoV.

**What are the known and potential risks and benefits of the test?**
Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Risk that the test result is incorrect (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of 2019-nCoV to your family and others in your community.

**What does it mean if I have a positive 2019-nCoV test result?**
If you have a positive test result, it is very likely that you are infected with 2019-nCoV. Therefore, it is also likely that you may be placed in isolation to avoid spreading

**Where can I go for updates and more information?** The most up-to-date information on 2019-nCoV is available at the CDC General webpage: [ HYPERLINK "https://www.cdc.gov/nCoV" ]. In addition, please also contact your healthcare provider with any questions/concerns.

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the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). However, your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, such as symptoms, possible exposures, and geographic location of places you have recently traveled.

**What does it mean if I have a negative test result?**
A negative test result means that 2019-nCoV was not found in your sample. For 2019-nCoV, a negative test result for a sample collected while a person has symptoms usually means that 2019-nCoV did not cause your recent illness.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with 2019-nCoV infection, meaning you could possibly still have an infection with 2019-nCoV even though the test is negative. Therefore, while a negative test most likely means you do not have 2019-nCoV infection, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

**Is this test FDA-approved or cleared?**
No. This test is not yet approved or cleared by the United States (U.S.) FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of in vitro diagnostics under EUA for the detection and/or diagnosis of 2019-nCoV. This EUA will remain in effect (meaning this test can be used) for the duration of the 2019-nCoV emergency, unless it is terminated or revoked by FDA (after which the test may no longer be used).

**Where can I go for updates and more information?** The most up-to-date information on 2019-nCoV is available at the CDC General webpage: [ HYPERLINK "https://www.cdc.gov/nCoV" ]. In addition, please also contact your healthcare provider with any questions/concerns.

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# CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

**For Emergency Use Only**

## Instructions for Use

**Catalog # 2019-nCoVEUA-01**
**1000 reactions**

For *In-vitro* Diagnostic (IVD) Use

Rx Only

Centers for Disease Control and Prevention
Division of Viral Diseases
1600 Clifton Rd NE
Atlanta GA 30329

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FDACDRH-p6-AO-000880
FDA-CVD-SCHERFU-00014455.0005
MULTI-HHS-20-0522-B, 20-0523-A-000055

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## Intended Use

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization.

## Summary and Explanation

An outbreak of pneumonia of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019. Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis 2019-nCoV and is based on widely used nucleic acid amplification technology. The product contains oligonucleotide primers and dual-labeled hydrolysis probes (TaqMan®) and control material used in rRT-PCR for the *in vitro* qualitative detection of 2019-nCoV RNA in respiratory specimens.

The term "qualified laboratories" refers to laboratories in which all users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC will limit the distribution of this device to laboratories whose users have successfully completed a training course provided by CDC instructors or designees.

## Principles of the Procedure

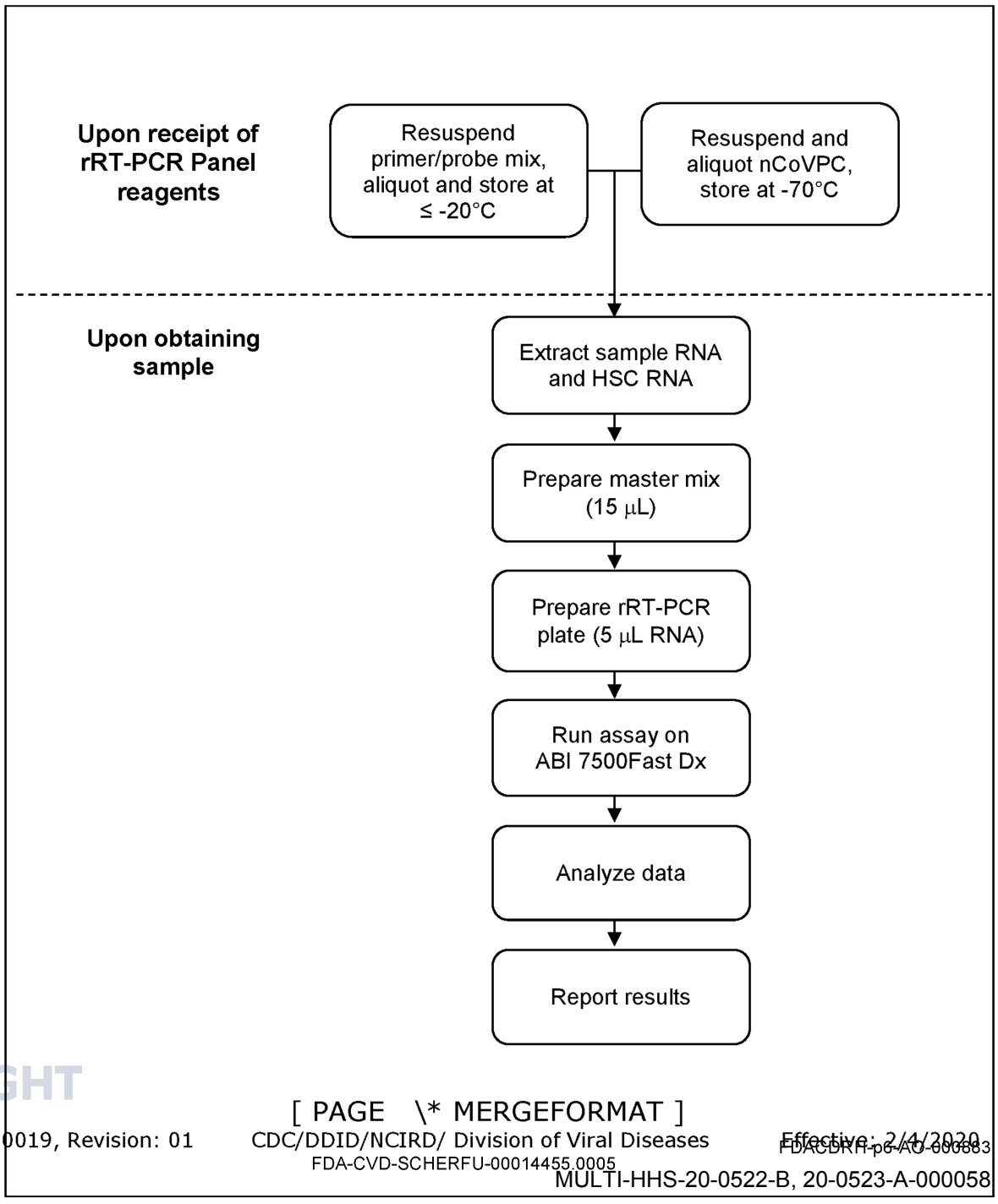
The oligonucleotide primers and probes for detection of 2019-nCoV were selected from regions of the virus nucleocapsid (N) gene. The panel is designed for both universal detection of SARS-like coronaviruses (one primer/probe set) as well as specific detection of the 2019-nCoV (two primer/probe sets). An additional primer/probe set to detect the human RNase P gene (RP) in control samples and clinical specimens is also included in the panel.

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RNA isolated and purified from upper and lower respiratory specimens is reverse transcribed to cDNA and subsequently amplified in the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS version 1.4 software. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5′ nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software.

Detection of viral RNA not only aids in the diagnosis of illness but also provides epidemiological and surveillance information.

## Summary of Preparation and Testing Process




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# Materials Required (Provided)

## 2019-nCoVEUA-01 Box #1: Primers and Probes

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
|---|---|---|---|---|
| 2019-nCoV_N1 | RV202001 | 2019-nCoV_N1 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N2 | RV202002 | 2019-nCoV_N2 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N3 | RV202003 | 2019-nCoV_N3 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| RP | RV202004 | Human RNase P Forward Primer/Probe Mix | 22.5 nmol | 1000 |

## Box #2: Positive Control

| *Reagent Label* | *Part #* | *Description* | *Quantity* | *Notes* |
|---|---|---|---|---|
| nCoVPC | RV202005 | 2019-nCoV Positive Control (nCoVPC)<br>For use as a positive control with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel procedure. The nCoVPC contains noninfectious positive control material supplied in a dried state and must be resuspended before use. nCoVPC consists of *in vitro* transcribed RNA. nCoVPC will yield a positive result with each assay in the 2019-nCoV Real-Time RT-PCR Diagnostic Panel including RP. | 4 tubes | Provides (800) 5 µL test reactions |

# Materials Required (But Not Provided)

## Human Specimen Control (HSC)

| Description | Quantity | CDC Catalog No. |
|---|---|---|
| Manufactured by CDC. For use as an RNA extraction procedural control to demonstrate successful recovery of RNA as well as extraction reagent integrity. The HSC consists of noninfectious (beta-Propiolactone treated) cultured human cell material supplied as a liquid suspended in 0.01 M PBS at pH 7.2-7.4. | 10 vials x 500uL | KT0189 |

## rRT-PCR Enzyme Mastermix Options

| Reagent | Quantity | Catalog No. |
|---|---|---|
| TaqPath™ 1-Step RT-qPCR Master Mix, CG (ThermoFisher) | 1000 reactions | A15299 |
| | 2000 reactions | A15300 |

## RNA Extraction Options

| Instrument/Manufacturer | Extraction Kit | Catalog No. |
|---|---|---|
| QIAGEN | QIAmp DSP Viral RNA Mini Kit | 50 extractions: 61904 |
| QIAGEN EZ1 Advanced XL | EZ1 DSP Virus Kit | 48 extractions: (62724)<br>Buffer AVL (19073)<br>EZ1 Advanced XL DSP Virus Card |

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FDACDRH-p6-AG-000065
FDA-CVD-SCHERFU-00014455.0005
MULTI-HHS-20-0522-B, 20-0523-A-000060

| Instrument/Manufacturer | Extraction Kit | Catalog No. |
|---|---|---|
| | | (9018703) |

## Equipment and Consumables Required (But Not Provided)

- Vortex mixer
- Microcentrifuge
- Micropipettes (2 or 10 µL, 200 µL and 1000 µL)
- Multichannel micropipettes (5-50 µl)
- Racks for 1.5 mL microcentrifuge tubes
- 2 x 96-well -20°C cold blocks
- 7500 Fast Dx Real-Time PCR Systems with SDS 1.4 software (Applied Biosystems; catalog #446985 or #4406984)
- Extraction systems (instruments): QIAGEN EZ1 Advanced XL
- Molecular grade water, nuclease-free
- 10% bleach (1:10 dilution of commercial 5.25-6.0% hypochlorite bleach)
- DNA*Zap*™ (Ambion, cat. #AM9890) or equivalent
- RNAse AwayTM (Fisher Scientific; cat. #21-236-21) or equivalent
- Disposable powder-free gloves and surgical gowns
- Aerosol barrier pipette tips
- 1.5 mL microcentrifuge tubes (DNase/RNase free)
- 0.2 mL PCR reaction plates (Applied Biosystems; catalog #4346906 or #4366932)
- MicroAmp Optical 8-cap Strips (Applied Biosystems; catalog #4323032)

## Warnings and Precautions

- For *in vitro* diagnostic use (IVD).
- For emergency use only.
- Follow standard precautions. All patient specimens and positive controls should be considered potentially infectious and handled accordingly.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCoV [ HYPERLINK "https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html" ].
- Specimen processing should be performed in accordance with national biological safety regulations.
- If infection with 2019-nCoV is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions.
- Performance characteristics have been determined with human upper respiratory specimens and lower respiratory tract specimens from human patients with signs and symptoms of respiratory infection.
- Perform all manipulations of live virus samples within a Class II (or higher) biological safety cabinet (BSC).

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- Use personal protective equipment such as (but not limited to) gloves, eye protection, and lab coats when handling kit reagents while performing this assay and handling materials including samples, reagents, pipettes, and other equipment and reagents.
- Amplification technologies such as PCR are sensitive to accidental introduction of PCR product from previous amplifications reactions. Incorrect results could occur if either the clinical specimen or the real-time reagents used in the amplification step become contaminated by accidental introduction of amplification product (amplicon). Workflow in the laboratory should proceed in a unidirectional manner.
    - Maintain separate areas for assay setup and handling of nucleic acids.
    - Always check the expiration date prior to use. Do not use expired reagent. Do not substitute or mix reagent from different kit lots or from other manufacturers.
    - Change aerosol barrier pipette tips between all manual liquid transfers.
    - During preparation of samples, compliance with good laboratory techniques is essential to minimize the risk of cross-contamination between samples, and the inadvertent introduction of nucleases into samples during and after the extraction procedure. Proper aseptic technique should always be used when working with nucleic acids.
    - Maintain separate, dedicated equipment (e.g., pipettes, microcentrifuges) and supplies (e.g., microcentrifuge tubes, pipette tips) for assay setup and handling of extracted nucleic acids.
    - Wear a clean lab coat and powder-free disposable gloves (not previously worn) when setting up assays.
    - Change gloves between samples and whenever contamination is suspected.
    - Keep reagent and reaction tubes capped or covered as much as possible.
    - Primers, probes (including aliquots), and enzyme master mix must be thawed and maintained on cold block at all times during preparation and use.
    - Work surfaces, pipettes, and centrifuges should be cleaned and decontaminated with cleaning products such as 10% bleach, "DNA*Zap*™" or "RNase AWAY®" to minimize risk of nucleic acid contamination. Residual bleach should be removed using 70% ethanol.
- RNA should be maintained on cold block or on ice during preparation and use to ensure stability.
- Dispose of unused kit reagents and human specimens according to local, state, and federal regulations.

## Reagent Storage, Handling, and Stability

- Store all dried primers and probes and the positive control, nCoVPC, at 2-8°C until re-hydrated for use. Store liquid HSC control materials at ≤ -20°C.
- Always check the expiration date prior to use. Do not use expired reagents.
- Protect fluorogenic probes from light.
- Primers, probes (including aliquots), and enzyme master mix must be thawed and kept on a cold block at all times during preparation and use.
- Do not refreeze probes.
- Controls and aliquots of controls must be thawed and kept on ice at all times during preparation and use.

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FDACDRH-p6-AG-000687
FDA-CVD-SCHERFU-00014455.0005
MULTI-HHS-20-0522-B, 20-0523-A-000062

## Specimen Collection, Handling, and Storage

Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Training in specimen collection is highly recommended due to the importance of specimen quality. CLSI MM13-A may be referenced as an appropriate resource.

- Collecting the Specimen
  - Refer to Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV) [ HYPERLINK "https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html" ]
  - Follow specimen collection devices manufacturer instructions for proper collection methods.
  - Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron®, and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media. NP and OP specimens should be kept in separate vials.
- Transporting Specimens
  - Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens. Store specimens at 2-8°C and ship overnight to CDC on ice pack. If a specimen is frozen at -70°C or lower, ship overnight to CDC on dry ice.
- Storing Specimens
  - Specimens can be stored at 2-8°C for up to 72 hours after collection.
  - If a delay in extraction is expected, store specimens at -70°C or lower.
  - Extracted nucleic acid should be stored at -70°C or lower.

## Specimen Referral to CDC

Referring a specimen to the CDC

- Ship all specimens overnight to CDC.
- Ship frozen specimens on dry ice and non-frozen specimens on cold packs.
- Refer to the International Air Transport Association (IATA - [ HYPERLINK "http://www.iata.org" ]) for requirements for shipment of human or potentially infectious biological specimens. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens.
- Prior to shipping, notify CDC Division of Viral Diseases (see contact information below) that you are sending specimens.

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FDACDRH-pe-AG-000688
FDA-CVD-SCHERFU-00014455.0005
MULTI-HHS-20-0522-B, 20-0523-A-000063

- Send all samples to the following recipient:

Centers for Disease Control and Prevention
c/o STATT
Attention: Dr. Stephen Lindstrom (Unit 84)
1600 Clifton Rd., Atlanta, GA 30329-4027
Phone: (404) 639-1587

**The emergency contact number for CDC Emergency Operations Center (EOC) is 770-488-7100.**

## Reagent and Controls Preparation

### Primer and Probe Preparation:

1) Upon receipt, store dried primers and probes at 2-8°C.
2) Precautions: These reagents should only be handled in a clean area and stored at appropriate temperatures (see below) in the dark. Freeze-thaw cycles should be avoided. Maintain cold when thawed.
3) Using aseptic technique, suspend dried reagents in 1.5 mL of nuclease-free water (50X working concentration) and allow to rehydrate for 15 min at room temperature in the dark.
4) Mix gently and aliquot primers/probe in 300 µL volumes into 5 pre-labeled tubes. Store a single aliquot of primers/probe at 2-8°C in the dark. Do not refreeze (stable for up to 4 months). Store remaining aliquots at ≤ -20°C in a non-frost-free freezer.

### 2019-nCoV Positive Control (nCoVPC) Preparation:

1) Precautions: This reagent should be handled with caution in a dedicated nucleic acid handling area to prevent possible contamination. Freeze-thaw cycles should be avoided. Maintain on ice when thawed.
2) Resuspend dried reagent in each tube in 1 mL of nuclease-free water to achieve the proper concentration. Make single use aliquots (approximately 30 µL) and store at ≤ -70°C.
3) Thaw a single aliquot of diluted positive control for each experiment and hold on ice until adding to plate. Discard any unused portion of the aliquot.

### Human Specimen Control (HSC) (not provided)

1) Human Specimen Control (HSC) must be extracted and processed with each specimen extraction run.
2) Refer to the Human Specimen Control (HSC) package insert for instructions for use.

### No Template Control (NTC) (not provided)

1) Sterile, nuclease-free water
2) Aliquot in small volumes
3) Used to check for contamination during specimen extraction and/or plate set-up

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# General Preparation

## Equipment Preparation

Clean and decontaminate all work surfaces, pipettes, centrifuges, and other equipment prior to use. Decontamination agents should be used including 5% bleach, 70% ethanol, and *DNAzap*™ or *RNase AWAY*® to minimize the risk of nucleic acid contamination.

# Nucleic Acid extraction

Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is dependent upon the amount and quality of template RNA purified from human specimens. The following commercially available RNA extraction kits and procedures have been qualified and validated for recovery and purity of RNA for use with the panel:

## Qiagen QIAamp® DSP Viral RNA Mini Kit

Recommendation(s): Utilize 100 µL of sample and elute with 100 µL of buffer or utilize 140 µL of sample and elute with 140 µL of buffer.

## Qiagen EZ1 Advanced XL

Kit: Qiagen EZ1 DSP Virus Kit and Buffer AVL (supplied separately) for offboard lysis
Card: EZ1 Advanced XL DSP Virus Card
Recommendation(s): Add 120 µL of sample to 280 µL of pre-aliquoted Buffer AVL (total input sample volume is 400 µL). Proceed with the extraction on the EZ1 Advanced XL. Elution volume is 120 µL.

Manufacturer's recommended procedures (except as noted in recommendations above) are to be followed for sample extraction. HSC must be included in each extraction batch.

***Disclaimer: Names of vendors or manufacturers are provided as examples of suitable product sources. Inclusion does not imply endorsement by the Centers for Disease Control and Prevention.***

# Assay Set Up

## Reaction Master Mix and Plate Set Up

Note: Plate set-up configuration can vary with the number of specimens and work day organization. NTCs and nCoVPCs must be included in each run.

1) In the reagent set-up room clean hood, place rRT-PCR buffer, enzyme, and primer/probes on ice or cold-block. Keep cold during preparation and use.
2) Thaw 4X Reaction Mix prior to use.
3) Mix buffer, enzyme, and primer/probes by inversion 5 times.
4) Centrifuge buffer and primers/probes for 5 seconds to collect contents at the bottom of the tube, and then place the tube in a cold rack.
5) Label one 1.5 mL microcentrifuge tube for each primer/probe set.
6) Determine the number of reactions (N) to set up per assay. It is necessary to make excess reaction mix for the NTC, nCoVPC, HSC (if included in the RT-PCR run), and RP reactions and for pipetting error. Use the following guide to determine N:

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- If number of samples (n) including controls equals 1 through 14, then N = n + 1
- If number of samples (n) including controls is 15 or greater, then N = n + 2

7) For each primer/probe set, calculate the amount of each reagent to be added for each reaction mixture (N = # of reactions).

**TaqPath™ 1-Step RT-qPCR Master Mix**

| Step # | Reagent | Vol. of Reagent Added per Reaction |
|---|---|---|
| 1 | Nuclease-free Water | N x 8.5 µL |
| 2 | Combined Primer/Probe Mix | N x 1.5 µL |
| 3 | TaqPath™ 1-Step RT-qPCR Master Mix (4x) | N x 5.0 µL |
| | **Total Volume** | **N x 15.0 µL** |

8) Dispense reagents into each respective labeled 1.5 mL microcentrifuge tube. After addition of the reagents, mix reaction mixtures by pipetting up and down. ***Do not vortex***.
9) Centrifuge for 5 seconds to collect contents at the bottom of the tube, and then place the tube in a cold rack.
10) Set up reaction strip tubes or plates in a 96-well cooler rack.
11) Dispense 15 µL of each master mix into the appropriate wells going across the row as shown below (**Figure 1**):

**Figure 1: Example of Reaction Master Mix Plate Set-Up**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A | N1 | N1 | N1 | N1 | N1 | N1 | N1 | N1 | N1 | N1 | N1 | N1 |
| B | N2 | N2 | N2 | N2 | N2 | N2 | N2 | N2 | N2 | N2 | N2 | N2 |
| C | N3 | N3 | N3 | N3 | N3 | N3 | N3 | N3 | N3 | N3 | N3 | N3 |
| D | RP | RP | RP | RP | RP | RP | RP | RP | RP | RP | RP | RP |
| E | | | | | | | | | | | | |
| F | | | | | | | | | | | | |
| G | | | | | | | | | | | | |
| H | | | | | | | | | | | | |

12) Prior to moving to the nucleic acid handling area, prepare the No Template Control (NTC) reactions for column #1 in the assay preparation area.
13) Pipette 5 µL of nuclease-free water into the NTC sample wells (**Figure 2**, column 1). Securely cap NTC wells before proceeding.
14) Cover the entire reaction plate and move the reaction plate to the specimen nucleic acid handling area.

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**Nucleic Acid Template Addition**

1) Gently vortex nucleic acid sample tubes for approximately 5 seconds.
2) Centrifuge for 5 seconds to collect contents at the bottom of the tube, and then place the tube in a cold rack.
3) After centrifugation, place extracted nucleic acid sample tubes in the cold rack.
4) Samples should be added to columns 2-11 (column 1 and 12 are for controls) to the specific assay that is being tested as illustrated in **Figure 2**. Carefully pipette 5.0 µL of the first sample into all the wells labeled for that sample (i.e. Sample "S1" down column #2). *Keep other sample wells covered during addition. Change tips after each addition.*
5) Securely cap the column to which the sample has been added to prevent cross contamination and to ensure sample tracking.
6) Change gloves often and when necessary to avoid contamination.
7) Repeat steps #3 and #4 for the remaining samples.
8) If necessary, add 5 µL of Human Specimen Control (HSC) extracted sample to the HSC wells (**Figure 2**, column 11). Securely cap wells after addition. NOTE: Per CLIA regulations, HSC must be tested at least once per day.
9) Cover the entire reaction plate and move the reaction plate to the positive template control handling area.

**Assay Control Addition**

1) Pipette 5 µL of nCoVPC RNA to the sample wells of column 12 (**Figure 2**). Securely cap wells after addition of the control RNA.

***NOTE:*** *If using 8-tube strips, label the TAB of each strip to indicate sample position.* ***DO NOT LABEL THE TOPS OF THE REACTION TUBES!***

*2)* Briefly centrifuge reaction tube strips for 10-15 seconds. After centrifugation return to cold rack.

***NOTE****: If using 96-well plates, centrifuge plates for 30 seconds at 500 x g, 4°C.*

**Figure 2. 2019-nCoV rRT-PCR Diagnostic Panel: Example of Sample and Control Set-up**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11[a] | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A | NTC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | S10 | nCoV PC |
| B | NTC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | S10 | nCoV PC |
| C | NTC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | S10 | nCoV PC |
| D | NTC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | S10 | nCoV PC |
| E | | | | | | | | | | | | |
| F | | | | | | | | | | | | |
| G | | | | | | | | | | | | |
| H | | | | | | | | | | | | |

[a]Replace the sample in this column with extracted HSC if necessary

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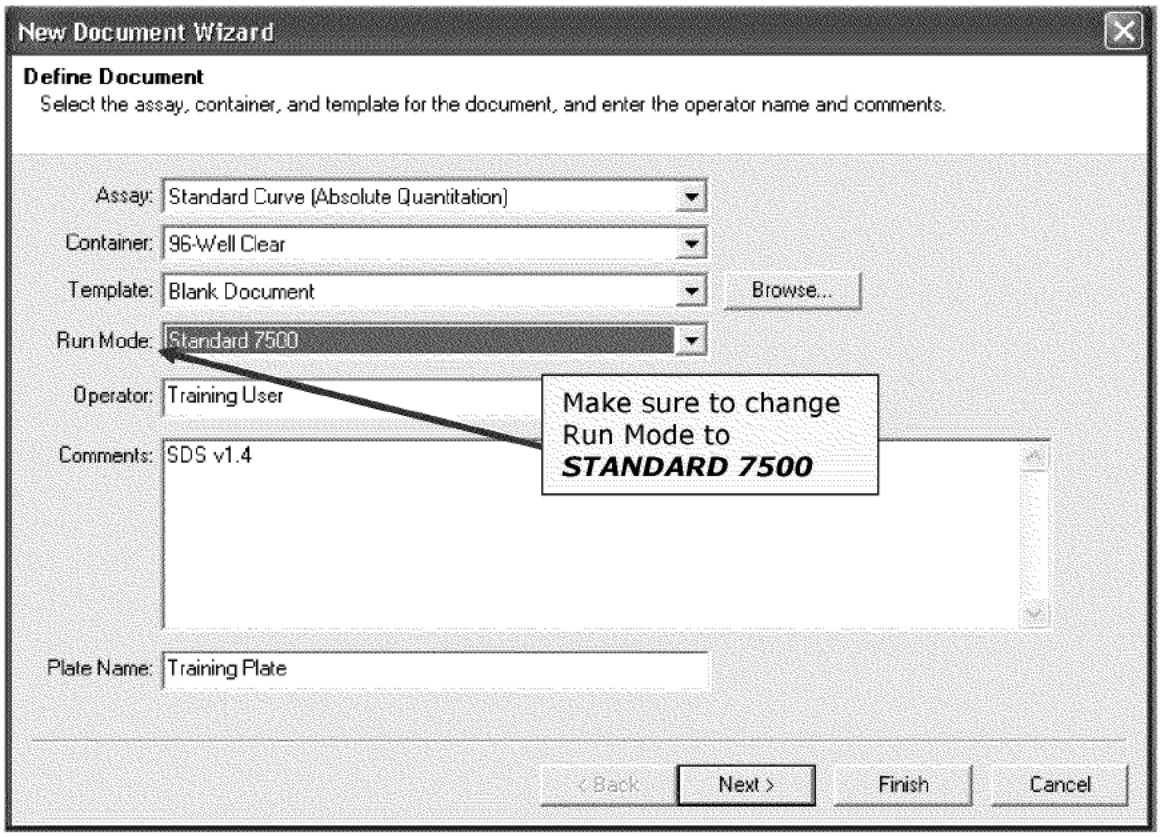

FDACDRH-p6-AO-000092
FDA-CVD-SCHERFU-00014455.0005
MULTI-HHS-20-0522-B, 20-0523-A-000067

# Create a Run Template on the Applied Biosystems 7500 Fast Dx Real-time PCR Instrument (Required if no template exists)

If the template already exists on your instrument, please proceed to the **RUNNING A TEST** section.

1) Launch the Applied Biosystems 7500 Fast Dx Real-time PCR Instrument by double clicking on the Applied Biosystems 7500 Fast Dx System icon on the desktop.
2) A new window should appear, select **Create New Document** from the menu.

**Figure 3. New Document Wizard Window**

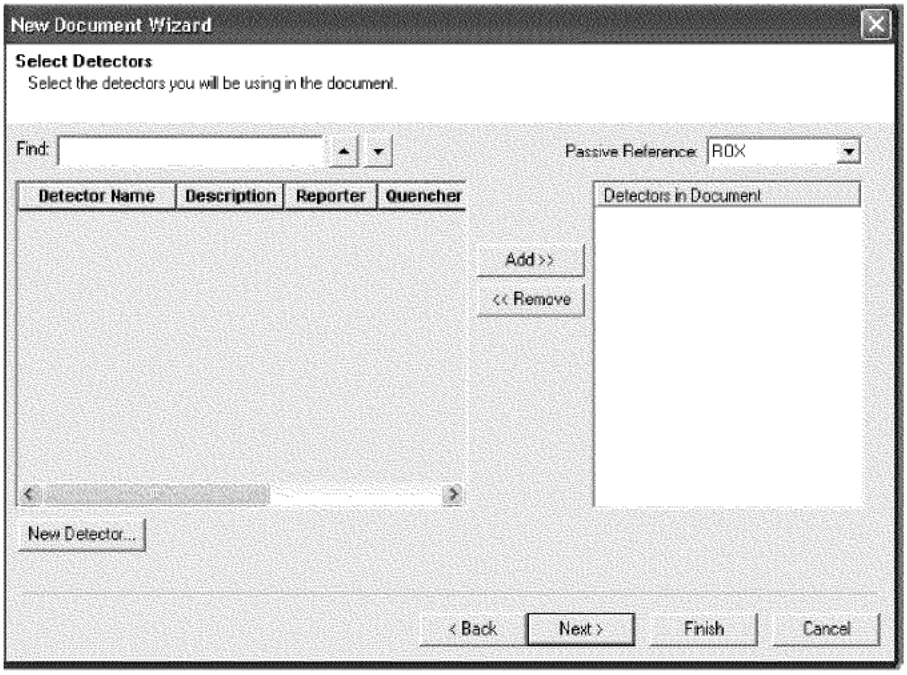



3) The **New Document Wizard** screen in **Figure 3** will appear. Select:
   a. Assay: **Standard Curve (Absolute Quantitation)**
   b. Container: **96-Well Clear**
   c. Template: **Blank Document**
   d. Run Mode: **Standard 7500**
   e. Operator: ***Your Name***
   f. Comments: **SDS v1.4**
   g. Plate Name: ***Your Choice***
4) After making selections click **Next** at the bottom of the window.

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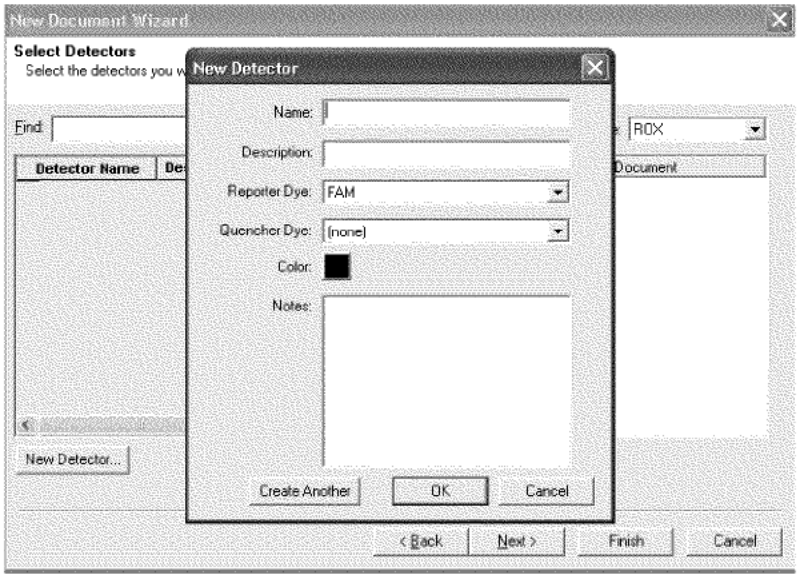

FDACDRH-p6-AO-000693
FDA-CVD-SCHERFU-00014455.0005
MULTI-HHS-20-0522-B, 20-0523-A-000068

**Figure 4. Creating New Detectors**




5) After selecting next, the ***Select Detectors*** screen (**Figure 4**) will appear.
6) Click the **New Detector** button (see **Figure 4**).
7) The **New Detector** window will appear (**Figure 5**). A new detector will need to be defined for each primer and probe set. Creating these detectors will enable you to analyze each primer and probe set individually at the end of the reaction.

**Figure 5. New Detector Window**



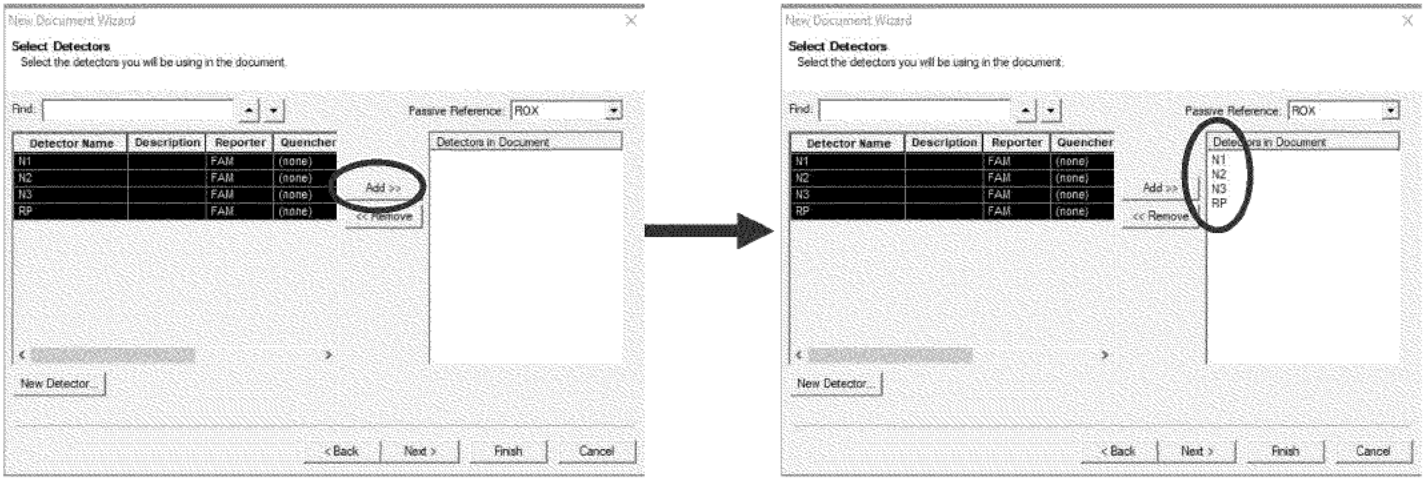

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8) Start by creating the N1 Detector. Include the following:
    a. Name: **N1**
    b. Description: *leave blank*
    c. Reporter Dye: **FAM**
    d. Quencher Dye: **(none)**
    e. Color: *to change the color of the detector indicator do the following:*
        ⇒ Click on the color square to reveal the color chart
        ⇒ Select a color by clicking on one of the squares
        ⇒ After selecting a color click **OK** to return to the New Detector screen
    f. Click the **OK** button of the New Detector screen to return to the screen shown in **Figure 4**.
9) Repeat step 6-8 for each target in the panel.

| Name | Reporter Dye | Quencher Dye |
|---|---|---|
| N1 | FAM | (none) |
| N2 | FAM | (none) |
| N3 | FAM | (none) |
| RP | FAM | (none) |

10) After each Detector is added, the **Detector Name**, **Description**, **Reporter** and **Quencher** fields will become populated in the **Select Detectors** screen (**Figure 6**).
11) Before proceeding, the newly created detectors must be added to the document. To add the new detectors to the document, click **ADD** (see **Figure 6**). Detector names will appear on the right hand side of the **Select Detectors** window (**Figure 6**).

**Figure 6. Adding New Detectors to Document**

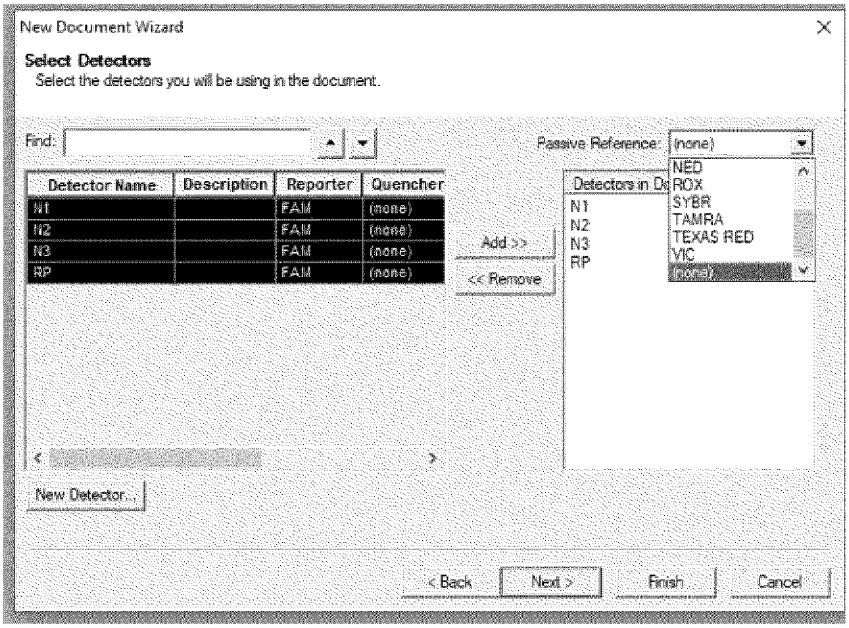



12) Once all detectors have been added, select **(none)** for **Passive Reference** at the top right hand drop down menu (**Figure 7**).

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FDACDRH-pb-AO-000095
MULTI-HHS-20-0522-B, 20-0523-A-000070

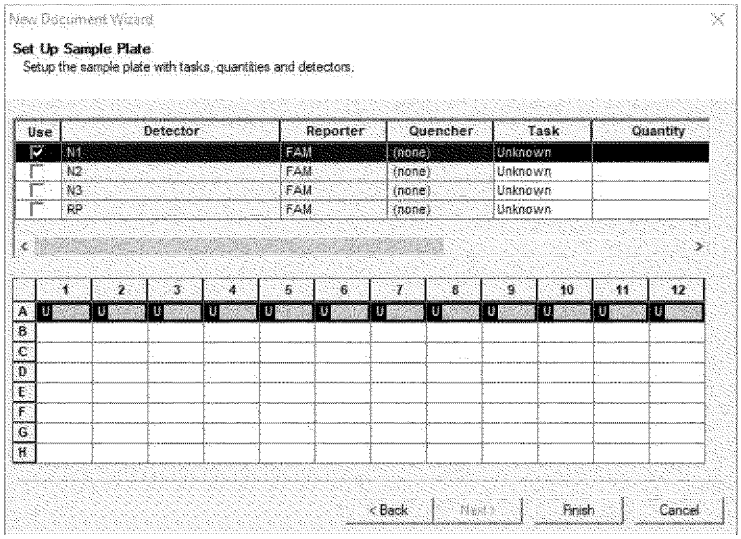
**Figure 7. Select Passive Reference**




**Passive reference should be set to "(none)" as described above.**

13) Click **Next** at the bottom of the **Select Detectors** window to proceed to the **Set Up Sample Plate** window (**Figure 8**).
14) In the **Set Up Sample Plate** window (**Figure 8**), use your mouse to select row A from the lower portion of the window, in the spreadsheet (see **Figure 8**).
15) In the top portion of the window, select detector **N1**. A check will appear next to the detector you have selected (**Figure 8**). You will also notice the row in the spreadsheet will be populated with a colored "U" icon to indicate which detector you've selected.
16) Repeat step 14-15 for each detector that will be used in the assay.

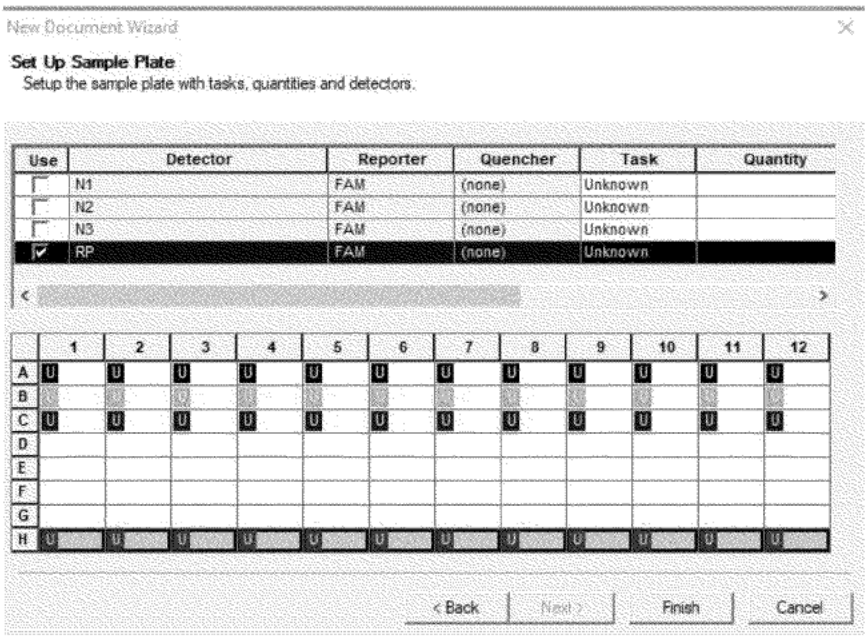
**Figure 8. Sample Plate Set-up**




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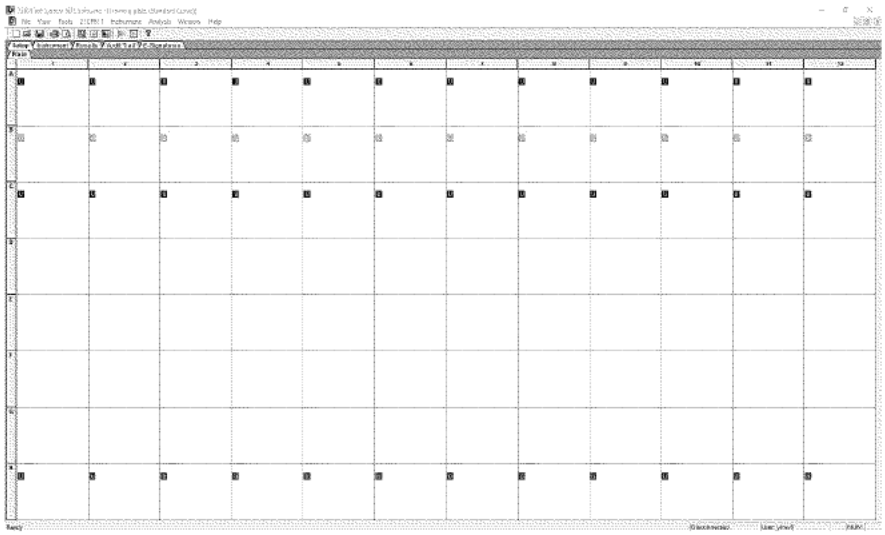
17) Select **Finish** after detectors have been assigned to their respective rows. (**Figure 9**).

**Figure 9. Finished Plate Set-up**




18) After clicking "Finish", there will be a brief pause allowing the Applied Biosystems 7500 Fast Dx to initialize. This initialization is followed by a clicking noise. ***Note: The machine must be turned on for initialization.***
19) After initialization, the **Plate** tab of the Setup (**Figure 10)** will appear.
20) Each well of the plate should contain colored U icons that correspond with the detector labels that were previously chosen. To confirm detector assignments, select **Tools** from the file menu, then select **Detector Manager.**

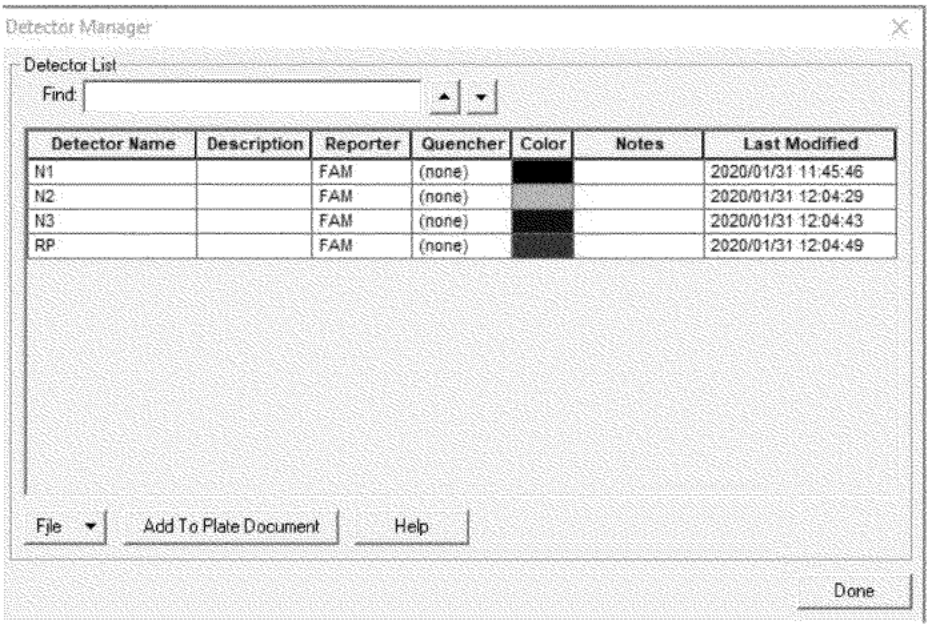
**Figure 10. Plate Set-up Window**



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21) The Detector Manager window will appear (**Figure 11**).

**Figure 11. Detector Manager Window**




22) Confirm all detectors are included and that each target has a **Reporter** set to **FAM** and the **Quencher** is set to **(none)**.
23) If all detectors are present, select **Done**. The detector information has been created and assigned to wells on the plate.

## Defining the Instrument Settings

1) After detectors have been created and assigned, proceed to instrument set up.
2) Select the **Instrument** tab to define thermal cycling conditions.
3) Modify the thermal cycling conditions as follows (**Figure 12**):

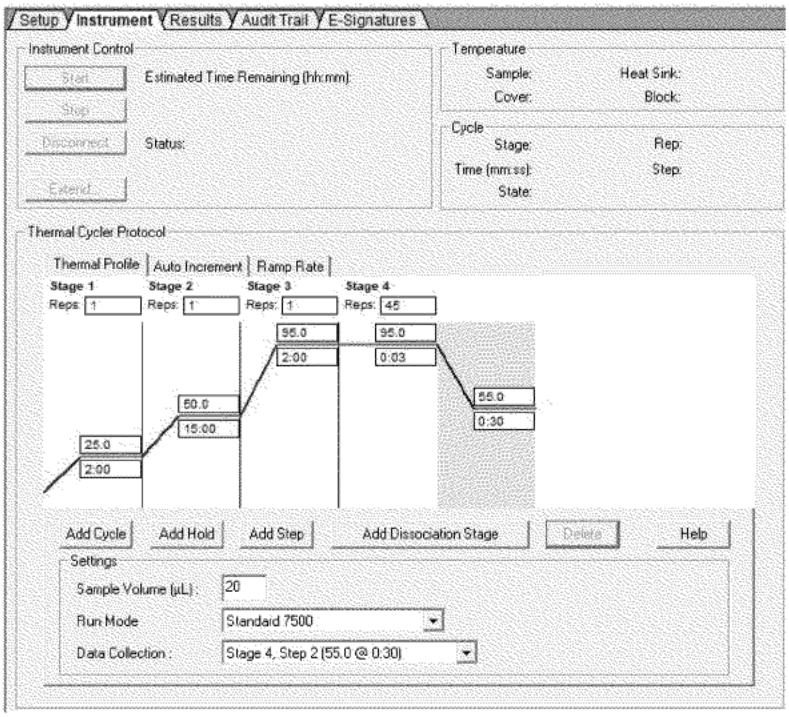
**TaqPath™ 1-Step RT-qPCR Master Mix, CG (ThermoFisher)**

a. In Stage 1, Set to 2 min at **25°C**; **1 Rep**.
b. In Stage 2, Set to 15 min at **50°C**; **1 Rep**.
c. In Stage 3, Set to 2 min at **95°C, 1 Rep.**
d. In Stage 4, Step 1 set to **3 sec** at **95°C**.
e. In Stage 4, Step 2 set to **30 sec** at **55.0°C.**
f. In Stage 4, Reps should be set to **45.**
g. Under **Settings** (**Figure 12**), bottom left-hand box, change volume to 20 µL.
h. Under **Settings**, **Run Mode** selection should be **Standard 7500**.
**i.** Step 2 of Stage 4 should be highlighted in yellow to indicate data collection (see **Figure 12**).

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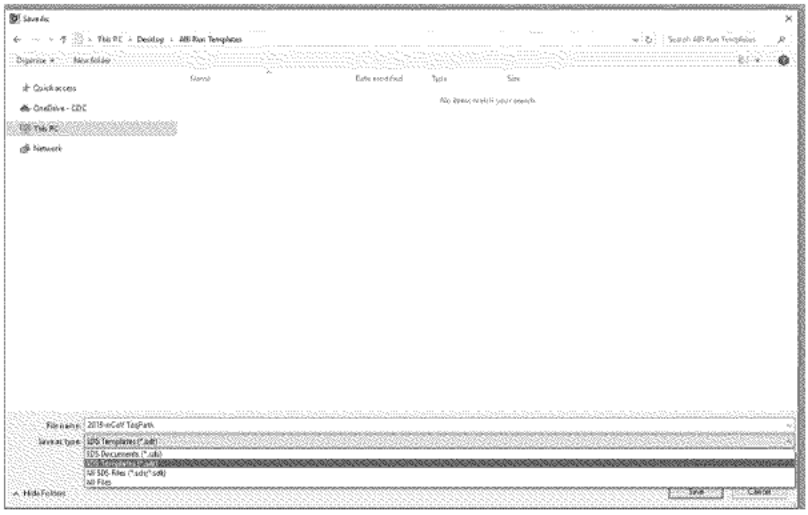

FDACDRH-p6-AO-000698
FDA-CVD-SCHERFU-00014455.0005
MULTI-HHS-20-0522-B, 20-0523-A-000073

**Figure 12. Instrument Window**




4) After making changes to the **Instrument** tab, the template file is ready to be saved. To save the template, select **File** from the top menu, then select **Save As**.
5) Save the template as **2019-nCoV TaqPath** as appropriate in the desktop folder labeled "***ABI Run Templates***" (*you must create this folder*). Save as type should be SDS Templates (*.sdt) (**Figure 13**).

**Figure 13. Saving Template**

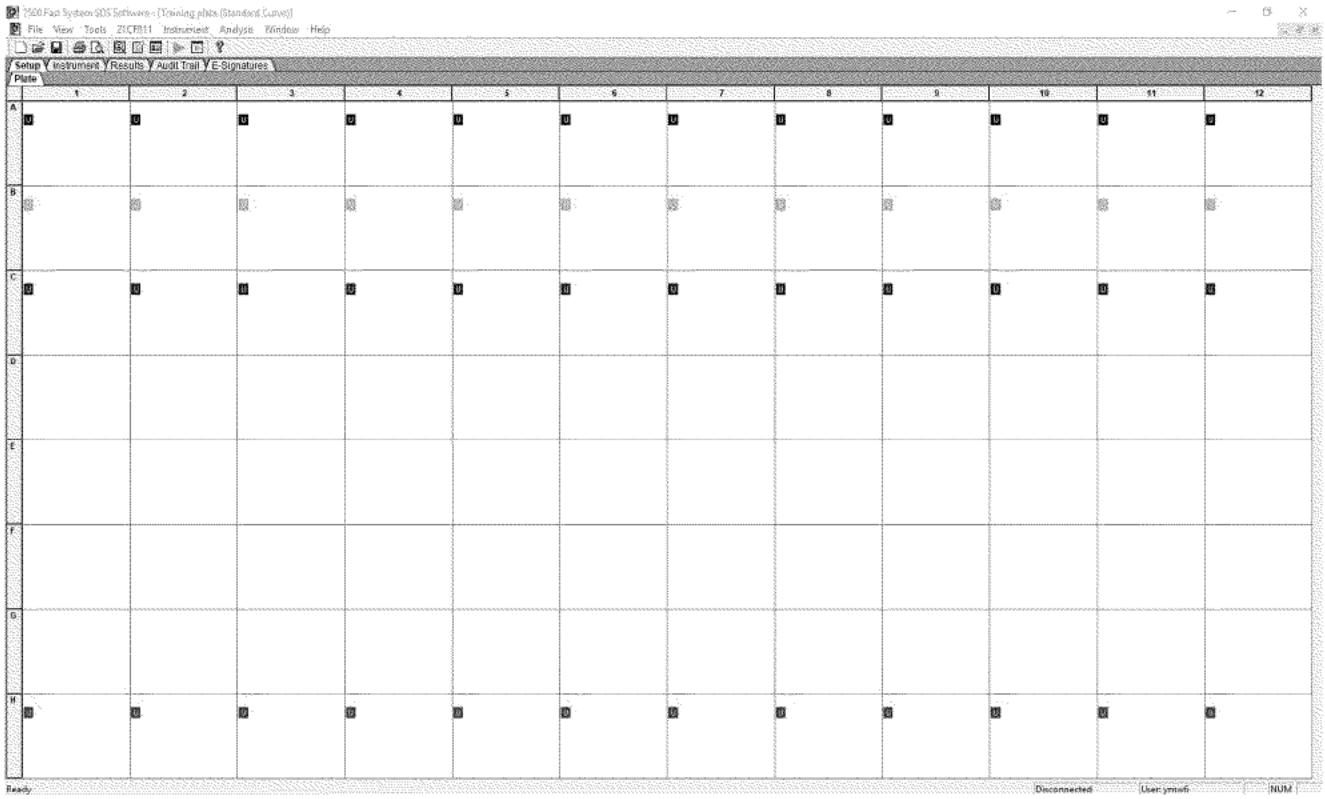


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## Running a Test

1) Turn on the ABI 7500 Fast Dx Real-Time PCR Instrument.
2) Launch the Applied Biosystems 7500 Fast Dx Real-time PCR System by double clicking on the 7500 Fast Dx System icon on the desktop.
3) A new window should appear, select **Open Existing Document** from the menu.
4) Navigate to select your ABI Run Template folder from the desktop.
5) Double click on the appropriate template file **(2019-nCoV TaqPath)**
6) There will be a brief pause allowing the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument to initialize. This initialization is followed by a clicking noise. ***Note: The machine must be turned on for initialization.***

**Figure 14. Plate Set-up Window**

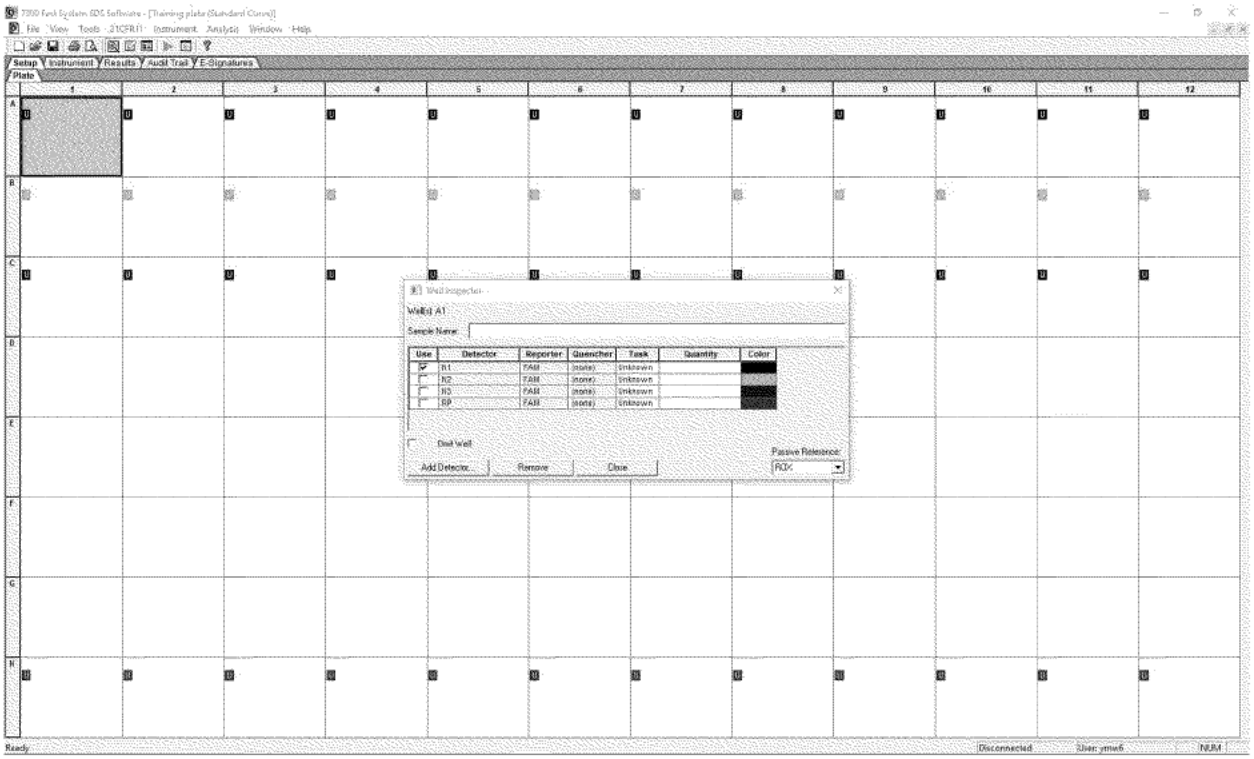



7) After the instrument initializes, a plate map will appear (**Figure 14**). The detectors and controls should already be labeled as they were assigned in the original template.
8) Click the **Well Inspector** icon  from the top menu.
9) Highlight specimen wells of interest on the plate map.
10) Type sample identifiers to **Sample Name** box in the **Well Inspector** window (**Figure 15**).

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FDACDRH-p6-AO-000900
FDA-CVD-SCHERFU-00014455 0005
MULTI-HHS-20-0522-B, 20-0523-A-000075

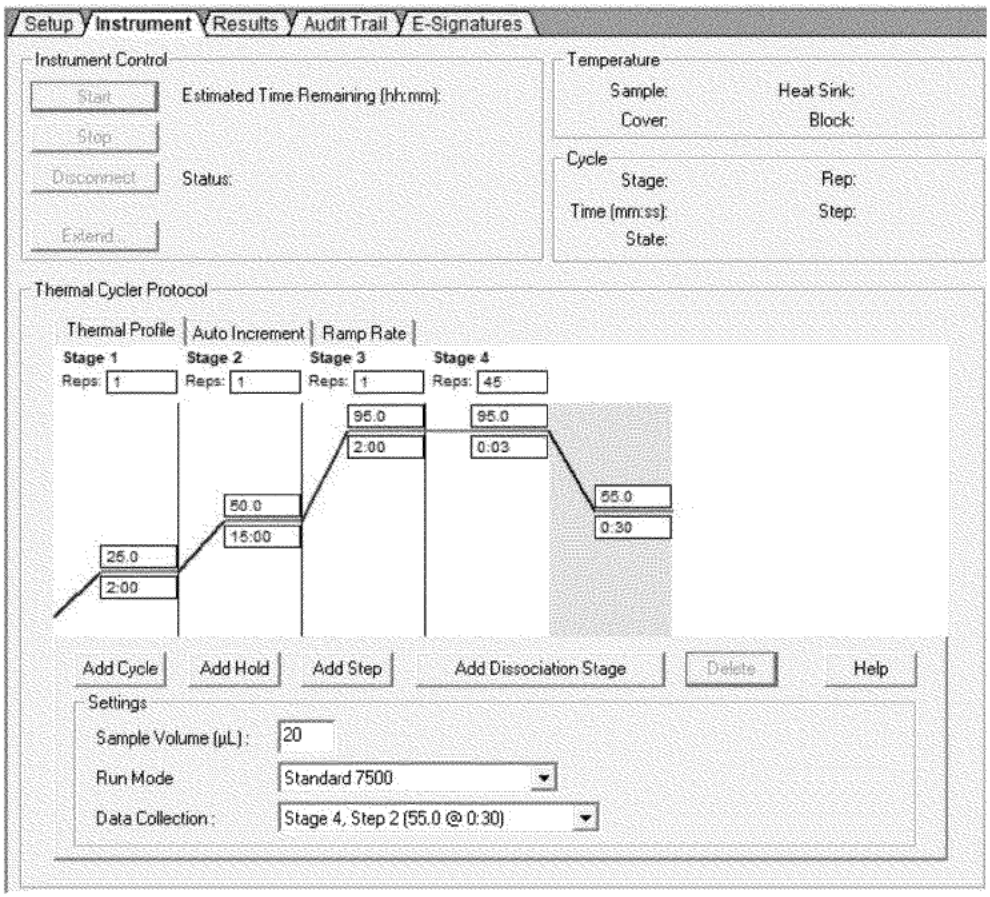
**Figure 15. Labeling Wells**




11) Repeat steps 9-10 until all sample identifiers are added to the plate setup.
12) Once all specimen and control identifiers are added click the **Close** button on the **Well Inspector** window to return to the **Plate** set up tab.
13) Click the **Instrument** tab at the upper left corner.
14) The reaction conditions, volumes, and type of 7500 reaction should already be loaded. (**Figure 16**).

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**Figure 16. Instrument Settings**



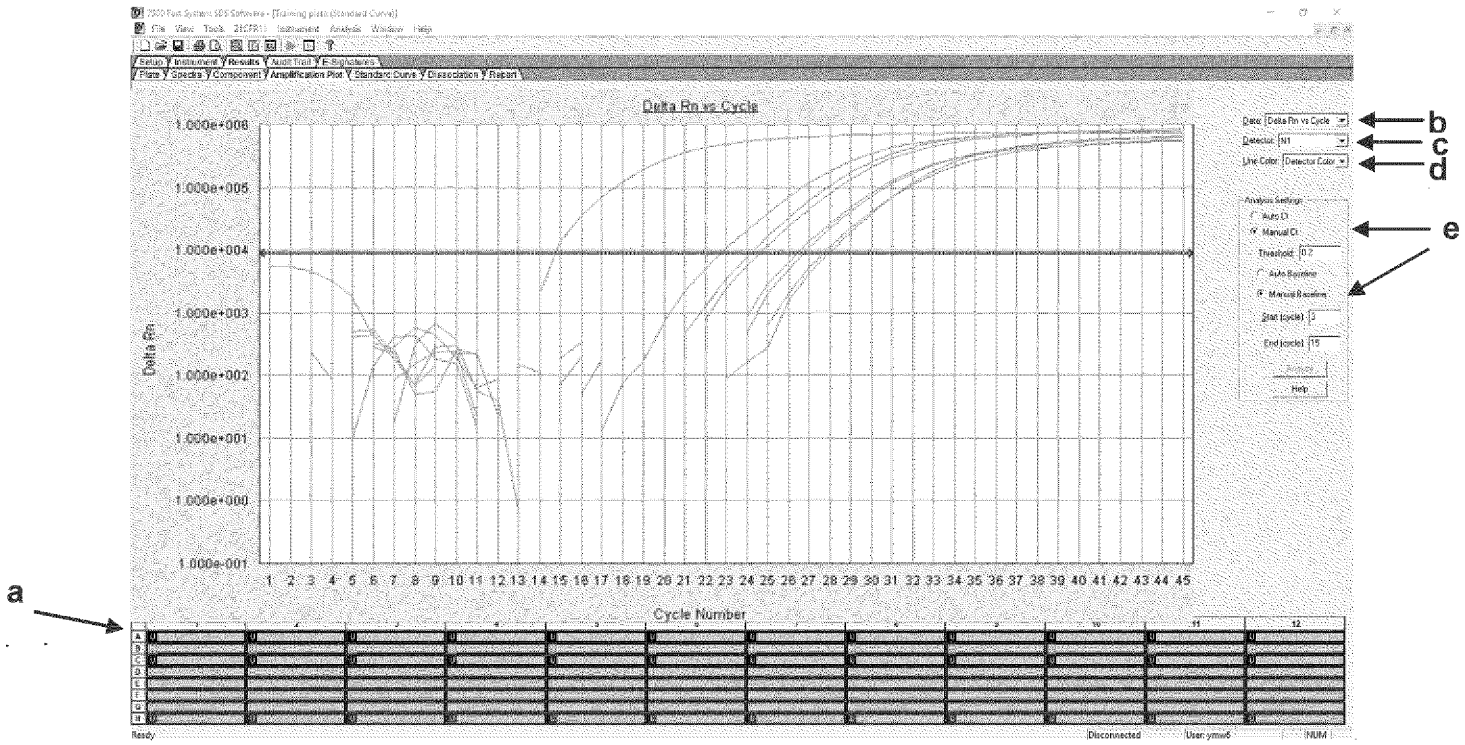

15) Ensure settings are correct (refer to the *Defining Instrument Settings*).
16) Before proceeding, the run file must be saved; from the main menu, select **File,** then **Save As**. Save in appropriate run folder designation.
17) Load the plate into the plate holder in the instrument. Ensure that the plate is properly aligned in the holder.
18) Once the run file is saved, click the **Start** button. *Note: The run should take approximately 1hr and 20 minutes to complete.*

## Data Analysis

1) After the run has completed, select the **Results** tab at the upper left corner of the software.
2) Select the **Amplification Plot** tab to view the raw data (**Figure 17**).

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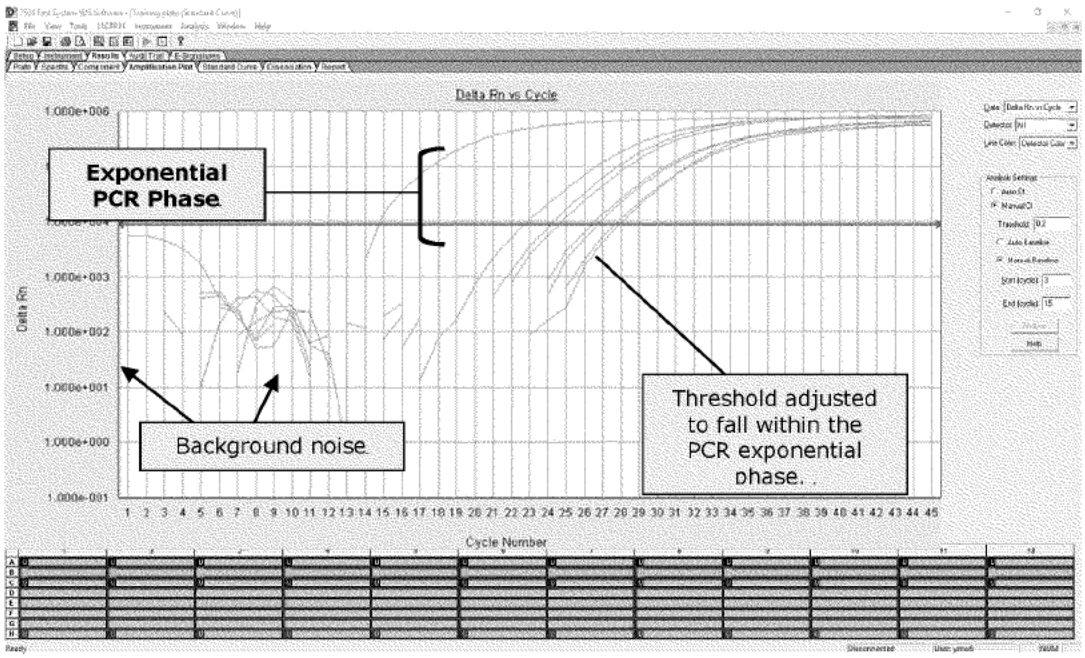
**Figure 17. Amplification Plot Window**




3) Start by highlighting all the samples from the run; to do this, click on the upper left hand box **(a)** of the sample wells (**Figure 17**). All the growth curves should appear on the graph.
4) On the right hand side of the window **(b)**, the **Data** drop down selection should be set to **Delta Rn vs. Cycle**.
5) Select **N1** from **(c)**, the **Detector** drop down menu, using the downward arrow.
    a. Please note that each detector is analyzed individually to reflect different performance profiles of each primer and probe set.
6) In the **Line Color** drop down **(d)**, **Detector Color** should be selected.
7) Under **Analysis Settings** select **Manual Ct (e)**.
    **b.** Do not change the **Manual Baseline** default numbers.
8) Using the mouse, click and drag the red threshold line until it lies within the exponential phase of the fluorescence curves and above any background signal **(Figure 18)**.

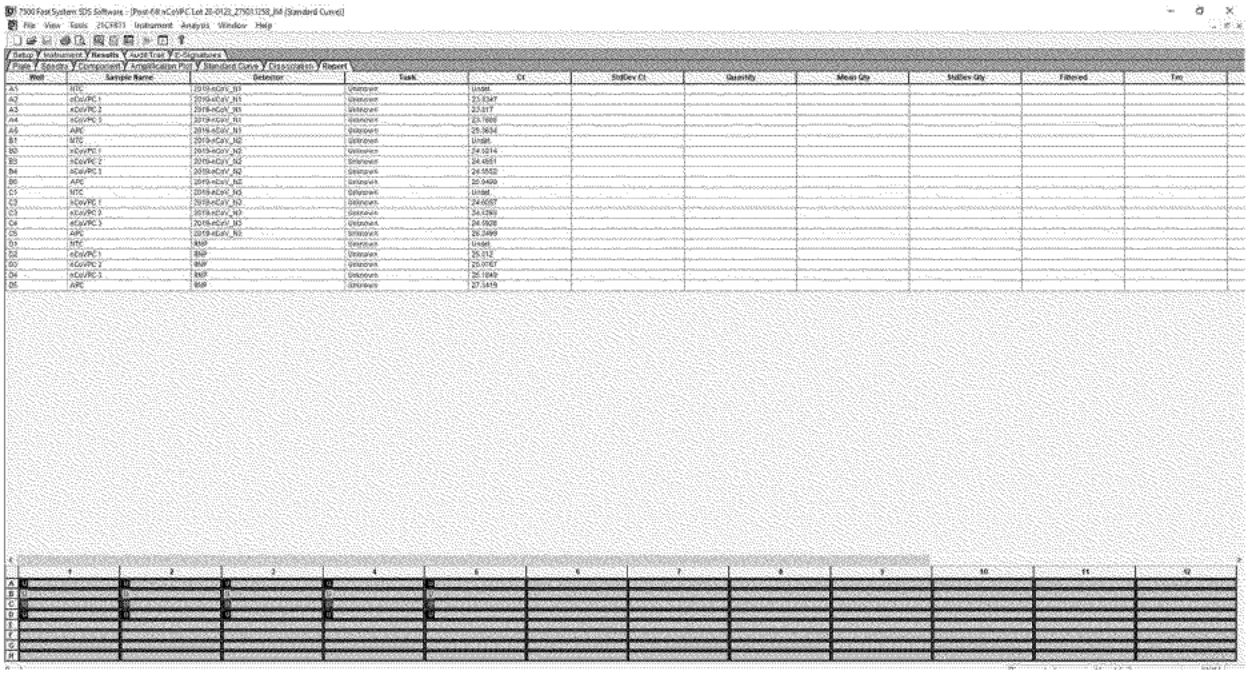
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**Figure 18. Amplification Plot**




9) Click the **Analyze** button in the lower right corner of the window. The red threshold line will turn to green, indicating the data has been analyzed.
10) Repeat steps 5-9 to analyze results generated for each set of markers (i.e. N1, N2, N3, etc).
11) Save analysis file by selecting **File** then **Save As** from the main menu.
12) After completing analysis for each of the markers, select the **Report** tab above the graph to display the Ct values (**Figure 19**). To filter report by sample name in ascending or descending order, simply click on **Sample Name** in the table.

**Figure 19. Report**



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## Interpretation of Results and Reporting

**Expected Performance of Controls Included in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel**

| Control Type | External Control Name | Used to Monitor | 2019 nCoV_N1 | 2019 nCoV_N2 | 2019 nCoV_N3 | RP | Expected Ct Values |
|---|---|---|---|---|---|---|---|
| Positive | nCoVPC | Substantial reagent failure including primer and probe integrity | + | + | + | + | < 40.00 Ct |
| Negative | NTC | Reagent and/or environmental contamination | - | - | - | - | None detected |
| Extraction | HSC | Failure in lysis and extraction procedure, potential contamination during extraction | - | - | - | + | < 40.00 Ct |

**If any of the above controls do not exhibit the expected performance as described, the assay may have been set up and/or executed improperly, or reagent or equipment malfunction could have occurred. Invalidate the run and re-test.**

**RNase P (Extraction Control)**

- All clinical samples should exhibit fluorescence growth curves in the RNase P reaction that cross the threshold line within 40.00 cycles (< 40.00 Ct), thus indicating the presence of the human RNase P gene. Failure to detect RNase P in any clinical specimens may indicate:
  - Improper extraction of nucleic acid from clinical materials resulting in loss of RNA and/or RNA degradation.
  - Absence of sufficient human cellular material due to poor collection or loss of specimen integrity.
  - Improper assay set up and execution.
  - Reagent or equipment malfunction.
- If the RP assay does not produce a positive result for human clinical specimens, interpret as follows:
  - If the 2019-nCoV N1, N2 and N3 are positive even in the absence of a positive RP, the result should be considered valid. It is possible, that some samples may fail to exhibit RNase P growth curves due to low cell numbers in the original clinical sample. A negative RP signal does not preclude the presence of 2019-nCoV virus RNA in a clinical specimen.

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- If all 2019-nCoV markers AND RNase P are negative for the specimen, the result should be considered invalid for the specimen. If residual specimen is available, repeat the extraction procedure and repeat the test. If all markers remain negative after re-test, report the results as invalid and a new specimen should be collected if possible.

**2019-nCoV Markers (N1, N2 and N3)**

- When all controls exhibit the expected performance, a specimen is considered negative if all 2019-nCoV marker (N1, N2, N3) cycle threshold growth curves DO NOT cross the threshold line within 40.00 cycles (< 40.00 Ct) AND the RNase P growth curve DOES cross the threshold line within 40.00 cycles (< 40.00 Ct).
- When all controls exhibit the expected performance, a specimen is considered presumptive positive for 2019-nCoV if all markers (N1, N2, N3) cycle threshold growth curve crosses the threshold line within 40.00 cycles (< 40.00 Ct) The RNase P may or may not be positive as described above, but the 2019-nCoV result is still valid.
- When all controls exhibit the expected performance and the growth curves for the 2019-nCoV markers (N1, N2, N3) AND the RNase P marker DO NOT cross the cycle threshold growth curve within 40.00 cycles (< 40.00 Ct), the result is invalid. The extracted RNA from the specimen should be re-tested. If residual RNA is not available, re-extract RNA from residual specimen and re-test. If the re-tested sample is negative for all markers and RNase P, the result is invalid and a new collection of specimen from the patient should be considered.
- When all controls exhibit the expected performance and the cycle threshold growth curve for any one or two markers (N1, N2, N3) (but not all three markers) crosses the threshold line within 40.00 cycles (< 40.00 Ct) the result is inconclusive. Repeat extraction and rRT-PCR.
- If HSC is positive for N1, N2, or N3, then contamination may have occurred during extraction or sample processing. Re-extract specimens and HSC and re-test.

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# 2019-nCoV rRT-PCR Diagnostic Panel Results Interpretation Guide

The table below lists the expected results for the 2019-nCoV rRT-PCR Diagnostic Panel. If results are obtained that do not follow these guidelines, re-extract and re-test the sample. If repeat testing yields similar results, contact CDC for consultation and possible specimen referral. See pages 8 and 31 for referral and contact information.

| 2019 nCoV_N1 | 2019 nCoV_N2 | 2019 nCoV_N3 | RP | Result Interpretation[a] | Report | Actions |
|---|---|---|---|---|---|---|
| + | + | + | ± | 2019-nCoV detected | Presumptive positive 2019-nCoV | Report results to CDC and sender. Contact CDC immediately for instructions for transfer of the specimen to CDC for additional testing and further guidance. |
| If only one, or two, of the three targets is positive | | | ± | Inconclusive Result | Inconclusive | Repeat extraction and rRT-PCR. If the repeated result remains inconclusive, contact CDC immediately for instructions for transfer of the specimen to CDC for additional testing and further guidance. |
| - | - | - | + | 2019-nCoV not detected | Not Detected | Report results to sender. Consider testing for other respiratory viruses.[b] |
| - | - | - | - | Invalid Result | Invalid | Repeat extraction and rRT-PCR. If the repeated result remains invalid, consider collecting a new specimen from the patient. |

**[a]Laboratories should report their diagnostic result as appropriate and in compliance with their specific reporting system.**

**[b]Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens from the same patient may be necessary to detect the virus.**

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## Quality Control

- Quality control requirements must be performed in conformance with local, state, and federal regulations or accreditation requirements and the user's laboratory's standard quality control procedures. For further guidance on appropriate quality control practices, refer to 42 CFR 493.1256.
- Quality control procedures are intended to monitor reagent and assay performance.
- Test all positive controls prior to running diagnostic samples with each new kit lot to ensure all reagents and kit components are working properly.
- Good laboratory practice (cGLP) recommends including a positive extraction control in each nucleic acid isolation batch.
- Although HSC is not included with the 2019-nCov rRT-PCR Diagnostic Panel, the HSC extraction control must proceed through nucleic acid isolation per batch of specimens to be tested.
- Always include a negative control (NTC), and the appropriate positive control (nCoVPC) in each amplification and detection run. All clinical samples should be tested for human RNAse P gene to control for specimen quality and extraction.

## Limitations

- All users, analysts, and any person reporting diagnostic results should be trained to perform this procedure by a competent instructor. They should demonstrate their ability to perform the test and interpret the results prior to performing the assay independently. CDC Division of Viral Diseases will limit the distribution of this device to only those users who have successfully completed training provided by CDC instructors or designees.
- Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has only been established in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).
- Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.
- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely when prevalence of disease is high. False positive test results are more likely when prevalence is moderate to low.
- Do not use any reagent past the expiration date.
- If the virus mutates in the rRT-PCR target region, 2019-nCoV may not be detected or may be detected less predictably. Inhibitors or other types of interference may produce a false negative result. An interference study evaluating the effect of common cold medications was not performed.
- Test performance can be affected because the epidemiology and clinical spectrum of infection caused by 2019-nCoV is not fully known. For example, clinicians and laboratories may not know the optimum types of specimens to collect, and when during the course of infection these specimens are most likely to contain levels of viral RNA that can be readily detected.

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- Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms.
- The performance of this test has not been established for monitoring treatment of 2019-nCoV infection.
- The performance of this test has not been established for screening of blood or blood products for the presence of 2019-nCoV.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.

## Conditions of Authorization for the Laboratory

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website: [ HYPERLINK "https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm" ]
Use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel must follow the procedures outlined in these manufacturer's Instructions for Use and the conditions of authorization outlined in the Letter of Authorization. Deviations from the procedures outlined are not permitted under the Emergency Use Authorization (EUA). To assist clinical laboratories running the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, the relevant Conditions of Authorization are listed verbatim below, and are required to be met by laboratories performing the EUA test.

- Authorized laboratories[1] will include with reports of the results of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

- Authorized laboratories will perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel as outlined in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use. Deviations from the authorized procedures, including the authorized RT-PCR instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel are not permitted.

- Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

- Authorized laboratories will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and CDC ([ HYPERLINK "mailto:respvirus@cdc.gov" ]) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

[1]Authorized Laboratories: For ease of reference, the Letter of Authorization refers to "qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests" as "authorized laboratories."

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- All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the test in accordance with the authorized labeling.

- CDC and authorized laboratories will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

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# Performance Characteristics

## ***Analytical Performance:***

*Limit of Detection (LoD):*

LoD studies determine the lowest detectable concentration of 2019-nCoV at which approximately 95% of all (true positive) replicates test positive. The LoD was determined by limiting dilution studies using characterized samples.

The analytical sensitivity of the rRT-PCR assays contained in the CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel were determined in Limit of Detection studies. Since no quantified virus isolates of the 2019-nCoV are currently available, assays designed for detection of the 2019-nCoV RNA were tested with characterized stocks of in vitro transcribed full length RNA (N gene; GenBank accession: MN908947.2) of known titer (RNA copies/µL) spiked into a diluent consisting of a suspension of human A549 cells and viral transport medium (VTM) to mimic clinical specimen. Samples were extracted using the QIAGEN EZ1 Advanced XL instrument and EZ1 DSP Virus Kit (Cat# 62724) and manually with the QIAGEN DSP Viral RNA Mini Kit (Cat# 61904). Real-Time RT-PCR assays were performed using the ThemoFisher Scientific TaqPath™ 1-Step RT-qPCR Master Mix, CG (Cat# A15299) on the Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use.

A preliminary LoD for each assay was determined testing triplicate samples of RNA purified using each extraction method. The approximate LoD was identified by extracting and testing 10-fold serial dilutions of characterized stocks of in vitro transcribed full-length RNA. A confirmation of the LoD was determined using 3-fold serial dilution RNA samples with 20 extracted replicates. The LoD was determined as the lowest concentration where ≥ 95% (19/20) of the replicates were positive.

**Table 4. Limit of Detection Confirmation of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with QIAGEN EZ1 DSP**

| Targets | 2019-nCoV_N1 | | | 2019-nCoV_N2 | | | 2019-nCoV_N3 | | |
|---|---|---|---|---|---|---|---|---|---|
| RNA Concentration[1] | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ |
| Positives/Total | 20/20 | 19/20 | 13/20 | 20/20 | 17/20 | 9/20 | 19/20 | 17/20 | 8/20 |
| Mean Ct[2] | 32.5 | 35.4 | NA | 35.8 | NA | NA | 33.2 | NA | NA |
| Standard Deviation (Ct) | 0.5 | 0.8 | NA | 1.3 | NA | NA | 0.9 | NA | NA |

[1] Concentration is presented in RNA copies/µL

[2] Mean Ct reported for dilutions that are ≥ 95% positive. Calculations only include positive results.

NA not applicable

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**Table 5. Limit of Detection Confirmation CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with QIAGEN QIAmp DSP Viral RNA Mini Kit**

| Targets | 2019-nCoV_N1 | | | 2019-nCoV_N2 | | | | 2019-nCoV_N3 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| RNA Concentration[1] | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ | $10^{-1.0}$ | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ |
| Positives/Total | 20/20 | 20/20 | 6/20 | 20/20 | 20/20 | 20/20 | 8/20 | 20/20 | 20/20 | 5/20 |
| Mean Ct[2] | 32.0 | 32.8 | NA | 33.0 | 35.4 | 36.2 | NA | 32.4 | 32.7 | NA |
| Standard Deviation (Ct) | 0.7 | 0.8 | NA | 1.4 | 0.9 | 1.9 | NA | 0.7 | 0.8 | NA |

[1] Concentration is presented in RNA copies/µL

[2] Mean Ct reported for dilutions that are ≥ 95% positive. Calculations only include positive results.

NA not applicable

**Table 6. Limit of Detection of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel**

| Virus | Material | Limit of Detection (RNA copies/µL) | |
|---|---|---|---|
| | | QIAGEN EZ1 Advanced XL | QIAGEN DSP Viral RNA Mini Kit |
| 2019 Novel Coronavirus | N Gene RNA Transcript | $10^{0.5}$ | $10^{0}$ |

FDA Sensitivity Evaluation: The analytical sensitivity of the test will be further assessed by evaluating an FDA-recommended reference material using an FDA developed protocol if applicable and/or when available.

*In Silico Analysis of Primer and Probe Sequences:*

An alignment was performed with the oligonucleotide primer and probe sequences of the CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel with all publicly available nucleic acid sequences for 2019-nCoV in GenBank as of February 1, 2020 to demonstrate the predicted inclusivity of the CDC 2019 nCoV Real-Time RT-PCR Diagnostic panel. All the alignments show 100% identity of the CDC panel to the available 2019-nCoV sequences with the exception of one nucleotide mismatch with the N1 forward primer in one deposited sequence. Similarly, a single mismatch is observed in the alignment of the N3 probe. The risk assessment of these single mismatches resulting in a significant loss in reactivity, and false negative result, is low due to the design of the primers and probes with melting temperatures > 60°C and run conditions of the assay with annealing temperature at 55°C to tolerate one to two mismatches. The alignment of the 2019-nCoV_N3 assay includes additional sequences for SARS, MERS, and other Bat coronaviruses to show that other than SARS viruses, the alignment shows low identities and would not predict significant reactivity.

*Specificity/Exclusivity Testing: In Silico Analysis*

BLASTn analysis queries of the 2019-nCoV rRT-PCR assays primers and probes were performed against public domain nucleotide sequences. The database search parameters were as follows: 1) The nucleotide collection consists of GenBank+EMBL+DDBJ+PDB+RefSeq sequences, but excludes EST, STS, GSS, WGS, TSA, patent sequences as well as phase 0, 1, and 2 HTGS sequences and sequences longer than 100Mb; 2) The database is non-redundant. Identical sequences have been merged into one entry, while preserving the accession, GI, title and taxonomy information for each entry; 3) Database was updated on 10/03/2019; 4) The search

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parameters automatically adjust for short input sequences and the expect threshold is 1000; 5) The match and mismatch scores are 1 and -3, respectively; 6) The penalty to create and extend a gap in an alignment is 5 and 2 respectively.

2019-nCoV_N1 Assay:
Probe sequence of 2019-nCoV rRT-PCR assay N1 showed high sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome. However, forward and reverse primers showed no sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome. Combining primers and probe, there is no significant homologies with human genome, other coronaviruses or human microflora that would predict potential false positive rRT-PCR results.

2019-nCoV_N2 Assay:
The forward primer sequence of 2019-nCoV rRT-PCR assay N2 showed high sequence homology to Bat SARS-like coronaviruses. The reverse primer and probe sequences showed no significant homology with human genome, other coronaviruses or human microflora. Combining primers and probe, there is no prediction of potential false positive rRT-PCR results.

2019-nCoV_N3 Assay:
Analysis of the forward and reverse primer and probe sequences of 2019-nCoV rRT-PCR assay N3 showed significant homology only to human SARS coronavirus and bat SARS coronavirus. No significant homology with human genome, other coronaviruses or human microflora was observed. that would predict potential false positive rRT-PCR results.

In summary, the 2019-nCoV rRT-PCR assay N1 and N2, designed for the specific detection of 2019-nCoV, showed no significant combined homologies with human genome, other coronaviruses, or human microflora that would predict potential false positive rRT-PCR results.

The 2019-nCoV rRT-PCR assay N3 was designed for universal detection of 2019-nCoV, human SARS coronavirus and bat SARS coronavirus. The 2019-nCoV rRT-PCR assay 3 showed no significant combined homologies with human genome, other human coronaviruses other than human SARS coronavirus or human microflora that would predict potential false positive rRT-PCR results.

In addition to the *in silico* analysis, several organisms were extracted and tested with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel to demonstrate analytical specificity and exclusivity. Studies were performed with nucleic acids extracted using the QIAGEN EZ1 Advanced XL instrument and EZ1 DSP Virus Kit. Nucleic acids were extracted from high titer preparations (typically $\geq 10^5$ PFU/mL or $\geq 10^6$ CFU/mL). Testing was performed using the ThemoFisher Scientific TaqPath™ 1-Step RT-qPCR Master Mix, CG on the Applied Biosystems™ 7500 Fast Dx Real-Time PCR instrument. The data demonstrate that the expected results are obtained for each organism when tested with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

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**Table 7. Specificity/Exclusivity of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel**

| Virus | Strain | Source | 2019-nCoV_N1 | 2019-nCoV_N2 | 2019-nCoV_N3 | Final Result |
|---|---|---|---|---|---|---|
| Human coronavirus | 229E | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Human coronavirus | OC43 | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Human coronavirus | NL63 | clinical specimen | 0/3 | 0/3 | 0/3 | Neg. |
| Human coronavirus | HKU1 | clinical specimen | 0/3 | 0/3 | 0/3 | Neg. |
| MERS-coronavirus | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| SARS-coronavirus | | isolate | 0/3 | 0/3 | 3/3 | Inc. |
| bocavirus | - | clinical specimen | 0/3 | 0/3 | 0/3 | Neg. |
| *Mycoplasma pneumoniae* | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| *Streptococcus* | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Influenza A(H1N1) | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Influenza A(H3N2) | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Influenza B | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Human adenovirus, type 1 | Ad71 | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Human metapneumovirus | - | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| respiratory syncytial virus | Long A | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| rhinovirus | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| parainfluenza 1 | C35 | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| parainfluenza 2 | Greer | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| parainfluenza 3 | C-43 | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| parainfluenza 4 | M-25 | isolate | 0/3 | 0/3 | 0/3 | Neg. |

*Endogenous Interference Substances Studies*:

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel uses conventional well-established nucleic acid extraction methods and based on our experience with CDC's other EUA assays, including the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay for the presumptive detection of novel influenza A (H7N9) virus that are both intended for use with a number of respiratory specimens, we do not anticipate interference from common endogenous substances.

*Specimen Stability and Fresh-frozen Testing:*

To increase the likelihood of detecting infection, CDC recommends collection of three specimen types, lower respiratory and upper respiratory specimens for testing. If possible, additional specimen types (e.g., stool, urine) should be collected and should be stored initially until decision is made by CDC whether additional specimen sources should be tested. Specimens should be collected as soon as possible once a PUI is identified regardless of symptom onset. Maintain proper infection control when collecting specimens. Store specimens at 2-8°C and ship overnight to CDC on ice pack. Label each specimen container with the patient's ID number (e.g., medical record number), unique specimen ID (e.g., laboratory requisition number), specimen type (e.g., nasal swabs) and the date the sample was collected. Complete a CDC Form 50.34 for each specimen submitted.

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***Clinical Performance:***

As of January 27, 2020, CDC has tested 253 respiratory specimens from 102 persons under investigation (PUI) in the U.S. using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Specimen types include buccal swab, nasal washes, nasopharyngeal swab, oral swab, sputum, and oropharyngeal (throat) swab.

**Table 8: Summary of CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Data Generated by Testing Human Respiratory Specimens Collected from PUI Subjects in the U.S.**

| Specimen Type | Number of Specimens | CDC 2019-nCoV Panel Positive | CDC 2019-nCoV Panel Negative | CDC 2019-nCoV Panel Inconclusive |
|---|---|---|---|---|
| Buccal Swab | 4 | 1 | 3 | 0 |
| Nasal Wash | 2 | 0 | 2 | 0 |
| Nasopharyngeal Swab | 103 | 5 | 98 | 0 |
| Oral Swab | 52 | 5 | 47 | 0 |
| Sputum | 50 | 5 | 45 | 0 |
| Swab[1] | 13 | 0 | 13 | 0 |
| Oropharyngeal (Throat) Swab | 29 | 2 | 27 | 0 |
| Total | 253 | 18 | 235 | 0 |

[1]Actual swab type information was missing from these upper respiratory tract specimens.

For 85 of the 102 PUI subjects, multiple respiratory specimens were collected from each subject and tested by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. A single respiratory specimen was collected and tested for each of the 17 remaining PUI subjects. Respiratory specimens for 97 of the 102 PUI subjects tested negative by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Most but not all of the specimens collected from the five remaining PUI subjects tested positive by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. The positive results were further investigated and confirmed by genetic sequencing. Longitudinal specimens were collected from two of the five confirmed 2019-nCoV positive patients and tested using the CDC 2019-nCoV Panel. For three of the five confirmed 2019-nCoV positive patients all samples collected tested positive by the CDC 2019-nCoV Panel. For the two remaining confirmed 2019-nCoV positive patients, upper and lower respiratory tract specimens were collected and tested from the first patient at one time point only, and from the second patient longitudinally over three time points. One buccal swab and one sputum specimen from the first patient tested positive by the CDC 2019-nCoV Panel, one nasopharyngeal swab specimen collected on the same day tested negative. For the second patient, one oral swab, one nasopharyngeal swab and one sputum specimen collected approximately eight days post onset of symptoms tested positive by the CDC 2019-nCoV Panel. While one sputum specimen collected approximately 10 days post symptoms onset tested positive, two oral swabs and two nasopharyngeal swabs collected on the same day tested negative. Approximately 12 days post onset of symptoms, one sputum specimen and one oral swab specimen from the second patient tested positive, but two nasopharyngeal swabs taken on the same day were negative.

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During the early phase of the testing, a total of 117 respiratory specimens collected from 46 PUI subjects were also tested with two analytically validated real-time RT-PCR assays that target separate and independent regions of the nucleocapsid protein gene of the 2019-nCoV, N4 and N5 assays. The nucleocapsid protein gene targets for the N4 and N5 assays are different and independent from the nucleocapsid protein gene targets for the three RT-PCR assays included in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, N1, N2, and N3. Any positive result from the N4 and/or the N5 assay was further investigated by genetic sequencing.

The performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel was estimated against a composite comparator. A specimen was considered comparator negative if both the N4 and the N5 assays were negative. A specimen was considered comparator positive when the N4 and/or the N5 assay generated a positive result, and the comparator positive result(s) were further investigated and confirmed to be 2019-nCoV RNA positive by genetic sequencing.

**Table 9: Percent Agreement of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with the Composite Comparator**

| **CDC 2019-nCoV Panel Result** | **Composite Comparator Result** | |
|---|---|---|
| | Positive | Negative |
| Positive | 13[1] | 0 |
| Inconclusive | 0 | 0 |
| Negative | 0 | 104 |

[1]Composite comparator results were available for 13 of 18 CDC 2019-nCoV Panel positive specimens only.

Positive percent agreement = 13/13 = 100% (95% CI: 77.2% - 100%)
Negative percent agreement = 104/104 = 100% (95% CI: 96.4% - 100%)

## Disposal

Dispose of hazardous or biologically contaminated materials according to the practices of your institution.

## References

1. Ballew, H. C., *et al*. "Basic Laboratory Methods in Virology," DHHS, Public Health Service 1975 (Revised 1981), Centers for Disease Control and Prevention, Atlanta, Georgia 30333.

2. Clinical Laboratory Standards Institute (CLSI), "Collection, Transport, Preparation and Storage of Specimens for Molecular Methods: Proposed Guideline," MM13-A

3. Lieber, M., *et al*. "A Continuous Tumor Cell Line from a Human Lung Carcinoma with Properties of Type II Alveolar Epithelial Cells." *International Journal of Cancer* 1976, 17(1), 62-70.

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FDACDRH-p6-AO-000916
FDA-CVD-SCHERFU-00014455.0005
MULTI-HHS-20-0522-B, 20-0523-A-000091

## Contact Information, Ordering, and Product Support

For technical and product support, contact the CDC Division of Viral Diseases directly.

Send email to: respvirus@cdc.gov

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FDACDRH-p6-AG-000917
FDA-CVD-SCHERFU-00014455.0005
MULTI-HHS-20-0522-B, 20-0523-A-000092

| | |
|---|---|
| | *Division of Viral Diseases/Respiratory Viruses Branch* |
| **2019-nCoV EUA-01** | **CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Product Information Sheet** |

****DO NOT DISCARD: Important product-specific information****

# CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel
## For use under EMERGENCY USE AUTHORIZATION (EUA) only.
## Rx only

**CATALOG: 2019-nCoVEUA-01**
**KIT LOT:**
**EXPIRATION DATE:**

**INTENDED USE**
The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization .

**PACKAGE CONTENTS**

| PACKAGING | COMPONENT | PART NUMBER | COMPONENT LOT NUMBER | VIALS PER KIT | QUANTITY /VIAL | STATE |
|---|---|---|---|---|---|---|
| Oligonucleotide Box | 2019-nCoV_N1 Combined Primer/Probe Mix | RV202001 | | 1 | 22.5 nmol | Dried |
| | 2019-nCoV_N2 Combined Primer/Probe Mix | RV202002 | | 1 | 22.5 nmol | Dried |
| | 2019-nCoV_N3 Combined Primer/Probe Mix | RV202003 | | 1 | 22.5 nmol | Dried |
| | RP Combined Primer/Probe Mix | RV202004 | | 1 | 22.5 nmol | Dried |
| Control Box | nCoVPC 2019-nCoV Positive Control (non-infectious) | RV202005 | | 4 | 1 x $10^4$ copies/µL | Dried |

**STORAGE INSTRUCTIONS**
Upon receipt, store at 2-8°C. Refer to the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use before opening and preparing reagents for use.

**PROCEDURE/INTERPRETATION/LIMITATIONS**
Users should refer to the **CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use** posted on the FDA website for all IVD products used under Emergency Use Authorization, http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm.

**IVD**

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| | |
|---|---|
| | *Division of Viral Diseases/Respiratory Viruses Branch* |
| **2019-nCoV EUA-01** | **CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Product Information Sheet** |

**PRECAUTIONS**

This reagent should be handled in an approved BSL-2 handling area to avoid contamination of laboratory equipment and reagents that could cause false positive results. This product is non-infectious. However, this product should be handled in accordance with Good Laboratory Practices.

**REAGENT COMPLAINTS/QUESTIONS**

If you have a question/comment about this product, please contact the CDC Division of Viral Diseases/Respiratory Viruses Branch by email at respvirus@cdc.gov.

**DISTRIBUTED BY**

Manufactured by the Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia, 30329, USA

**IVD**

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**** DO NOT DISCARD: Important product-specific information ****

# CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel – Verification Requirements

Please consult the following guidance from CMS regarding Emergency Use Authorized diagnostic tests: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/QSO18-19-CLIA

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Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization.

## REQUIRED MATERIALS

The 2019 novel coronavirus positive control (nCoVPC) is provided with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel and should be prepared according to the instructions for use. The nCoVPC consists of an RNA transcript of the 2019-nCoV N gene as well as human RNase P gene segment. nCoVPC will yield a positive result with the following primer and probe sets: 2019-nCoV_N1, 2019-nCoV_N2, 2019-nCoV_N3 and RP.

Approximately 2 mL of an upper respiratory specimen (e.g. nasopharyngeal swabs (NPS) in transport media) will be needed for testing. Specimens may be pooled if less than 2mL of one specimen is available.

Refer to CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel package insert (manufacturer instructions) for additional reagents, materials, and instructions.

## PRECAUTIONS

This reagent should be handled in an approved BSL-2 handling area to avoid contamination of laboratory equipment and reagents that could cause false positive results. This product is an RNA transcript and is non-infectious. However, the nCoVPC should be handled in accordance with Good Laboratory Practices.

Store reagent at appropriate temperatures (see below) and hold on ice when thawed.

Please use standard precautions when handling respiratory specimens.

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# CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel – Verification Requirements

****** DO NOT DISCARD: Important product-specific information ******

## INSTRUCTIONS FOR PREPARING SAMPLES BEFORE EXTRACTION WITH THE QIAmp DSP VIRAL RNA MINI KIT

- Refer to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use for reconstitution of the materials for use. RNA should be kept cold during preparation and use.
- Make a 1/10 dilution of nCoVPC in by adding 5 µL of nCoVPC into 45 µL of nuclease-free water or 10 mM Tris
- Aliquot 560 µL of lysis buffer into each of nine tubes labeled 1-9.
- Add 140 µL of upper respiratory specimen (e.g. NPS in viral transport media) into each of the nine labeled tubes with lysis buffer
- To prepare samples at a moderate concentration, spike 14 µL of undiluted nCoVPC (rehydrated as described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use) into each tube labeled 1-3 containing lysis buffer and specimen
- To prepare samples at a low concentration, spike 14 µL of 1/10 dilution of nCoVPC into each tube labeled 4-6 containing lysis buffer and specimen
- To prepare negative samples, spike 14 µL of nuclease-free water into each tube labeled 7-9 containing lysis buffer and specimen
- Perform extractions of all nine samples according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use

## INSTRUCTIONS FOR PREPARING SAMPLES BEFORE EXTRACTION WITH THE QIAGEN EZ1 ADVANCED XL

- Refer to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use for reconstitution of the materials for use. RNA should be kept cold during preparation and use.
- Make a 1/10 dilution of nCoVPC in by adding 5 µL of nCoVPC into 45 µL of nuclease-free water or 10 mM Tris
- Aliquot 280 µL of lysis buffer into each of nine tubes labeled 1-9.
- Add 120 µL of upper respiratory specimen (e.g. NPS in viral transport media) into each of the nine labeled tubes with lysis buffer
- To prepare samples at a moderate concentration, spike 12 µL of undiluted nCoVPC (rehydrated as described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use) into each tube labeled 1-3 containing lysis buffer and specimen
- To prepare samples at a low concentration, spike 12 µL of 1/10 dilution of nCoVPC into each tube labeled 4-6 containing lysis buffer and specimen
- To prepare negative samples, spike 12 µL of nuclease-free water into each tube labeled 7-9 containing lysis buffer and specimen
- Perform extractions of all nine samples according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use

## PROCEDURE

Follow the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use for testing the 9 extracted samples at least once.

## EXPECTED RESULTS

Moderate nCoVPC samples should be presumptive positive for 2019-nCoV.
Low nCoVPC samples should be presumptive positive for 2019-nCoV.
Negative upper respiratory samples should be negative for 2019-nCoV.

≥ 90% of test results should be in agreement with the expected results. If test results are less than 90% in agreement with expected results, contact CDC at respvirus@cdc.gov.

## QUESTIONS

Please send questions or comments by email to respvirus@cdc.gov.

## DISTRIBUTION:

Distributed to qualified laboratories designated by Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA, 30329 USA

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FDACDRH-p6-AQ-00021
FDA-CVD-SCHERFU-00014455.0006
MULTI-HHS-20-0522-B, 20-0523-A-000096

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/3/2020 10:13:01 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** RE: Limit of detection study data

Excellent, I let Julie know. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 10:12 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Limit of detection study data

It looks ok. (b) (5)
For the N2 assay, the LoD for the automated extraction is (b) (5)

Li

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 03, 2020 10:08 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Limit of detection study data
**Importance:** High

From what I could see it looks good to me, or do I miss anything?

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Monday, February 3, 2020 9:54 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>

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**Subject:** Limit of detection study data
**Importance:** High

Hi all,

Attached are the data from the limit of detection experiment incorporated into the EUA template. Please let us know if you would like to discuss. We are still in the office, of course.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 10:43 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC qualified laboratories

Dear Julie,

Please find attached DMD edits to the documents you sent last night.

1) Appendix E Instructions for use: We went through the Instructions for Use with OCET, OCC and DMD this morning and had some minor edits that are highlighted in green.
2) Cover Letter: minor suggestion for CDC consideration
3) EUA template: minor edits – tracked changes – some to match edits made in the instructions for use
4) HCP Fact Sheet: Edits acceptable with the exception of including (b) (4), (b) (5)

I also have FDA responses to CDC comments in the Letter of Authorization – does CDC want to see them?

Let us know if you need a call to discuss – hope the LoD study data is going okay.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION
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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 02, 2020 9:52 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: CDC qualified laboratories

Hi Kim,

Thank you for the recommendation. I incorporated the statement below into our instructions for use. I did not add it elsewhere in other documents at this time which I think is fine.

Our CDC colleagues had a few comments on our documents. I've attached four documents with tracked changes. Please let us know if you accept these changes.

We plan to share the remaining data tomorrow. Thank you for your patience. Again I cannot thank you all enough for your comradery and collaboration!

Julie

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 9:15 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: CDC qualified laboratories

Dear Julie,

Thanks for the attaching the CDC comments in the LOA – we are discussing them internally with OCET and OCC tomorrow AM.

We discussed internally your question about defining "qualified laboratory" and think it is best to include similar wording to what you proposed somewhere in the instructions for use. One thought would be in:

## Summary and Explanation

An outbreak of pneumonia of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019. Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis 2019-nCoV and is based on widely used nucleic acid amplification technology. The product contains

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oligonucleotide primers and dual-labeled hydrolysis probes (TaqMan®) and control material used in rRT-PCR for the *in vitro* qualitative detection of 2019-nCoV RNA in respiratory specimens.

The term "qualified laboratories" refers to laboratories in which all users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

If CDC agree just let us know. Also we thought(b) (4), (b) (5) .

In addition, please note that there may be additional comments from OCET/OCC on the Instructions for Use – and I still need to double check that the Conditions of Authorization for Laboratories Section in the IFU matches the Letter of Authorization wording once I finalize with OCET/OCC tomorrow.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 02, 2020 6:47 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Subject:** CDC qualified laboratories
**Importance:** High

Hi all,

We are getting a lot of questions regarding what the term "qualified laboratory" means. We do not want to change the intended use but recommend that we put some additional language in our documents to clarify. The Influenza Division uses language such as this: All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

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My question is: how can we edit the language above to include in our EUA and in which documents should include this language?

I'm also attaching feedback from our Office of General Counsel on the authorization letter. We haven't been through full clearance yet here but thought we should share this now in case there are any issues.

Thanks,
Julie

Julie Villanueva, Ph.D.
Chief, Laboratory Preparedness and Response Branch
Division of Preparedness and Emerging Infections, NCEZID, CDC
404-639-3851

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/3/2020 10:08:01 PM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: Limit of detection study data
**Attachments**: EUA Template CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Executive Summary 03FEB2020 CDC.doc

**Importance**: High

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Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 9:15 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>;

Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: CDC qualified laboratories

Dear Julie,

Thanks for the attaching the CDC comments in the LOA – we are discussing them internally with OCET and OCC tomorrow AM.

We discussed internally your question about defining "qualified laboratory" and think it is best to include similar wording to what you proposed somewhere in the instructions for use. One thought would be in:

## Summary and Explanation

An outbreak of pneumonia of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019. Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis 2019-nCoV and is based on widely used nucleic acid amplification technology. The product contains oligonucleotide primers and dual-labeled hydrolysis probes (TaqMan®) and control material used in rRT-PCR for the *in vitro* qualitative detection of 2019-nCoV RNA in respiratory specimens.

The term "qualified laboratories" refers to laboratories in which all users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

If CDC agree just let us know. Also we thought (b) (4), (b) (5)

In addition, please note that there may be additional comments from OCET/OCC on the Instructions for Use – and I still need to double check that the Conditions of Authorization for Laboratories Section in the IFU matches the Letter of Authorization wording once I finalize with OCET/OCC tomorrow.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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AMERICAN OVERSIGHT

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 02, 2020 6:47 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Subject:** CDC qualified laboratories
**Importance:** High

Hi all,

We are getting a lot of questions regarding what the term "qualified laboratory" means. We do not want to change the intended use but recommend that we put some additional language in our documents to clarify. The Influenza Division uses language such as this: All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

My question is: how can we edit the language above to include in our EUA and in which documents should include this language?

I'm also attaching feedback from our Office of General Counsel on the authorization letter. We haven't been through full clearance yet here but thought we should share this now in case there are any issues.

Thanks,
Julie

Julie Villanueva, Ph.D.
Chief, Laboratory Preparedness and Response Branch
Division of Preparedness and Emerging Infections, NCEZID, CDC
404-639-3851

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/11/2020 7:00:40 PM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject**: RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel discussion Feb 10

Tamara, noon to 1 PM works for me. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 6:57 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel discussion Feb 10

Julie, we may be available between 12 and 1 PM. I'll check with others and we'll respond tomorrow.

Tamara

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 11, 2020 6:12 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel discussion Feb 10

Hi everyone,

Would you be available for another call tomorrow sometime between 12 and 2pm? I would like to discuss the ongoing CDC investigations surrounding 2019-nCoV.

AMERICAN OVERSIGHT

Thanks,
Julie

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 6:27 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel discussion Feb 10

Dear Julie and Steve,

Thank you for the providing detailed feedback during our discussion today at 2 PM about your activities and assessment regarding the (b) (5)

Best regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
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***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Monday, February 10, 2020 3:11 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel discussion Feb 10

Dear Uwe, Kim, Li, and Tamara,

Thank you for meeting with us today regarding the reporting of approximately 10 laboratories of sporadic aberrant reactivity in the negative controls (HSC and/or NTC) of the N3 assay of the CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel. We appreciate your feedback on our options for resolving this issue. Because we have had no reports of other problems with other assays in the Panel, we feel that our best option for immediate resolution is to manufacture a new primer/probe set for the N3 assay as a component replacement.

Please let us know if you concur with this approach. Again thank you for your continued collaboration.

Best regards,
Julie

AMERICAN OVERSIGHT

Julie Villanueva, Ph.D.
Chief, Laboratory Preparedness and Response Branch
Division of Preparedness and Emerging Infections, NCEZID, CDC
404-639-3851

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/3/2020 10:04:25 PM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Limit of detection study data

Julie,

Thanks, got it. Looking at it now, will get back to you shortly. Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Monday, February 3, 2020 9:54 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Limit of detection study data
**Importance:** High

Hi all,

Attached are the data from the limit of detection experiment incorporated into the EUA template. Please let us know if you would like to discuss. We are still in the office, of course.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 10:43 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC qualified laboratories

Dear Julie,

AMERICAN OVERSIGHT

Please find attached DMD edits to the documents you sent last night.

1) Appendix E Instructions for use: We went through the Instructions for Use with OCET, OCC and DMD this morning and had some minor edits that are highlighted in green.
2) Cover Letter: minor suggestion for CDC consideration
3) EUA template: minor edits – tracked changes – some to match edits made in the instructions for use
4) HCP Fact Sheet: Edits acceptable with the exception of including (b) (4), (b) (5)

I also have FDA responses to CDC comments in the Letter of Authorization – does CDC want to see them?

Let us know if you need a call to discuss – hope the LoD study data is going okay.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 02, 2020 9:52 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: CDC qualified laboratories

Hi Kim,

Thank you for the recommendation. I incorporated the statement below into our instructions for use. I did not add it elsewhere in other documents at this time which I think is fine.

Our CDC colleagues had a few comments on our documents. I've attached four documents with tracked changes. Please let us know if you accept these changes.

We plan to share the remaining data tomorrow. Thank you for your patience. Again I cannot thank you all enough for your comradery and collaboration!

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Julie

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 9:15 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: CDC qualified laboratories

Dear Julie,

Thanks for the attaching the CDC comments in the LOA – we are discussing them internally with OCET and OCC tomorrow AM.

We discussed internally your question about defining "qualified laboratory" and think it is best to include similar wording to what you proposed somewhere in the instructions for use. One thought would be in:

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An outbreak of pneumonia of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019. Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported.

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If CDC agree just let us know. (b) (4), (b) (5) – see yellow highlight.

In addition, please note that there may be additional comments from OCET/OCC on the Instructions for Use – and I still need to double check that the Conditions of Authorization for Laboratories Section in the IFU matches the Letter of Authorization wording once I finalize with OCET/OCC tomorrow.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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Kim.Sapsford@fda.hhs.gov

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**Sent:** Sunday, February 02, 2020 6:47 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Subject:** CDC qualified laboratories
**Importance:** High

Hi all,

We are getting a lot of questions regarding what the term "qualified laboratory" means. We do not want to change the intended use but recommend that we put some additional language in our documents to clarify. The Influenza Division uses language such as this: All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

My question is: how can we edit the language above to include in our EUA and in which documents should include this language?

I'm also attaching feedback from our Office of General Counsel on the authorization letter. We haven't been through full clearance yet here but thought we should share this now in case there are any issues.

Thanks,
Julie

Julie Villanueva, Ph.D.
Chief, Laboratory Preparedness and Response Branch
Division of Preparedness and Emerging Infections, NCEZID, CDC
404-639-3851

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/3/2020 11:35:44 AM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Zale, Amy (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=259a8ac6fdee4f1baf12a36a0fe5078f-HHS-Amy.Zal]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Muehlenbachs, Atis (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6070ec618264cfb8ecdcdd32de70829-HHS-vkd6-cd]
**CC**: Rager, Stacy (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9981c603ae364ec38dbd5a6cb260caf1-HHS-vmk4-cd]
**Subject**: RE: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel verification requirements

Julie,

Looks good, we don't have any comments. Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Monday, February 3, 2020 11:11 AM
**To:** Zale, Amy (CMS) <Amy.Zale@cms.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Muehlenbachs, Atis (CDC) <vkd6@cdc.gov>
**Cc:** Rager, Stacy (CDC) <vmk4@cdc.gov>
**Subject:** CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel verification requirements
**Importance:** High

Hi everyone,

We are maintaining the verification requirements as we discussed, but we felt that we needed to provide more detailed instructions to the laboratories. Please take a look at the attached document and let us know if you concur. We appreciate your swift attention to this document.

Thanks,
Julie

Julie Villanueva, Ph.D.
Chief, Laboratory Preparedness and Response Branch
Division of Preparedness and Emerging Infections, NCEZID, CDC
404-639-3851

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/11/2020 10:07:00 AM
**To**: Tobin, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73743f92978348feb96d1aba89e818b9-Peter.Tobin]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: CLIA Tri-Agency Teleconference

Peter,

Thanks, Kim will be presenting DMD at the CLIA call.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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---

**From:** Tobin, Peter <Peter.Tobin@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 10:00 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: CLIA Tri-Agency Teleconference

Hi Kim and Uwe,

Would one of you or someone from DMD be able to attend the CLIA Tri-Agency call tomorrow at 2-3pm? CDC will be presenting updates on 2019-nCoV response, see below. I'll forward you the invite for the call.

Thanks,

Peter

---

**From:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 3:01 PM
**To:** Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Tobin, Peter <Peter.Tobin@fda.hhs.gov>
**Subject:** RE: CLIA Tri-Agency Teleconference

Agreed. I would suggest Kim and/or Uwe.

AMERICAN OVERSIGHT
**Toby Lowe**
*CDRH/OIR*
Tel: 301-796-6512

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---

**From:** Lias, Courtney H <Courtney.Lias@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 2:57 PM
**To:** Tobin, Peter <Peter.Tobin@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Subject:** RE: CLIA Tri-Agency Teleconference

Hi Peter –

Would you see if DMD can have someone sit in to hear the Corona virus update and discuss FDA's side if there are questions?

Thanks

Courtney

Courtney H. Lias, Ph.D.
*Deputy Director for Patient Safety and Product Quality*
OHT7:Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3516 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5458
courtney.lias@fda.hhs.gov






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**From:** Anderson, Nancy L. (CDC/DDPHSS/CSELS/DLS) <nla0@cdc.gov>
**Sent:** Monday, February 10, 2020 12:23 PM
**To:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>; Tobin, Peter <Peter.Tobin@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Grove, Andrew D <Andrew.Grove@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>; Dyer, Karen (CMS) <Karen.Dyer@cms.hhs.gov>; Van Brakle, Regina (CMS) <Regina.VanBrakle@cms.hhs.gov>; Salerno, Reynolds M (CDC) <yyw2@cdc.gov>; Leaumont, Collette F (CDC) <chf3@cdc.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Henderson, Deborah L (CDC) <mvx3@cdc.gov>; Morris, Tamara (CMS) <Tamara.Morris@cms.hhs.gov>; Stang, Heather L (CDC) <btg0@cdc.gov>; Howard, Stacy M (CDC) <sam5@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: CLIA Tri-Agency Teleconference

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Good morning Jennifer – CDC would like to include the following to the agenda for Wednesday's call:

- April CLIAC agenda – will send an updated agenda prior to the meeting
- Updates on 2019-nCoV response

If there is time, we would also like to hear any relevant details from CMS related to their recent reorganization and how it might have affected the CLIA staff.

Thank

---

**From:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>
**Sent:** Wednesday, February 5, 2020 1:00 PM
**To:** Tobin, Peter (FDA/CDRH) <Peter.Tobin@fda.hhs.gov>; Lowe, Toby A (FDA/CDRH) <Toby.Lowe@fda.hhs.gov>; St. Pierre, Don J. (FDA/CDRH) <don.st.pierre@fda.hhs.gov>; Grove, Andrew D (FDA/CDRH) <Andrew.Grove@fda.hhs.gov>; Brenner, Sara (FDA/CDRH) <Sara.Brenner@fda.hhs.gov>; Dyer, Karen (CMS/CCSQ) <Karen.Dyer@cms.hhs.gov>; Van Brakle, Regina S. (CMS/CCSQ) <Regina.VanBrakle@cms.hhs.gov>; Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>; Anderson, Nancy L. (CDC/DDPHSS/CSELS/DLS) <nla0@cdc.gov>; Leaumont, Collette Fitzgerald (CDC/DDPHSS/CSELS/DLS) <chf3@cdc.gov>; Lias, Courtney H (FDA/CDRH) <Courtney.Lias@fda.hhs.gov>; Henderson, Deborah (CDC/DDPHSS/CSELS/DLS) <mvx3@cdc.gov>; Morris, Tamara (CMS/CCSQ) <Tamara.Morris@cms.hhs.gov>
**Cc:** Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** CLIA Tri-Agency Teleconference

Good afternoon, in preparation next week's teleconference, February 12th at 12pm, please forward any agenda items to me by noon Monday, February 10th.

**Jennifer Campbell**
*Management Analyst*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/7/2020 8:32:29 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Intended use wording

Agree, for the clinical evaluation, (b) (5) The other edits are good. Thanks, Uwe

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, February 7, 2020 5:39 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Intended use wording

It looks good. I think a mix of (b) (5)

Li

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 07, 2020 4:38 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Intended use wording

Please review the updated agreed upon studies/numbers below
Just to clarify for the (b) (5)
correct?

Hi Kim,

We are only a few days out from our initial authorization, but we are ready to discuss study design for amendments. We are currently working on the virus LoD studies as discussed (**Propose** (b) (5)
We are proposing the following:

1. Extraction Platform Limit of Detection Equivalency

(b) (4)

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(b) (4)

Do you have time either at 9:30am or after 3pm tomorrow to discuss?

Thank you again,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 8:45 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>
**Subject:** RE: Intended use wording

Dear Julie, Steve and Steve,

We just wanted to follow-up on some of the outstanding items/questions from yesterday's Telcon:

**For Current EUA Package:**

1) (b) (5)

**For Future EUA Amendments:**

1) Condition of authorization – (b) (5)

2) (b) (5)

3) (b) (5) (5)

If we missed anything let us know. FYI, the Fact sheets had some edits from OCET and OCC so we are working through those and hope to have them to you tomorrow (sorry for the delay) – we will also update based on out intended use

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discussion today. Authorization letter and contact fact sheet are also being worked on and we hope to share them with you ASAP.

Any questions, let us know

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 29, 2020 5:52 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** [WARNING : MESSAGE ENCRYPTED] RE: Intended use wording

Hi Kim and Li,

I am attaching the clinical line item data sheet, password protected. I'll send a separate email with that. We will actually more data to add to this tomorrow. I've arranged the data by case but removed names. I've identified the positive cases by location. As Julie explained, the additional N gene assays (N4 and N5 in the file) were initially run with all specimen testing, but eventually the testing only included the N1 through N3 assays that we're including in the EUA request.

Also attached are the LoD and Exclusivity testing performed for the CLIA validation with the N1, N2, N3 assays. I've included the results for the additional N gene assays N4 and N5. In these summaries.

Regards,
Steve

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Wednesday, January 29, 2020 11:49 AM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>

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**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** RE: Intended use wording

Hi Kim,

We agree with the proposed change below. Thank you for proposing it. Would you mind sending all of the intended use language so we can be sure we are using the correct version in our documents?

Thank you all again,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 11:08 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** Intended use wording

Julie as discussed on the call:

Current:

(b) (4)

Potential:

(b) (4)

I am going to draft the contact fact sheet (b) (4)

If in the future that were to change and we need and/or we could update the factsheets accordingly via amendment.

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/12/2020 11:57:44 AM
**To:** Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov]; Humes, Rosemary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6de8a41cc8d54da69787255ca964affa-HHS-Rosemar]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Opdyke, Jason A CIV USARMY (USA [jason.a.opdyke.civ@mail.mil]; Lee, John S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e4f96466514fd28ccf07549b54d598-HHS-John.Le]
**CC:** Faison, Tremel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4945bc9afa3c4d34a274cb286e2f2a09-HHS-Tremel.]; Stemple, Jojo J (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1313cf6a6d4449bd81a08bf297056672-HHS-kstempl]
**Subject:** RE: CoV Dx FDA/developer needs discussion

Maureen, thanks for this important update. Great news!

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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---

**From:** Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>
**Sent:** Wednesday, February 12, 2020 11:20 AM
**To:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA <jason.a.opdyke.civ@mail.mil>; Lee, John S (OS) <John.Lee@hhs.gov>
**Cc:** Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Stemple, Jojo J (NIH) (b) (6) @niaid.nih.gov>
**Subject:** RE: CoV Dx FDA/developer needs discussion

Dear Dx Team,
I have updated information from BEI regarding the possible availability of COVID-2019 genomic RNA and inactivated viruses. Keeping our fingers crossed - it looks as though these reagents may become available in the next 4-6 weeks.

| BEI catalog # | Reagent | Quantity | Estimated time |
|---|---|---|---|
| NR-52281 | Novel Coronavirus 2019-nCoV/USA-WA1/2020 (culture) | 150 | Available now, pending QC tests |

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| | | | |
|---|---|---|---|
| NR-52285 | Genomic RNA, 2019-nCoV/USA-WA1/2020 | 200 | Available as BSL-2 product# on 21 Feb 2020 with pending QC testing; after full QC the product will be available mid-March* |
| NR-52286 | Heat inactivated, 2019-nCoV/USA-WA1/2020 | 100 | late March* |
| NR-52287 | Irradiated infected cell lysate, 2019-nCoV/USA-WA1/2020 | 400 | early April* |

* Includes safety testing of reagent (4 weeks duration, 2 passages each for 14 days).
#For native viral RNA product release as BSL-2 product after a 7-days of safety testing. The safety test will continue for the 4-week duration for release as BSL-1 product.

I'm still waiting for information from WRCEVA.
Thanks,
Maureen

-----Original Appointment-----
**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Sunday, February 9, 2020 12:49 PM
**To:** Humes, Rosemary (OS/ASPR/BARDA); Scherf, Uwe (FDA/CDRH); Sapsford, Kim E (FDA/CDRH); Feldblyum, Tamara (FDA/CDRH); Li, Li (CDRH) (FDA/CDRH); Kuhnert-Tallman, Wendi (CDC/DDID/OD); Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI); Opdyke, Jason A CIV USARMY (USA; Lee, John (OS/ASPR/BARDA)
**Cc:** Faison, Tremel (OS/ASPR/BARDA); Beanan, Maureen (NIH/NIAID) [E]
**Subject:** CoV Dx FDA/developer needs discussion
**When:** Monday, February 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** WebEx info added

Agenda
(b) (5)

Next steps
***DO NOT DELETE OR CHANGE ANY OF THE TEXT BELOW THIS LINE***

Rosemary Humes has scheduled this WebEx meeting.

CoV Dx FDA/developer needs discussion
Host: Rosemary Humes

When it's time, start or join the WebEx meeting from here:
(b) (6)

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Meeting Number: (b) (6)
Meeting Password: (This meeting does not require a password.)

Audio Connection

(b) (6) (Meeting Server Main Number)

Access Code:
(b) (6)

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(b) (6)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/13/2020 11:46:20 AM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Zale, Amy (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=259a8ac6fdee4f1baf12a36a0fe5078f-HHS-Amy.Zal]
**CC**: Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Rager, Stacy (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9981c603ae364ec38dbd5a6cb260caf1-HHS-vmk4-cd]; Murray, Janna' R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efb910a5827d49e6b931a6cc7c450b0d-HHS-hko3-cd]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]
**Subject**: RE: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel - kit rework instructions DRAFT

Julie,

Yes, we are. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Thursday, February 13, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Zale, Amy (CMS) <Amy.Zale@cms.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Rager, Stacy (CDC) <vmk4@cdc.gov>; Murray, Janna' R (CDC) <hko3@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel - kit rework instructions DRAFT
**Importance:** High

Hi Uwe,

Thank you for your swift reply. One sentence that we will add to the document is the following:

Please contact respvirus@cdc.gov to confirm compliance with these instructions and destruction of the 2019-nCoV_N3 reagent Lot 20-0121 vial.

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Are you supportive of this language as well?

Thanks,
Julie

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 10:34 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Zale, Amy M. (CMS/CCSQ) <Amy.Zale@cms.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Rager, Stacy (CDC/DDID/NCEZID/DPEI) <vmk4@cdc.gov>; Murray, Janna' R. (CDC/DDID/NCIRD/DVD) (CTR) <hko3@cdc.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel - kit rework instructions DRAFT

Julie,

FDA has no edits/comments for this draft package insert for the newly manufactured N3 primer/probe set.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Thursday, February 13, 2020 10:10 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Zale, Amy (CMS) <Amy.Zale@cms.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Rager, Stacy (CDC) <vmk4@cdc.gov>; Murray, Janna' R (CDC) <hko3@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Subject:** CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel - kit rework instructions DRAFT
**Importance:** High

Hello everyone,

We would greatly appreciate your feedback on this draft package insert for our newly manufactured N3 primer/probe set. Thank you for your attention to this urgent matter.

Thanks,
Julie

AMERICAN OVERSIGHT

Julie Villanueva, Ph.D.
Chief, Laboratory Preparedness and Response Branch

Division of Preparedness and Emerging Infections, NCEZID, CDC
404-639-3851

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/11/2020 12:46:19 PM
**To**: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]
**CC**: Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]
**Subject**: RE: URGENT 1pm deadline for : CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine

Looks good to me. Uwe

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 12:45 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Subject:** RE: URGENT 1pm deadline for : CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine

OK with me. Thanks.

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 12:42 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Subject:** RE: URGENT 1pm deadline for : CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine

Hi all - I tried to consolidate the edits from Liz and Uwe with those from CDER. Does this look ok? Thank you!

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






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**From:** McSeveney, Megan
**Sent:** Tuesday, February 11, 2020 12:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Subject:** RE: URGENT 1pm deadline for : CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine

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Hi – will send back consolidated edits asap as there have been some edits to CDRH sections and want to make sure all are ok. Uwe has already seen many of these and provided feedback but, there are a few good ones from CDER too– you all are quick ☺Thank you!

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 11:47 AM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Choe, Lena <Lena.Choe@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Subject:** RE: URGENT 1pm deadline for : CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine

Megan,

A couple of comments from the diagnostics perspective. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 11:14 AM
**To:** CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Choe, Lena <Lena.Choe@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan

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<Keagan.Lenihan@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Subject:** URGENT 1pm deadline for : CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine
**Importance:** High

Hi all – please see the attached PR from ASPR. Asking for concurrent clearance given the short turnaround and the reference to multiple products – vaccines, diagnostics, and therapeutics. CDRH -copying Heather Agler through the IMG, as well as Uwe and Kim since this references the EUA. Also, ccing Jennifer Ross from OCET and Toby Lowe (CDRH) given reference to EUA.
**Comments are now due today @ 1:00 p.m.**

V/R,

Naweed Lemar
U.S. Department of Health and Human Services
Direct (b) (6)
Mobile: (b) (6)
Email: naweed.lemar@hhs.gov

---

**From:** OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>
**Sent:** Tuesday, February 11, 2020 9:02 AM
**To:** OS - ASPA - Clearance <OS.ASPA-Clearance@hhs.gov>; OS - ASPA - Public Health Clearance <OS.ASPA-PublicHealthClearance@hhs.gov>
**Cc:** Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>; Walz, Christopher (OS/ASPR/OEA) <Christopher.Walz@hhs.gov>
**Subject:** CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine

**Close-Hold**

**Agency/Office**: ASPR

**Subject (or headline)**: 2019-nCoV vaccine development

**Materials**: Press release

**Deadline for comments**: Today @ 3:00 p.m.

**Planned release date**: Wednesday, February 12

**Driving Event**: Other Transaction Authority agreement expansion signed; company news release timed for stock market opening

V/R,

Naweed Lemar
U.S. Department of Health and Human Services
Direct: (b) (6)
Mobile (b) (6)
Email: naweed.lemar@hhs.gov

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| Surgical N95 masks | Company | Country | Avg Production Volume | Max. production Volume | Is Manufacturing Impacted by COVID-19 |
|---|---|---|---|---|---|
| | 3M COMPANY | US | (b) (4), (b) (5) | | |
| | 3M U.K., PLC | UK | | | |
| | AERO PRO CO., LTD. | Taiwan | | | |
| | AlphaProTech | US | | | |
| | AOK TOOLING LIMITED | China | | | |
| | Cardinal Health | US | | | |
| | Dukal Corporation | US | | | |
| | LA ADA DE ACUNA | Mexico | | | |
| | LOUIS M. GERSON CO., INC. | US | | | |
| | Moldex/Metric, Inc | US | | | |
| | Pasture Pharm PTE LTD | Singapore | | | |
| | Phillips-Medisize Costa Mesa LLC | US | | | |
| | PRESTIGE AMERITECH | US | | | |
| | SHANGHAI DASHENG HEALTH PRODUCTS MANUFACTURE CO. L | China | | | |
| | SHANGHAI GANGKAI PURIFYING PRODUCTS CO., LTD. | China | | | |
| | SHANGHAI MASCO NONWOVEN PRODUCTS CO., LTD. | China | | | |
| | Sure On Industries, Ltd. | China | | | |
| | SUZHOU JINGLE POLYMER MEDICAL APPARATUS CO., LTD | China | | | |

AMERICAN OVERSIGHT

| | Company | Country | Avg Production Volume | Max. production Volume | Is Manufacturing Impacted by COVID-19 |
|---|---|---|---|---|---|
| **Non-surgical, Industrial N95 masks** | | | | | |
| | 3M COMPANY | US | (b) (4), (b) (5) | | |
| | AlphaProTech | US | | | |
| | AOK TOOLING LIMITED | China | | | |
| | Cardinal Health | US | | | |
| | Honeywell Safety | US | | | |
| | Moldex/Metric, Inc | US | | | |
| | Pasture Pharma Pte Ltd | Singapore | | | |
| | SAN-M PACKAGE CO., LTD. | Japan | | | |

AMERICAN OVERSIGHT

**Surgical Masks**

(b) (5)

Firms have been contacted
Firms have supplied sufficient information
Firms have not provided sufficient information

| Company | Country | Avg Production Volume | Market Share | Max. production Volume | Is Manufacturing Impacted by COVID-19 |
|---|---|---|---|---|---|
| COPIOUS (CAMBODIA) INTERNATIONAL INC. | CAMBODIA | (b) (4), (b) (5) | | | |
| A.R. MEDICOM INC. (SHANGHAI) CO., LTD. | CHINA | | | | |
| BH Medical Products Co., Ltd. | CHINA | | | | |
| COPIOUMED INTERNATIONAL, INC. | CHINA | | | | |
| DONGGUAN SHIN YI HEALTHCARE PRODUCTS FACTORY | CHINA | | | | |
| GUANGZHOU FUZELONG HYGIENE MATERIAL CO.,LTD. | CHINA | | | | |
| HUBEI RAYXIN INDUSTRY CO., LTD. | CHINA | | | | |
| MOTEX HEALTHCARE (ANHUI) CO., LTD | CHINA | | | | |
| QING DAO TONG HUI CLOTHING CO., LTD. | CHINA | | | | |
| QINGDAO BESTEX RUBBER & PLASTIC PRODUCTS CO., LTD | CHINA | | | | |
| Sure On Industries, Ltd. | CHINA | | | | |
| SUZHOU AVON TEXTILE CO., LTD. | CHINA | | | | |
| Wellmed Dental Medical Supply | CHINA | | | | |
| WINNER MEDICAL (HUANGGANG) CO., LTD. | CHINA | | | | |
| WUHAN DYMEX HEALTHCARE CO., LTD. | CHINA | | | | |
| XIANNING ECO MEDICAL ARTICLES CO., LTD. | CHINA | | | | |
| XIANTAO RAYXIN MEDICAL PRODUCTS CO., LTD. | CHINA | | | | |
| XIANTAO SHUANGYAN PLASTICS CO., LTD | CHINA | | | | |
| XIANTAO ZHIBO NONWOVEN PRODUCTS CO.,LTD | CHINA | | | | |
| ZHANGJIAGANG ZHIYI MEDICAL HEALTH PRODUCTS CO., LTD | CHINA | | | | |
| SAN-M PACKAGE CO., LTD. | JAPAN | | | | |
| CREATIVE CONTRACT (M) SDN BHD | MALAYSIA | | | | |
| N.S. UNI-GLOVES SDN. BHD. | MALAYSIA | | | | |
| 3M EDUMEX, S.A DE C.V | MEXICO | | | | |
| Medline Industries (AMMAR APPAREL II S. DE R.L DE C.V.) | MEXICO | | | | |
| Pasture Pharm PTE LTD | SINGAPORE | | | | |
| Pasture Pharma FTE Ltd | SINGAPORE | | | | |
| Pasture Pharma Pte Ltd | SINGAPORE | | | | |
| CHINA SURGICAL DRESSINGS CENTER CO., LTD | TAIWAN | | | | |
| MEDICOM ASIA-PACIFIC HOLDINGS LIMITED. TAIWAN BRANCH | TAIWAN | | | | |
| MODERN HEALTHCARE CORP. | TAIWAN | | | | |
| EMERALD NONWOVENS INTL. CO., LTD. | THAILAND | | | | |
| 3M COMPANY | UNITED STATES | | | | |
| AlphaProTech | UNITED STATES | | | | |
| ALPHAPROTECH, INC. | UNITED STATES | | | | |
| Busse Hospital Disposables | UNITED STATES | | | | |
| Cardinal Health | UNITED STATES | | | | |
| CrossTex International | UNITED STATES | | | | |
| Dukal Corporation | UNITED STATES | | | | |
| MOLDED PRODUCTS INC. | UNITED STATES | | | | |
| Rite Care Supply | UNITED STATES | | | | |
| Septodont, Inc. | UNITED STATES | | | | |
| SYNTECH INTERNATIONAL | UNITED STATES | | | | |
| TIDI PRODUCTS, LLC | UNITED STATES | | | | |
| UNITED MEDICAL ENTERPRISES | UNITED STATES | | | | |

**Concerns**

(b) (5)

Export restrictions
Shortage of raw materials
Fewer than normal number of employees
Our contract manufacturer is in China
Shut down production of masks that are not N95
Supplier not approved to resume production
NY state law prohibits 24/7 workdays

AMERICAN OVERSIGHT

| Company | Country | Avg Production Volume | Max. production Volume | Is Manufacturing Impacted by COVID-19 |
|---|---|---|---|---|
| STGT SURAT THANI | | (b) (4), (b) (5) | | |
| MAXTER GLOVE MANUFACTURING SDN BHD | | | | |
| Cardinal Health | | | | |
| JASMINE GLOVE (Sritrang) | | | | |
| Blue Sail Medical Co Ltd | | | | |
| VANDA GLOVE | | | | |
| YTY INDUSTRY (MANJUNG) SDN. BHD. | | | | |
| Comfort Rubber Gloves Industries Sdn. Bhd. | | | | |
| MAXWELL GLOVE MANUFACTURING BHD | | | | |
| BRIGHTWAY HOLDINGS SDN. BHD | | | | |
| SUQIAN RUIJIANG MEDICAL SUPPLIES CO., LTD. | | | | |
| JIANGSU JAYSUN GLOVE CO., LTD. | | | | |
| IDEAL QUALITY SDN BHD | | | | |
| RIVERSTONE RESOURCES SDN. BHD. | | | | |
| Medisafe Technologies (Deepak Bang, CEO) | | | | |
| Jiangxi Jaysun Medcare Co. Ltd | | | | |
| Jiangxi Jaysun Medcare Co., Ltd. | | | | |
| Mercator Medical | | | | |
| SUQIAN CLEAN GLOVE CO., LTD | | | | |
| YTY ACHEH | | | | |
| SUPERMAX GLOVE MANUFACTURING SDN BHD | | | | |
| Shen Wei (USA), Inc. | | | | |
| INDUSTRIAL CLOTHINGS (PVT) LTD. | | | | |
| W.A. RUBBERMATE CO., LTD. | | | | |
| GALLANT QUALITY SDN. BHD. | | | | |
| MEXPO INTERNATIONAL, INC | | | | |
| NAM VIET GLOVE JOINT STOCK COMPANY | | | | |
| GREEN PROSPECT SDN BHD II | | | | |
| GREEN PROSPECT SDN BHD | | | | |
| PRIMUS GLOVES PVT LIMITED | | | | |
| International Biomedical, LTD | | | | |
| SUZHOU COLOUR-WAY ENTERPRISE DEVELOPMENT CO., LTD | | | | |
| Shamrock Marketing Col, Inc. | | | | |
| ANSELL LANKA (PVT.), LTD. | | | | |
| MARCON RUBBER INDUSTRY SDN. BHD. | | | | |
| SMITHS MEDICAL ASD, INC. | | | | |
| ANSELL N.P. SDN. BHD. | | | | |
| TOP GLOVE MEDICAL (THAILAND) CO., LTD. | | | | |
| CRANBERRY (M) SDN. BHD. | | | | |
| GMP MEDICARE SDN BHD(F25) | | | | |
| MEDICAL GLOVE CO., LTD | | | | |
| SHANGHAI MOTEX HEALTHCARE CO., LTD. | | | | |
| CrossTex International | | | | |
| KANAM LATEX INDUSTRIES PVT. LTD. | | | | |
| FOSHAN NANHAI PLUS MEDICAL CO LTD | | | | |
| MEDITECH GLOVES SDN BHD | | | | |
| TG MEDICAL SDN BHD | | | | |
| ADVENTA HEALTH SDN BHD | | | | |
| UG Healthcare | | | | |
| Haywood Vocational Opportunities | | | | |
| WRP RUBBER PRODUCTS SDN BHD | | | | |
| MOLNLYCKE HEALTH CARE SDN BHD | | | | |
| SEMPERIT TECHNISCHE PRODUKTE GESELLSCHAFT MBH | | | | |
| MOLNLYCKE HEALTH CARE SDN. BHD. | | | | |
| SHANGHAI JINXIANG LATEX PRODUCTS CO., LTD. | | | | |
| N.S. UNI-GLOVES SDN. BHD. | | | | |
| HARTALEGA NGC SDN BHD | | | | |
| Honeywell Safety | | | | |
| ST.MARYS RUBBERS PVT LTD | | | | |
| OON CORP RESOURCES (M) SDN BHD | | | | |
| Innovative Gloves Co, LTD | | | | |
| P.T. MAJA AGUNG LATEXINDO | | | | |
| ANSELL HEALTHCARE EUROPE N.V. | | | | |
| PolyConversions, Inc. | | | | |
| TAN SIN LIAN INDUSTRIES SDN. BHD. | | | | |
| AGSA GOMMA SRL | | | | |
| TIANCHANG KANGTEMEI PROTECTIVE PRODUCTS CO., LTD | | | | |
| PT. INTAN HEVEA INDUSTRY | | | | |
| TOP GLOVE SDN. BHD. | | | | |
| PURNABINA SDN BHD | | | | |
| GENESEE BIOMEDICAL, INC. | | | | |
| QUALITY LATEX PRODUCTS MALAYSIA SDN BHD | | | | |
| Wear Tex/ Encompasse Group | | | | |
| QUBE MEDICAL PRODUCTS SDN BHD | | | | |
| CENTRAL MEDICARE SDN BHD9 | | | | |
| Rite Care Supply | | | | |
| CHANGZHOU DAYA IMPORT & EXPORT CORPORATION LTD. | | | | |
| Elastomade | | | | |

AMERICAN OVERSIGHT

**Isolation Gowns**

(b) (5)

Firms have been contacted
Firms have provided sufficient information
Firms have not provided sufficient information

| Company | Country | A |
|---|---|---|
| Camapi Medical Co. | CAMBODIA | (b) (4), (b) (5) |
| COPIOUS (CAMBODIA) INTERNATIONAL INC. | CAMBODIA | |
| Master & Frank (Combodia) Co., LTD | CAMBODIA | |
| SAMARITAN TEXTILE (CAMBODIA) CO., LTD. | CAMBODIA | |
| BH Medical Products Co., Ltd. | CHINA | |
| COPIOUS INTL., INC. | CHINA | |
| COPIOUS INTL., INC. | CHINA | |
| DONGGUAN SHIN YI HEALTHCARE PRODUCTS FACTORY | CHINA | |
| FOSHAN NANHAI PLUS MEDICAL CO LTD | CHINA | |
| GRI Medical & Electronic Company, Ltd. | CHINA | |
| HANGZHOU A-TEK MEDICAL & TEXTILES CO., LTD. | CHINA | |
| HENAN SHENGXING MEDICAL NON-WOVEN PRODUCTS CO., LTD. | CHINA | |
| Honsun (Nantong) Co., Ltd. | CHINA | |
| HUBEI HAIXIN PROTECTIVE PRODUCTS GROUP CO.,LTD | CHINA | |
| HUBEI SAFEWAY PROTECTIVE PRODUCTS CO LTD | CHINA | |
| JIANGSU WONDERFUL NONWOVEN TECHNOLOGY CO., LTD | CHINA | |
| JINGMEN HUASHENG ASIA DYNAMICS SANITARY PRODUCTS CO., LTD. | CHINA | |
| JINGZHOU HAIXIN GREEN CROSS MEDICAL PRODUCTS CO.,LTD | CHINA | |
| WUHAN AIMMAX TRADE CO., LTD | CHINA | |
| XIAMEN PROBTAIN NONWOVEN INC | CHINA | |
| XIANTAO SHUANGYAN PLASTICS CO., LTD | CHINA | |
| ZHANGJIAGANG BLACKBOX PLASTIC PRODUCTS CO., LTD | CHINA | |
| ICAT S.A. DE C.V. | EL SALVADOR | |
| IIMAK Medicana S DE RL DE CV | MEXICO | |
| Medline Industries (AMMAR APPAREL II S. DE R.L DE C.V.) | MEXICO | |
| Wear Tex/ Encompasse Group | MEXICO | |
| Universal Weavers Corp. | PHILIPINES | |
| EMERALD NONWOVENS INTL. CO., LTD. | THAILAND | |
| Busse Hospital Disposables | UNITED STATES | |
| Cardinal Health | UNITED STATES | |
| CrossTex International | UNITED STATES | |
| Dukal Corporation | UNITED STATES | |
| ENCOMPASS GROUP, LLC. | UNITED STATES | |
| Honeywell Safety | UNITED STATES | |
| Poly Conversions Inc. | UNITED STATES | |
| PolyConversions, Inc. | UNITED STATES | |
| Sterile Surgical Systems | UNITED STATES | |

**Concerns**

Export restrictions
Diminished factory workforce
Contract manufacturer is in China
Suppliers do not have full production capacity
Insufficient raw material supply
Factory closed
Increased demand

(b) (5)

AMERICAN OVERSIGHT

**Surgical Gowns**

| Company | Country | Avg monthly production | Market share | Max monthly production | Is Manufacturing Impacted by COVID-19 |
|---|---|---|---|---|---|
| 3A MEDICAL PRODUCTS CO., LTD. | CHINA | (b) (4), (b) (5) | | | |
| ALLMED MEDICAL PRODUCTS CO., LTD. | CHINA | | | | |
| Anhui Ivymed Medical Products Co.,Ltd | CHINA | | | | |
| BINZHOU DINGYUE CLOTHING COMPANY LIMITED | CHINA | | | | |
| CHANGZHOU HOLYMED PRODUCTS CO., LTD | CHINA | | | | |
| COBES INDUSTRIES (JINZHAI) CO., LTD. | CHINA | | | | |
| COBES INDUSTRIES(HEFEI) CO.,LTD. | CHINA | | | | |
| COPIOUS INTL., INC. | CHINA | | | | |
| DONGGUAN SHIN YI HEALTHCARE PRODUCTS FACTORY | CHINA | | | | |
| EXACT MEDICAL MANUFACTURING, INC | CHINA | | | | |
| FOSHAN NANHAI PLUS MEDICAL CO LTD | CHINA | | | | |
| FOSHAN NANHAI PLUS MEDICAL CO LTD | CHINA | | | | |
| GRI Medical & Electronic Technology Company, Ltd. | CHINA | | | | |
| JIANGSU PROVINCE JIANERKANG MEDICAL DRESSING CO., | CHINA | | | | |
| JIANGSU YIKANG STERILIZATION TECHNOLOGY CO.,LTD | CHINA | | | | |
| JIANGYIN PUREMED | CHINA | | | | |
| KUNSHAN JIEHONG NONWOVEN PRODUCT CO., LTD. | CHINA | | | | |
| LIANYUNGANG ANSON NON-WOVEN PRODUCT CO., LTD. | CHINA | | | | |
| MEDWELL MEDICAL PRODUCTS CO., LTD. | CHINA | | | | |
| PRINCIPLE & WILL BIOTECH (PINGHU) CO., LTD. | CHINA | | | | |
| PRINCIPLE & WILL BIOTECH (XIANTAO) CO. LTD | CHINA | | | | |
| S.E.S. HEALTHCARE PRODUCTS CO., LTD | CHINA | | | | |
| SINO PROTECTION (HEFEI) MEDICAL PRODUCTS CO. LTD. | CHINA | | | | |
| SINO PROTECTION (LIUAN) MEDICAL PRODUCTS CO., LTD. | CHINA | | | | |
| SUZHOU MECCAN IMPORT AND EXPORT CORP. | CHINA | | | | |
| WEIHAI HONGYU NONWOVEN FABRIC PRODUCTS CO., LTD | CHINA | | | | |
| Wellmed Dental Medical Supply | CHINA | | | | |
| XIAMEN PROBTAIN NONWOVEN INC | CHINA | | | | |
| XIANTAO SHUANGYAN PLASTICS CO., LTD | CHINA | | | | |
| XU ZHOU VIMED NONWOVEN CO. LTD. | CHINA | | | | |
| XUCHANG ZHENGDE ENVIRONSTAR MEDICAL PRODUCTS CO.,LTD | CHINA | | | | |

**Concerns**
**Employees not available**
**Export restrictions**
**Shortage of supply (raw material)**
**Raw material from China**
**Increased deman**

(b) (5)

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 3/1/2020 10:00:50 AM
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**Subject:** RE: Three items

Jennifer,

Yes, the KMQA you are working on would be helpful. (b) (5)

(b) (5)

Jeff

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 9:43 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Three items

Jeff,

For tomorrow's Hill briefing (b) (5) ) – would the KMQA we are working on be helpful? (b) (5) you're likely to be asked:

(b) (5)

And is there anything else you need for the Hill briefing?

(b) (5)

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

AMERICAN OVERSIGHT

U.S. FOOD & DRUG ADMINISTRATION

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 3/1/2020 8:31:21 AM
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
**Subject:** Re: [champ] - RE: AMP Advocacy Update Regarding COVID-19

Adding Anand

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** March 1, 2020 at 8:29:13 AM EST
**To:** Hahn, Stephen <SH1@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** FW: [champ] - RE: AMP Advocacy Update Regarding COVID-19

Many China tests not working highlighting need for good regulatory process and guidelines. See below.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** March 1, 2020 at 8:10:33 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** FW: [champ] - RE: AMP Advocacy Update Regarding COVID-19

fyi

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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AMERICAN OVERSIGHT

**From:** Tim Stenzel <ttstenzel@gmail.com>
**Sent:** Sunday, March 1, 2020 5:12 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Fwd: [champ] - RE: AMP Advocacy Update Regarding COVID-19

Sent from my iPad

Begin forwarded message:

**From:** "CHAMP Discussion; on behalf of YiWei Tang" <champ@lists.amp.org>
**Date:** February 29, 2020 at 10:29:25 PM EST
**To:** champ@lists.amp.org
**Cc:** policy@amp.org
**Subject: [champ] - RE: AMP Advocacy Update Regarding COVID-19**
**Reply-To:** champ@lists.amp.org

From my personal experience in epicenter in China, since the beginning of this outbreak, hundreds of testing devices for SARS-CoV-2 have been generated and submitted to China FDA for clearance. Till yesterday, 11 devices have received "EUA" in China. Although there are multiple reasons, it seemed that most of them have not working as expected so far.

While we are eager to have diagnostic devices ready for the COVID-19, I think necessary standards and guidelines are still needed to regulate/QC these devices. I think AMP can surely help FDA and ourselves on this.

**Yi-Wei Tang, MD, PhD, FAAM, FIDSA**
Chief Medical Officer, China
Cepheid
518 North Fuquan Road, Shanghai, P. R. China
DIRECT (b) (6)
CELL +
EMAIL yi-wei.tang@cepheid.com
**WWW.CEPHEID.COM**

On Sun, Mar 1, 2020 at 4:08 AM CHAMP Discussion; on behalf of Yang Shangxin <champ@lists.amp.org> wrote:

> Dear AMP Colleagues,
> In order to help with combating the COVID-19 outbreak, the clinical microbiology laboratories around the country are eager to prepare for testing the virus. However, FDA has very strict rules for pre-EUA approval and stringent validation policy which requires using the virus or the viral RNA that are not readily available to most clinical laboratories. A more available DNA plasmids that can be used as reference materials for the test validation are not endorsed by FDA currently.
>
> There is a huge frustration in the medical community right now and we are all asking: "what is preventing us from doing the laboratory-developed test (LDT) for COVID-19?". I hope we could join together to request FDA to change its stand and understand that this is a crisis and the virus would not wait for us. As the precious time window of preparedness is narrowing down, if the clinical laboratories are still restricted from doing the LDT for COVID-19, then we are not going to win this battle as a society!
>
> Shangxin (Shaun) Yang, PhD, D(ABMM), MLS(ASCP)
> Assistant Clinical Professor
> Assistant Medical Director, Clinical Microbiology Laboratory

AMERICAN OVERSIGHT

UCLA Department of Pathology and Laboratory Medicine
shangxinyang@mednet.ucla.edu

On Fri, Feb 28, 2020 at 3:19 PM CHAMP Discussion; on behalf of Mary Williams <champ@lists.amp.org> wrote:

Dear CHAMP Community,

AMP is actively monitoring the latest developments related to the coronavirus disease (COVID-19) outbreak. With a predicted pervasive impact on the public, this outbreak underscores the urgent need for deployment of high-quality Laboratory Developed Testing Procedures (LDPs) and the involvement of appropriately trained and qualified laboratory professionals. We support and send our best wishes to our members across the globe who are working tirelessly to serve the public.

AMP is also committed to sharing our expertise with stakeholders and the broader laboratory community. We have more than 1,200 members in our Infectious Diseases Subdivision, most of whom have roles in the development and performance of accurate and reliable testing procedures; correct test utilization; professional interpretation; and/or communication of test results and their application to patient management.

I would like to give you an update regarding what advocacy we are doing to address test implementation challenges here in the U.S. Since turnaround times for these tests are critical for both patient care and surveillance, high complexity, CLIA-certified laboratories satisfying appropriate BSL requirements must have the ability to use the CDC's test kit and/or develop and validate their own LDPs to provide immediate and local patient care and to partner with public health laboratories in their mission to help contain the outbreak. AMP is actively advocating for this now and coordinating efforts and responses with several other professional organizations. Our advocacy team also plans to discuss this with congressional staff on Monday morning.

**We need your input to inform our advocacy efforts!**
If your lab is working on validating assays to detect SARS-CoV-2, please send an email to policy@amp.org with information on your experiences regarding any challenges you are encountering.

**The AMP Infectious Diseases Subdivision Leadership is here to provide guidance and support!**
If you have specific questions for our ID subdivision leadership, please email amp@amp.org and we will pass them along. We are very grateful to ID Subdivision Chair Dr. Frederick (Rick) Nolte and the entire subdivision leadership team, who have been very engaged and stand ready to assist in our endeavors.

If you were not able to attend the webinar organized by the ID representatives to our Training & Education Committee, Drs. Erin Graf and Gerald Capraro and featuring excellent presentations by Dr. Capraro and Dr. James Versalovic, you can access it for free at http://educate.amp.org/store/seminar/seminar.php?seminar=152504. As a service to the broader community, we have made this webinar and continuing education credits free to all so please feel free to distribute the webinar URL to your non-member colleagues.

We will continue to provide updates as we have additional information.

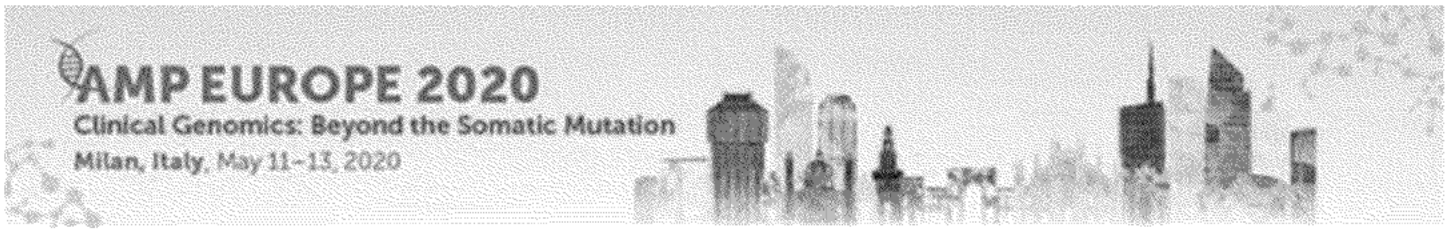
Regards,
Mary

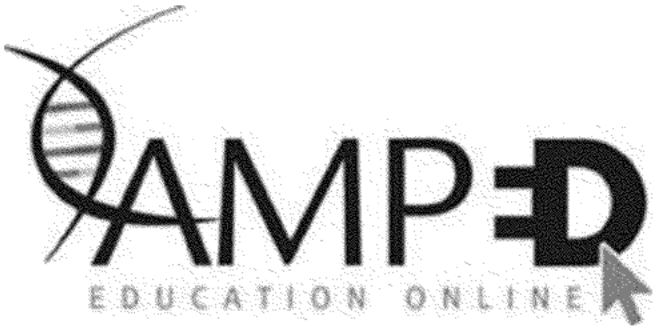
**Mary Steele Williams, MNA, MT(ASCP)SM, CAE**
Executive Director
Association for Molecular Pathology (AMP)
6120 Executive Blvd, Suite 700
Rockville, MD 20852

Tel: 301-634-7921
Fax: 301-634-7995
Email: mwilliams@amp.org
Web: www.amp.org
Twitter: @AMPath

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*Providing Global Expertise in Molecular Testing that Drives Patient Care*




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Posted By: Mary Steele Williams at Association for Molecular Pathology
Email Address: mwilliams@amp.org

**Attachment Links:** image005.jpg (13 k) image006.jpg (8 k)
**Site Links:** View post in thread online View community discussion online Start new thread via email Unsubscribe from this mailing list Manage your subscription

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Thank you,
Shaun

---

Posted By: SHANGXIN YANG at
Email Address: yang.shangxin@gmail.com

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Posted By: Yi-Wei Tang, Service Chief at Mem Sloan Kettering Cancer Ctr
Email Address: yiweitangmd@gmail.com

**Attachment Links:** image005.jpg (13 k) image006.jpg (8 k)
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AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 3/1/2020 12:17:19 PM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject**: RE: email to OCE

Elizabeth,

Very, very nice – as always. I will send the email.

Thank you.

Jeff

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 11:55 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** email to OCE

Jeff,
Suggestion for email to OCE below:

Dear OCE,

As the federal government works to address the public health emergency for COVID-19, I wanted to take a moment to thank you for your significant contributions to this effort.

On Friday morning you came to the office expecting a normal work day followed by a weekend away from work. By noon Friday it became clear that we would need to roll out a novel policy for COVID-19 testing later that evening. You dropped everything to develop and implement a comprehensive and strategic communications roll-out. Late Friday night the roll-out was bumped to Saturday morning, so you just kept working. Also late Friday we received a new EUA request for a COVID-19 test, which lead to a second major roll-out late Saturday night and additional comms Sunday morning. You just kept working. These two significant weekend roll-outs would typically take weeks to plan, but with your hard work they were executed in a day, and executed well. Thank you for dropping your other work and personal plans to make this possible.

Our work is not done. We are planning a webinar for tomorrow and there will be additional EUA authorizations with little advance notice to come. I know you will continue to rise to the occasion. Thank you for your ongoing extraordinary efforts to meet the public health needs in this emergency.

I know it has been a long road and it is far from over but we, our country, and our global neighbors will get through this, together.

Jeff

**Elizabeth Hillebrenner**
*Associate Director for Scientific and Regulatory Programs*
Center for Devices and Radiological Health
Office of the Center Director
U.S. Food and Drug Administration
Tel: 301-796-6346
elizabeth.hillebrenner@fda.hhs.gov

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 3/1/2020 2:16:32 PM
**To**: CDRH-OCE [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4c0b81e0ccd424c8dae5a3711e4130d-CDRH-OCE]; Stephanie Caccomo (Stephanie.Caccomo@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Tomasello, Jennifer (Jennifer.Tomasello@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=Jennifer.Tomasello]
**CC**: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Ellen Flannery (Ellen.Flannery@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject**: Thank You

Dear OCE, Stephanie, and Jennifer,

As the federal government works to address the public health emergency for COVID-19, I wanted to take a moment to thank you for your significant contributions to this effort.

On Friday morning you came to the office expecting a normal work day followed by a weekend away from work. By noon Friday it became clear that we would need to roll out a novel policy for COVID-19 testing later that evening. You dropped everything to develop and implement a comprehensive and strategic communications roll-out. Late Friday night the roll-out was bumped to Saturday morning, so you just kept working. Also late Friday we received a new EUA request for a COVID-19 test, which led to a second major roll-out late Saturday night and additional comms Sunday morning. You just kept working. These two significant weekend roll-outs would typically take weeks to plan, but with your hard work they were executed in a day, and executed well. Thank you for dropping your other work and personal plans to make this possible.

Our work is not done. We are planning a webinar and a Hill briefing for tomorrow and there will be additional EUA authorizations with little advance notice to come. I know you will continue to rise to the occasion. Thank you for your ongoing extraordinary efforts to meet the public health needs in this emergency.

I know it has been a long road and it is far from over but we, our country, and our global neighbors will get through this, together.

Jeff

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 3:08:33 PM
**To:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

We have the right of reference in writing via email so good on that front.

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 2:42 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

We understand that it was granted but haven't seen anything in writing from CDC. Adding Tim.

Uwe called me. They have all the data in house. Seems promising. They may be done later today and then need OCET and HHS clearance so it may not get officially authorized until late tonight or tomorrow.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:36 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: NYS Wadsworth Center COVID-19 Test

Jeff,

I'm not sure how close DMD is to authorizing NY, but I haven't seen any further email traffic on this request for a right of reference from cdc. I would have expected something by now. (b) (5) [redacted].

Elizabeth

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:37 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

AMERICAN OVERSIGHT

Hi Dan, Thanks for the quick call this morning. A simple email to the FDA/me stating "Yes, The New York State Wadsworth Center can reference the data in the CDC's 2019 nCoV EUA application" is sufficient for the FDA's

review purposes that should lead to a quick EUA authorization for Wadworth's EUA, as early as this afternoon. Therefore, this is obviously an urgent matter.

Best,

*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**

Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Hi Dan and Wendi,

This right of reference is important to get this and additional assays based on the CDC through the EUA process quickly. The other two companies we discussed today will be similar.

I believe a simple email stating "Yes, The New York State Wadsworth Center can reference the data in the CDC 2019 nCoV EUA application".

Hope this helps.

Thanks in advance!

AMERICAN OVERSIGHT

Best,

Tim

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 7:55:22 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Adding additional people.

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:50 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** NYS Wadsworth Center COVID-19 Test
**Importance:** High

Wendi, Dan, Laura,

NYS Wadsworth Center submitted an EUA request to us this afternoon for a test that uses the CDC protocol but only for N1/N2 (consistent with the CDC test currently subject to enforcement discretion). To support their EUA, Wadsworth conducted a bridging study that demonstrates performance similar to CDC's N1/N2 test. We know their performance is comparable because we have seen CDC's data but Wadsworth has not. **Would CDC allow Wadsworth to have a right of reference to its data, under which does not get access to the data but can reference it in support of their EUA?** Wadsworth has one more test to perform, which if it looks good, we would otherwise grant the EUA.

Thanks,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/29/2020 11:42:47 PM
**To**: Stephanie Caccomo (Stephanie.Caccomo@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
**Subject**: Washington Post

Stephanie,

FYI – Per our conversation this evening please see the following statement from tonight's Washington Post article: "Another failure in the U.S. response has been a faulty CDC coronavirus diagnostic test. The United States has tested far fewer people than other nations have, and the criteria for who gets tested remained exceedingly narrow until Thursday."

https://www.washingtonpost.com/politics/inside-trumps-frantic-attempts-to-minimize-the-coronavirus-crisis/2020/02/29/7ebc882a-5b25-11ea-9b35-def5a027d470_story.html

This is along the lines of what we discussed.

Jeff

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 3/1/2020 9:56:39 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: applicant name

TY!

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** March 1, 2020 at 9:54:03 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: applicant name

Jeff,

Here the number:

(b) (4)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AMERICAN OVERSIGHT

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 9:35 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** Re: applicant name

Uwe,

That's terrific. Can you/someone on your team please ask them, and subsequent notifiers, how many specimens/patients they can test per week and if that is their maximum capacity or if they can increase their weekly throughput?

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** March 1, 2020 at 9:30:10 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** FW: applicant name
**Importance:** High

Jeff, Tim and Don,

We just got the 1st notification under the accelerated EUA program that UW will start testing patients for SARS-CoV-2 at 8 am tomorrow morning.

We confirmed the receipt of this request in our mailbox and an acknowledgment email went out.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Alex Greninger <agrening@uw.edu>
**Sent:** Sunday, March 1, 2020 9:11 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Keith R. Jerome <kjerome@uw.edu>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Subject:** Re: applicant name

AMERICAN OVERSIGHT

Apologies, Li.

This email serves to notify the FDA that UW Virology is beginning clinical testing for SARS-CoV-2 at 8am tomorrow morning PST.

UW Virology
Keith Jerome
1616 Eastlake Avenue Suite 320
Seattle, WA 98102

contact person: Alex Greninger, agrening@uw.edu, (b) (6)

Best wishes,
Alex

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/29/2020 2:11:59 PM
**To**: Taylor, Jill (HEALTH) [jill.taylor@health.ny.gov]
**Subject**: RE: Two pre-EUA questions....advice please

Indeed!

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Saturday, February 29, 2020 2:11 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Two pre-EUA questions....advice please

Interesting times.

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:10 PM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Subject:** RE: Two pre-EUA questions....advice please

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

That's great.

Jeff

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Saturday, February 29, 2020 2:09 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Subject:** RE: Two pre-EUA questions....advice please

The dilution testing is done Jeff.
Kirsten will send ASAP.
Jill

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:42 AM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Subject:** RE: Two pre-EUA questions....advice please

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Jill,

And likewise our engagement with you and your team have been terrific.

AMERICAN OVERSIGHT

We also will continue to work on the EUA. Do you have a sense on timing for submitting results of dilution testing? I want to make sure that we are ready to wrap up quickly.

Jeff

---

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Saturday, February 29, 2020 11:11 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Two pre-EUA questions....advice please

Jeff,
Thank you so much. This is a great relief. I have to say that it has been a pleasure to work with your incredibly professional and responsive staff.
Jill

Sent from my iPhone

On Feb 29, 2020, at 10:58 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Jill,

I wanted to let you know that today we announced a policy that would allow appropriate laboratories that are certified to perform high-complexity testing consistent with requirements under CLIA develop, validate, and use SARS-CoV-2 tests if they notify FDA and submit an EUA request within 15 days of the notification. Other conditions are described in the guidance we posted on our website today. Our intent is to more quickly increase the national capability for testing while assuring accurate and reliable tests are being used.

Because you have already notified us, you can proceed with patient testing. Please see the guidance for additional details. If you have any questions or there is anything we can do to help, I, Uwe, or Tim would be happy to discuss. (Kim is currently out of the office.)

Our press release and guidance can be found at the following:
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia-prior

Best regards,

Jeff

AMERICAN OVERSIGHT

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Friday, February 28, 2020 7:38 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Two pre-EUA questions....advice please

Jeff,
Thank you for your note. Kim, and FDA are being very helpful and responsive and we really appreciate that. We are working very hard to submit our application to the FDA today.
Jill
Sent from my iPhone

On Feb 28, 2020, at 7:18 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Jill,

We saw Dr. Zucker on CNN last night and also wanted to check if there is anything else we can do to be helpful. Please let us know. You are welcome to reach out to me, as well, at any time.

Best regards,

Jeff

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:15 AM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Two pre-EUA questions....advice please

Dear Jill,

Thank you for your questions. Since we know the issues around the CDC assay – if New York would like to (b) (4)

GMP can be waived for EUA so this is not a concern.

I would recommend submitting today, please call Uwe or Tamara if you have any questions as I will be out of the office for most of the day:

AMERICAN OVERSIGHT

| | | | |
|---|---|---|---|
| Uwe Scherf | DMD – Division Director | Uwe.Scherf@fda.hhs.gov | 301-796-5456 |
| Tamara Feldblyum | DMD – Branch Chief | Tamara.Feldblyum@fda.hhs.gov | 301-796-6195 |

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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<image012.jpg.secure>

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**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Thursday, February 27, 2020 10:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** Two pre-EUA questions....advice please

Hello Kim,
We are having an internal discussion at Wadsworth on strategy and need some advice please.
I am also copying this email to Dr. Jen Rakeman who directs the NYC lab as the answers will affect her strategy also.

(b) (4)

AMERICAN OVERSIGHT

(b) (4)



Thank you for your patience with us as we learn the FDA process.
Best wishes
Jill and Colleagues.

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 3/1/2020 4:16:43 PM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: HOLD for Hill Call with CDC

I would be prepared. On a related note, (b) (5)

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 4:15 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: HOLD for Hill Call with CDC

Should we be anticipating that by 2pm tomorrow, (b) (5)

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov




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-----Original Appointment-----
**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 4:00 PM
**To:** Shuren, Jeff; Schwartz, Suzanne; Stenzel, Timothy
**Subject:** HOLD for Hill Call with CDC
**When:** Monday, March 2, 2020 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** TBD

This will be a joint FDA/CDC call to provide an update to bicameral, bipartisan Hill staff re COVID-19 testing. Logistics and location TBD. Other HHS OPDIVs will participate though FDA and CDC will lead with an update on testing, and then the call will be open to questions about testing and COVID-19 generally.

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 6:35:56 PM
**To:** Watts, Mary Lee [mwatts@asmusa.org]
**CC:** Lloyd, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338a759166e74b13a5c9b385cde90eb9-Lindsay.Llo]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Bertuzzi, Stefano [sbertuzzi@asmusa.org]; Patel, Robin, M.D. [patel.robin@mayo.edu]; Miller, Melissa [Melissa.Miller@unchealth.unc.edu]; Segal, Allen [asegal@asmusa.org]; McNult, Peggy [PMCNULT@asmusa.org]
**Subject:** RE: Letter from the American Society for Microbiology re COVID 19 EUA and clinical testing

Dear Mary Lee,

Terrific. Let's plan for 8 AM to 8:30 AM. Please use the following call-in number:

877-465-7975 US Toll Free

(b) (6) Attendee access code

I look forward to talking on Monday.

Best regards,

Jeff

---

**From:** Watts, Mary Lee <mwatts@asmusa.org>
**Sent:** Saturday, February 29, 2020 6:10 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Bertuzzi, Stefano <sbertuzzi@asmusa.org>; Patel, Robin, M.D. <patel.robin@mayo.edu>; Miller, Melissa <Melissa.Miller@unchealth.unc.edu>; Segal, Allen <asegal@asmusa.org>; McNult, Peggy <PMCNULT@asmusa.org>
**Subject:** Re: Letter from the American Society for Microbiology re COVID 19 EUA and clinical testing

Dear Jeff,

Yes. 8 am Monday can work for us.

Thank you!

Best,
Mary Lee

On Feb 29, 2020, at 4:54 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

Dear Mary Lee,

Would 8 AM on Monday work for everyone? Several time slots during the day are already scheduled with related phone calls.

AMERICAN OVERSIGHT

Best regards,

Jeff

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 4:53 PM
**To:** Watts, Mary Lee <mwatts@asmusa.org>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Varnado, Martina <Martina.Varnado@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Bertuzzi, Stefano <sbertuzzi@asmusa.org>; 'Patel, Robin, M.D.' <patel.robin@mayo.edu>; 'Miller, Melissa' <Melissa.Miller@unchealth.unc.edu>; Segal, Allen <asegal@asmusa.org>; McNult, Peggy <PMCNULT@asmusa.org>
**Subject:** RE: Letter from the American Society for Microbiology re COVID 19 EUA and clinical testing

Dear Mary Lee,

We would be happy to talk on Monday before the webinar. I'll follow up with some times and take other folks not participating off subsequent emails. I will have Tim Stenzel join me on the call.

Best regards,

Jeff

---

**From:** Watts, Mary Lee <mwatts@asmusa.org>
**Date:** February 29, 2020 at 4:09:31 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, FDA Commissioner <Stephen.Hahn@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
**Cc:** Varnado, Martina <Martina.Varnado@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Bertuzzi, Stefano <sbertuzzi@asmusa.org>, 'Patel, Robin, M.D.' <patel.robin@mayo.edu>, 'Miller, Melissa' <Melissa.Miller@unchealth.unc.edu>, Segal, Allen <asegal@asmusa.org>, McNult, Peggy <PMCNULT@asmusa.org>
**Subject:** RE: Letter from the American Society for Microbiology re COVID 19 EUA and clinical testing

Dear Dr. Shuren,

Thank you so much for the quick response, and we applaud the changes that were announced today regarding the expansion of testing to clinical settings.

We would like to take you up on your offer to speak by phone Monday, and I am looping in our CEO Dr. Stefano Bertuzzi, our president Dr. Robin Patel, and Dr. Melissa Miller, chair of our Clinical and Public Health Microbiology Committee, all of whom we would want to include on a call with you. As there may still be some clinical challenges and concerns, we would like the chance to discuss those with you prior to the webinar if possible.

Please let me know what time(s) work for you and I can coordinate schedules on this end. Again, thank you so much for your response. We look forward to speaking with you and others at FDA. We appreciate your leadership during this rapidly evolving situation, and your attention to our community's concerns.

AMERICAN OVERSIGHT

Best,

Mary Lee

Mary Lee Watts, MPH, RD

Director, Federal Affairs

Public Policy and Advocacy

American Society for Microbiology

1752 N St., NW

Washington, DC 20036

Direct: (b) (6)

mwatts@asmusa.org

---

**From:** Shuren, Jeff [mailto:Jeff.Shuren@fda.hhs.gov]
**Sent:** Saturday, February 29, 2020 11:47 AM
**To:** Watts, Mary Lee <mwatts@asmusa.org>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
**Cc:** Varnado, Martina <Martina.Varnado@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: Letter from the American Society for Microbiology re COVID 19 EUA and clinical testing

Dear Ms. Watts,

Thank you for reaching out to us. You should have received notification of the FDA issuing a press release and guidance this morning, and holding a webinar this Monday. I hope you and/or your colleagues can participate.

I would be happy to talk with you either before or after the webinar if you are have any questions.

Best regards,

Jeff

---

**From:** Watts, Mary Lee <mwatts@asmusa.org>
**Sent:** Friday, February 28, 2020 2:22 PM
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Varnado, Martina <Martina.Varnado@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** Letter from the American Society for Microbiology re COVID 19 EUA and clinical testing

AMERICAN OVERSIGHT

Dear Dr. Hahn, Dr. Abernethy, and Dr. Shuren,

The American Society for Microbiology is one of the largest professional societies dedicated to the life sciences and is composed of 30,000 scientists and health practitioners, including clinical microbiologists and laboratory professionals. ASM's mission is to promote and advance the microbial sciences. We thank you for your leadership during this COVID-19 outbreak.

Attached is a letter from our leadership expressing our concerns about challenges that the current EUA is presenting to clinical labs and their ability to test for the virus. We appreciate your consideration of our views, and we look forward to working with you.

Best,

Mary Lee Watts, MPH, RD

Director, Federal Affairs

Public Policy and Advocacy

American Society for Microbiology

1752 N St., NW

Washington, DC 20036

Direct: (b) (6)

mwatts@asmusa.org

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 11:15:30 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: IDT

Looks good to me. Let me run it by Ellen.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:01 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: IDT

See edits in green below.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:44 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: IDT

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 10:28 AM
**To:** Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** IDT

Tim,

Updates

AMERICAN OVERSIGHT

Below is a draft email not yet ready to be share but I wanted to get your feedback on whether it captures what would be

(b) (5)

Dear Wendi,

(b) (5)

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 12:13:22 PM
**To:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** FW: Request for FDA EUA exemption

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 11:47 AM
**To:** Vince Stine <VStine@aacc.org>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
**Cc:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
**Subject:** RE: Request for FDA EUA exemption

Dr. Stine,

Thank you for reaching out to us. You should have received notification of the FDA issuing a press release and guidance this morning, and holding a webinar this Monday that are relevant to your request. I hope you and/or your colleagues can participate.

I would be happy to talk with you either before or after the webinar if you have any questions.

Best regards,

Jeff

---

**From:** Vince Stine <VStine@aacc.org>
**Sent:** Friday, February 28, 2020 1:06 PM
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
**Subject:** Request for FDA EUA exemption

Dr. Hahn,

I am attaching a letter from the American Association for Clinical Chemistry requesting that the Food and Drug Administration (FDA) exercise its enforcement discretion to permit qualified laboratories to use laboratory developed tests to detect SARS-CoV-2 and diagnose COVID-19. We appreciate your consideration of our request.

Sincerely

Vincent Stine, PhD
Senior Director, Government & Global Affairs
American Association for Clinical Chemistry

**Vince Stine, PhD**
Senior Director, Government Affairs
AACC | 900 Seventh Street, NW, Suite 400 | Washington, DC 20001

P +1 202.835.8721
VStine@aacc.org
www.aacc.org

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 7:42:57 AM
**To**: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject**: Fwd: Two pre-EUA questions....advice please
**Attachments**: image007.png; image008.jpg; image009.jpg; image010.jpg; image011.jpg; image012.jpg

Last email on NYS for now — see Jill's positive comment which you are welcome to use if needed.

---

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Date:** February 28, 2020 at 7:38:12 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>, McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>, Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>, Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>, Rakeman, Jennifer <jrakeman@health.nyc.gov>, Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Two pre-EUA questions....advice please

Jeff,
Thank you for your note. Kim, and FDA are being very helpful and responsive and we really appreciate that. We are working very hard to submit our application to the FDA today.
Jill
Sent from my iPhone

On Feb 28, 2020, at 7:18 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Jill,

We saw Dr. Zucker on CNN last night and also wanted to check if there is anything else we can do to be helpful. Please let us know. You are welcome to reach out to me, as well, at any time.

Best regards,

Jeff

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:15 AM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire,

AMERICAN OVERSIGHT

Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Two pre-EUA questions....advice please

Dear Jill,

Thank you for your questions. Since we know the issues around the CDC assay – if New York would like to (b) (4) (b) (4)

GMP can be waived for EUA so this is not a concern.

I would recommend submitting today, please call Uwe or Tamara if you have any questions as I will be out of the office for most of the day:

| | | | |
|---|---|---|---|
| Uwe Scherf | DMD – Division Director | Uwe.Scherf@fda.hhs.gov | 301-796-5456 |
| Tamara Feldblyum | DMD – Branch Chief | Tamara.Feldblyum@fda.hhs.gov | 301-796-6195 |

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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<image012.jpg.secure>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Thursday, February 27, 2020 10:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH)

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<kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>

**Subject:** Two pre-EUA questions....advice please

Hello Kim,

We are having an internal discussion at Wadsworth on strategy and need some advice please.

I am also copying this email to Dr. Jen Rakeman who directs the NYC lab as the answers will affect her strategy also.

(b) (4)



Thank you for your patience with us as we learn the FDA process.

Best wishes

Jill and Colleagues.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 11:48:59 AM
**To:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; MacLennan, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e3684d6a36e4002bc07015b7506b803-Lori.MacLen]
**Subject:** RE: Azar says 40 public health labs can test for coronavirus

It may be a new one. I hadn't heard the latest decision.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Date:** February 27, 2020 at 11:47:11 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>
**Subject:** RE: Azar says 40 public health labs can test for coronavirus

Am I correct to infer from Jeff's use of the term "EUA supplement" that this is being handled under the original EUA and not a new one? (We are getting questions)

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 11:24 AM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>
**Subject:** RE: Azar says 40 public health labs can test for coronavirus

(b) (5)

The bottom line is that the 40 or more labs can proceed to test now (actually as of yesterday when we granted ED but CDC had to finalize and send them new instructions).

And, as an aside, we told CDC they could do it. It's their lab folks who had to warm up to the idea so any hold up was not on our end.

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**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 11:15 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>
**Subject:** FW: Azar says 40 public health labs can test for coronavirus

FYI—from Azar testimony this AM. I told Politico off the record it has not happened.

(b) (5)

---

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>
**Sent:** Thursday, February 27, 2020 11:00 AM
**To:** Stark, Angela <Angela.Stark@fda.hhs.gov>
**Subject:** Azar says 40 public health labs can test for coronavirus

**Azar says 40 public health labs can test for coronavirus**

By Adam Cancryn

02/27/2020 10:59 AM EST

HHS Secretary Alex Azar told lawmakers today that at least 40 public health laboratories can now test for the coronavirus, weeks after the initial version of a CDC-developed diagnostic proved faulty.

Those labs can now use the diagnostic after the FDA approved a process that involves just two of the test kit's original three steps.

"FDA authorized the use of those tests using just the first and second step to provide a definitive diagnostic," Azar told the House Ways and Means Committee. FDA has not yet posted notice of the authorization on its website.

Azar added that HHS expects 93 labs around the country to be able to conduct their own coronavirus tests by Monday, using either the CDC's diagnostic or a private-sector alternative that could be available as early as tomorrow.

The CDC has conducted more than 3,600 screenings so far, and there is currently no backlog. But the delayed rollout of tests to public health labs around the country has raised concerns that the coronavirus could be spreading undetected, slowing the federal and state response.

The agency is investigating a coronavirus case in California that involves a person with no known links to existing cases and no history of travel to China.

In the meantime, the federal government is also working on developing a separate diagnostic that could be distributed to hospitals, Azar said, calling it the "next step" in the response but declining to offer a specific timeline.

*David Lim contributed to this report.*

*To view online*:
https://subscriber.politicopro.com/health-care/whiteboard/2020/02/azar-says-40-public-health-labs-can-test-for-coronavirus-3977055

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**Sent:** 2/28/2020 9:17:44 AM
**To:** Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]
**Subject:** RE: Press

Nothing other than we have been working with them. I'm not sure we can say that publicly. We have been working with several developers.

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Date:** February 28, 2020 at 8:55:21 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Stark, Angela <Angela.Stark@fda.hhs.gov>
**Subject:** RE: Press

Ok, thanks—Michelle Cortez at Bloomberg was inquiring yesterday about the CDC test, so my guess is she's the one poking around. Is there anything in particular to know about the Thermo Fisher discussions?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:44 AM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
**Subject:** FW: Press

Heads up that Bloomberg is reaching out to potential COVID-19 test developers, at least to Thermo Fisher, with whom we have had discussions.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:25 AM
**To:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Press

Hi Peter, You texted, "Tim
We received an inquiry this morning from Bloomberg on whether we've got anything brewing for an EUA. Have FDA been advising companies on how to answer that question?
Thx
Peter"

Thanks for reaching out Peter, I defer to Jeff.

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Thank!

Best,
Tim

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/28/2020 7:38:01 AM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**CC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]
**Subject:** Fwd: Two pre-EUA questions....advice please

Uwe,

Can your folks please put together our piece of the EUA package together today and bring OCET into the loop so our review of the NYS submission and authorization of the EUA, if supported by the evidence, can occur within the next 24 hours, or sooner?

Jeff

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** February 28, 2020 at 7:22:46 AM EST
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>, McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>, Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>, Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>, Rakeman, Jennifer <jrakeman@health.nyc.gov>, Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Two pre-EUA questions....advice please

Excellent thanks Jill

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Friday, February 28, 2020 7:19 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Two pre-EUA questions....advice please

Thank you so much Kim. This is exactly what we needed to know. We are working very hard and it is our intention to submit today.
Jill

Sent from my iPhone

On Feb 28, 2020, at 7:15 AM, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov> wrote:

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Dear Jill,

Thank you for your questions. Since we know the issues around the CDC assay – if New York would like to (b) (4)

GMP can be waived for EUA so this is not a concern.

I would recommend submitting today, please call Uwe or Tamara if you have any questions as I will be out of the office for most of the day:

| | | | |
|---|---|---|---|
| Uwe Scherf | DMD – Division Director | Uwe.Scherf@fda.hhs.gov | 301-796-5456 |
| Tamara Feldblyum | DMD – Branch Chief | Tamara.Feldblyum@fda.hhs.gov | 301-796-6195 |

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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---

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Thursday, February 27, 2020 10:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** Two pre-EUA questions....advice please

Hello Kim,
We are having an internal discussion at Wadsworth on strategy and need some advice please.
I am also copying this email to Dr. Jen Rakeman who directs the NYC lab as the answers will affect her strategy also.

(b) (4)

[redacted]

Thank you for your patience with us as we learn the FDA process.
Best wishes
Jill and Colleagues.

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 12:29:25 PM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Minimal Criteria for test validation

Sorry, doing trade press interview, mercifully on another topic.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 11:35 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

Already shared with the CDC. They got word on 2 pm deadline too.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 28, 2020 at 11:22:07 AM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

Giving further thought it looks good. Jeff, Can I share with the CDC?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:48 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Minimal Criteria for test validation

Hi Uwe,

This is wonderful. Can we change the (b) (5) [redacted]

Thanks in advance Uwe! :)

Best,
Tim

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 10:41:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Minimal Criteria for test validation

Jeff and Tim,

The minimal criteria acceptable to validate the test to be developed by the target laboratories are listed below. We foresee that it will take 3-4 days for a CLIA-certified, high-complexity laboratory to complete these evaluations.

(b) (5) [redacted]

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Let me know if you have any questions.

Uwe

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 7:34:50 AM
**To**: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject**: Re: Two pre-EUA questions....advice please

Wadsworth Director replies they'll send their EUA in today. Will review quickly.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 28, 2020 at 7:21:00 AM EST
**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** FW: Two pre-EUA questions....advice please

We've followed up with NYS Wadsworth Center again this morning. They were figuring out strategy with their test. We provided advice, asked if they could send us their data today, and asked if there is anything else we can do to be helpful. (Please see below)

---

**From:** Shuren, Jeff
**Sent:** Friday, February 28, 2020 7:18 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Two pre-EUA questions....advice please

Dear Jill,

We saw Dr. Zucker on CNN last night and also wanted to check if there is anything else we can do to be helpful. Please let us know. You are welcome to reach out to me, as well, at any time.

Best regards,

Jeff

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:15 AM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Two pre-EUA questions....advice please

Dear Jill,

AMERICAN OVERSIGHT

Thank you for your questions. Since we know the issues around the CDC assay – if New York would like to (b) (4)

GMP can be waived for EUA so this is not a concern.

I would recommend submitting today, please call Uwe or Tamara if you have any questions as I will be out of the office for most of the day:

| | | | |
|---|---|---|---|
| Uwe Scherf | DMD – Division Director | Uwe.Scherf@fda.hhs.gov | 301-796-5456 |
| Tamara Feldblyum | DMD – Branch Chief | Tamara.Feldblyum@fda.hhs.gov | 301-796-6195 |

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

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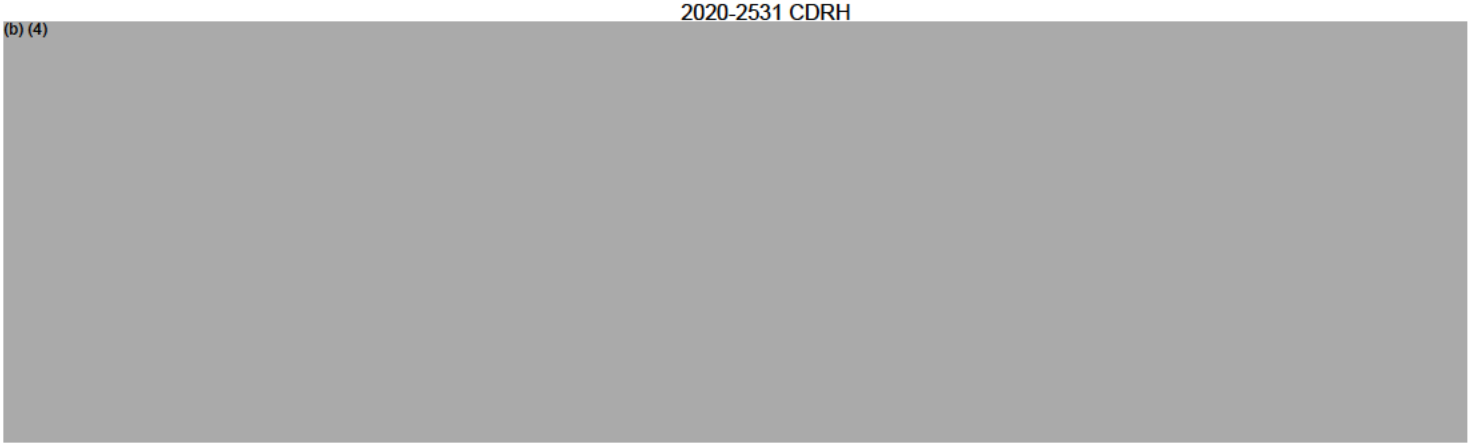
**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Thursday, February 27, 2020 10:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** Two pre-EUA questions....advice please

Hello Kim,
We are having an internal discussion at Wadsworth on strategy and need some advice please.
I am also copying this email to Dr. Jen Rakeman who directs the NYC lab as the answers will affect her strategy also.

(b) (4)

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(b) (4)



Thank you for your patience with us as we learn the FDA process.
Best wishes
Jill and Colleagues.

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 12:28:04 PM
**To**: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: TP for accelerated EUA for COVID-19.docx

If no one else has comments, then "yes". TY

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 12:27 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: TP for accelerated EUA for COVID-19.docx

Looks good to me---Jeff, did you want me to clean up and forward to Keagan

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 12:26 PM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: TP for accelerated EUA for COVID-19.docx

Looks good. Suggested edits in attachment.

Jeff

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 12:13 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: TP for accelerated EUA for COVID-19.docx

Much higher level TPs, based on what Keagan suggested. She just pinged me on TPs—if you all agree, can we get them to her asap.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 11:57 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** TP for accelerated EUA for COVID-19.docx

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Proposed TP for your review.

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/26/2020 11:56:53 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Question

Thank you.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 26, 2020 at 11:53:50 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Question

Hi Jeff,

I just reconfirmed the Coronavirus labs doing testing here at the CDC that also did the bulk of the key manufacturing for the first distributed lot sent to the PHLs is a CLIA lab and the surge lab here at the CDC is also a CLIA lab though under a different certificate.

Neither of these labs are being used for manufacturing Coronavirus kits going forward. The primers and probes are still being made in the Oligo lab here the CDC but then all subsequent manufacturing is being done at IDT in Iowa. I believe the CDC will continue to use this manufacturing process for some time.

In addition, just for clarity, the CDC has contracted with IDT and Biosearch to make GMP kits from the ground up including the primers and probes manufactured at these companies.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 9:07 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Question

Hi Jeff,

About 100 of the 300 CDC labs that do testing are CLIA certified. The Coronavirus labs is CLIA certified. They have expanded into additional space just recently. I will check on that new space now.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 6:17 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Question

Tim,

Do you know whether the CDC labs that make LDTs are CLIA certified or are they exempt from CLIA?

Jeff

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/26/2020 11:55:08 AM
**To:** Shuren, Allison W. [Allison.Shuren@arnoldporter.com]
**Subject:** Re: AdvaMinute | Coronavirus Update

ThNk you. I'm not.

---

**From:** Shuren, Allison W. <Allison.Shuren@arnoldporter.com>
**Date:** February 26, 2020 at 11:43:53 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: AdvaMinute | Coronavirus Update

I assume you are on the mailing list?

**From:** AdvaMed <web@advamed.org>
**Sent:** Wednesday, February 26, 2020 11:39 AM
**To:** Shuren, Allison W. <Allison.Shuren@arnoldporter.com>
**Subject:** AdvaMinute | Coronavirus Update

External E-mail

AdvaMinute

Give us a minute. We'll give you MedTech!

Good Morning, AdvaMed Nation—

Since the onset of the coronavirus (COVID-19) outbreak, at least 31 **AdvaMed member companies have donated medical products worth approximately $26.8 million and made cash donations worth $4.1 million** to the China Red Cross Foundation and other medical institutions, such as hospitals and clinics in Hubei Province. Donations and the medtech community's work will only grow in the coming weeks as the threat continues to elevate.

In a press release issued this morning, AdvaMed President and CEO Scott Whitaker

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said:

"At AdvaMed, we help industry and government work together to solve problems on behalf of the patients we serve, and that collaboration has never been more important than it is now in the face of this global health emergency. We're doing everything we can to help stop the spread of the coronavirus. For the medtech industry, that means donating key medical technologies, providing on-the-ground medical support, and developing new diagnostics, treatments, and vaccines. For AdvaMed, it means connecting industry to public officials and those who are on the front lines fighting this disease. The medical technology community has always stepped up during times of crisis, and AdvaMed is proud of the tremendous work and charity the industry has committed so far."

## AdvaMed Working With Key U.S. Government Agencies

AdvaMed has been working daily with key U.S. government agencies – including HHS, FDA, CDC, and ASPR – and the Chinese government to identify ways the industry can help ensure that providers and patients have access to the medical technologies they need to prevent, diagnose, and treat the coronavirus. This close coordination has facilitated information sharing; anticipated, identified, and reconciled supply-chain challenges; and prompted strategic product and capital donations.

## Coronavirus Task Force

The association has also assembled a coronavirus task force focused on personnel, transportation, and supply, among other needs. The task force meets regularly to receive government, industry, and member-company status updates, and to coordinate industry response. AdvaMed has also distributed to its membership a list of personal protective equipment (PPEs) identified by the Chinese government as essential to the emergency response (e.g., protective clothing, masks, gloves, and gowns; non-contact infrared thermometers; etc.), and is partnering with authorities to increase access to those medtech products.

## Member Company Response Effort

Below is a collection of some of the efforts undertaken recently by AdvaMed member companies:

**3M** is continuing to increase the production of respirators at their facilities around the

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globe. 3M has also donated respirators, surgical masks, and hand sanitizer to affected areas in China. View the press release here.

**Bayer** is donating medicine and money with a total value of approximately EUR 1.5 million. View the press release here.

**BD** has donated medical devices such as catheters, syringes, sharps, blood collection tubes, and flush products valued at approximately $300,000 to the local Red Cross in Wuhan. In addition, BD has donated $50,000 that will be used to supply personal protective equipment (PPE) to frontline health workers. Read more here.

**Cepheid** is developing an automated molecular test for the qualitative detection of COVID-19 with the ability to deliver point-of-care results in about 30 minutes. View the press release here.

**Danaher Corporation:** Five Danaher operating companies donated RMB 10 million ($1.4 million) of diagnostic equipment, reagents and other products to hospitals in Wuhan, China to combat COVID-19. Included in the donation is: Beckman Coulter Diagnostics' hematology analyzers, Beckman Coulter Life Sciences' flow cytometers, Radiometer's blood gas analyzers, Cepheid's Xpert® Xpress Flu/RSV assay, and Hach's UV-Vis spectrometers.

**GE** Healthcare CEO Kieran Murphy shared here that the company has prioritized and fulfilled hundreds of medical technology installations – including CT, ultrasound, digital x-ray, respirators and patient monitors – in China and other impacted regions. Additionally, GE Healthcare has donated $2.8 million worth of medical equipment in Wuhan, and has accelerated its global supply chain to help cut production times for its new Revolution Maxima CT from around one week to only three days. More details here.

**Johnson & Johnson** has donated one million surgical masks to China and $1 million RMB to the Chinese Red Cross Foundation. They have also donated thermometers, respirators, an electrosurgical generator, 50,000 bottles of isopropyl alcohol, and PPE including goggles and protective suits. Additionally, Johnson & Johnson is diligently working with partners around the globe to develop a vaccine. Read more here.

**Medtronic** and the Medtronic Foundation are committing $1.5 million to coronavirus relief efforts across the globe. Product donations to Wuhan Huoshenshan Hospital

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include ventilators, respiratory filters, pulse oximeters, sensors, and centrifugal blood pump systems. View the press release here.

**Olympus** installed endoscope systems into the Wuhan Huo Shen Shan Hospital within 10 days to treat infected patients. In addition to monetary donations to the Red Cross Society of China Huanggang, Olympus has donated 15 sets of laryngoscopes to the China Social Welfare Foundation, and 25 biological microscopes to the Chinese Center for Disease Control and Prevention, totaling approximately $500,000 in donations.

**QIAGEN** has sent the first group of 200 QIAstat-Dx cartridges for syndromic detection of respiratory pathogens – including COVID-19 –to China; they're now being validated at four hospitals. This comes as an evaluation was also successfully completed at the Bichat-Claude Bernard Hospital in Paris. The use of QIAstat-Dx is increasingly important for detection of the COVID-19 infections, as well as to provide differential diagnostics involving the more than 20 other respiratory pathogens included in this syndromic test.

**ResMed** CEO Mick Farrell stated that the company has sent more than 100 ventilators from ResMed's facility near Shanghai to Wuhan. He also stated they will send hundreds more ventilators and thousands of masks. Read more here.

**Roche** is working with Chinese health authorities and the government to ensure people can access screening and healthcare. Roche is also working to support the government and local health officials and hospitals in Hubei Province in dealing with the coronavirus. Recently, Roche has donated diagnostic tests, medical supplies, and financial support for the affected region. View the press release here.

**Varian** has donated 1 million RMB to the China Red Cross. View the press release here.

**For more information, contact Jim Jeffries.**

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AdvaMed
Advanced Medical Technology Association

AdvaMed 701 Pennsylvania Ave Suite 800 Washington DC 20004

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/25/2020 6:31:28 PM
**To:** Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]
**Subject:** RE: Breakout of funding: coronavirus supplemental funding

Yes, that seems appropriate.

Jeff

---

**From:** Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Date:** February 25, 2020 at 6:25:55 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Breakout of funding: coronavirus supplemental funding

Would this work?

(b) (5)

[redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 6:14 PM
**To:** Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Subject:** Re: Breakout of funding: coronavirus supplemental funding

Denise,

Most in #4, least in #3.

Jeff

---

**From:** Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Date:** February 25, 2020 at 5:08:41 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Breakout of funding: coronavirus supplemental funding

Jeff,

(b) (5)

[redacted]

---

**From:** Huttenlocker, Denise
**Sent:** Tuesday, February 25, 2020 1:53 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** coronavirus supplemental funding

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Jeff,

As you are probably aware, (b) (5) [redacted]

(b) (5) [redacted]

Denise

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/29/2020 1:05:56 PM
**To**: CDRH-OIR-Group [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c973b23547f4039b6d4168c0b5c3291-CDRH-OIR-Gr]
**CC**: Maisel, William (William.Maisel@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=WZM]; Faris, Owen P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d919c42856449589d2d24454b2f774e-OPF]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject**: Great Job!

Dear OHT7,

As the federal government works to address the public health emergency for COVID-19, I wanted to take a moment to thank you for your significant contributions to this effort. For the past two months, DMD has been actively encouraging and supporting development and validation of diagnostics. This includes significant outreach to developers with molecular capabilities, development of a template for EUA submission, interactions with over 75 individual developers, review and authorization of CDC's assay, resolving problems as they arise, and, over the course of the past 24 hours, developing and publishing of a final guidance on policy for this specific emergency. It has been a truly herculean effort.

The guidance titled Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency was posted on our website this morning along with an updated COVID-19 EUA template. This policy allows labs to develop, validate and run LDTs for COVID-19 during this emergency, provided certain criteria are met:

- Tests should meet validation criteria described in the guidance before clinical use
- Labs should notify FDA when clinical use of a validated test begins
- Labs should confirm the first 5 positive and negative samples with an EUA authorized test (likely in another lab)
- Test reports should indicate the test has been validated but that independent review by FDA is not yet complete
- Labs should submit an EUA within 15 days of initiating testing
- If any specimens fail confirmatory testing or if FDA is unable to authorize the EUA, labs should stop testing and issue corrected test reports indicating prior results may not be valid

DMD was instrumental in development of reasonable guardrails around the limited enforcement discretion in this policy.

Our work, particularly that of DMD, is not done. In fact many of you are still working now, even after many late nights and long weekends of EUA review work. We will need to continue reviewing EUA requests as quickly as possible for the foreseeable future. DMD has an incredible track record and I know you will continue to rise to the occasion. I also wanted to acknowledge the entire office, as I know OHT7 works as a team to support one another.

Thank you for your ongoing extraordinary efforts to meet the public health needs in this emergency.

I know it has been a long road and it is far from over but we, our country, and our global neighbors will get through this, together.

Jeff

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 2:44:32 PM
**To**: Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject**: RE: Request for FDA EUA exemption

Okay with me.

Jeff

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:48 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: Request for FDA EUA exemption

Yes, I'll make sure both Dr. Stine and Lindsay Baden (per Elizabeth's message) receive the outreach invites.

Elizabeth and I just discussed including Lindsay Baden on both the media and stakeholder invites. Let me know if you have any concerns with that approach.

Alicia

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:38 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** FW: Request for FDA EUA exemption
**Importance:** High

Alicia,

Can you please make sure that Dr. Stine is part of the outreach for the stakeholder call today? Please let me know when stakeholders are informed of the call and I will reply to Vince's email below. Thank you.

Jeff

---

**From:** Vince Stine <VStine@aacc.org>
**Sent:** Friday, February 28, 2020 1:06 PM
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
**Subject:** Request for FDA EUA exemption

Dr. Hahn,

I am attaching a letter from the American Association for Clinical Chemistry requesting that the Food and Drug Administration (FDA) exercise its enforcement discretion to permit qualified laboratories to use laboratory developed tests to detect SARS-CoV-2 and diagnose COVID-19. We appreciate your consideration of our request.

Sincerely

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Vincent Stine, PhD
Senior Director, Government & Global Affairs
American Association for Clinical Chemistry

**Vince Stine, PhD**
Senior Director, Government Affairs
AACC | 900 Seventh Street, NW, Suite 400 | Washington, DC 20001

P +1 202.835.8721
VStine@aacc.org
www.aacc.org




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OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/26/2020 11:53:44 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Re: Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits

I might be able to join a 3 PM call.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 26, 2020 at 11:51:22 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits

Hi Jeff,

There was some concern in speaking with Scott just now that based on a CDC call yesterday that some labs may destroy their existing kits and we want to stop that immediately.

The call with all the PHLs will be at 3 pm today. Scott would still like to keep the 4:30 pm call.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 11:49 AM
**To:** Scott.Becker@aphl.org
**Cc:** Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits

Please hold for additional follow on information.

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For now, do not destroy your existing CDC 2019 nCoV Coronavirus EUA kits.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 9:45:58 AM
**To:** Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 4:21 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Dear Wendi,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

On February 24, 2020, CDRH/FDA was informed that enforcement discretion from FDA was needed for the following:

1. CDC qualified laboratories to perform testing using only the already distributed N1 and N2 (and not N3) primers of CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel, upon verification of those primers by the laboratory, until such time as they receive and verify new primers that will be supplied by CDC and/or Integrated DNA Technologies (IDT) and begin performing testing with them. CDC would also distribute and these laboratories would use new result interpretation instructions that FDA has reviewed but has not yet authorized as part of an EUA, for performing testing with only the N1 and N2 primers. CDC requests this enforcement discretion to address the manufacturing issues that have been identified with certain N3 primers and to avoid significant delays in testing given increased testing demands. CDC and IDT, a CDC-identified third-party manufacturer, are preparing new lots and kits for the new primers, but it will take some time to complete quality control testing and to send these primers to the CDC qualified laboratories.

2. CDC qualified laboratories to test individuals who meet COVID-19 clinical and/or epidemiological criteria using the authorized test and the two primer test (as set forth above). This enforcement discretion is being requested to address growing concerns of community transmission of COVID-19, and would be until authorization of a new or amended EUA for this use.

CDC has generated data indicating that testing using the N1 and N2 primers of the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel may be effective in the detection of SARS-CoV-2, and CDC and FDA have worked interactively in connection with FDA's review of the data. At this time, there are no adequate, approved, and available alternative tools that can detect SARS-CoV-2.

Our understanding of the facts and the public health concerns at issue here are: that there is currently no other test available to detect SARS-CoV-2 to respond to this emergency; significant public health concerns are

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presented by the infectious disease; and the proposed testing may help to prevent the spread of the infectious disease COVID-19. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the conditions that presumptive positives and inconclusive results will be confirmed by testing at the CDC headquarters in Atlanta, GA, and that CDC will act promptly to submit a new or amended EUA to authorize the testing described above.

Sincerely,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov






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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/29/2020 10:59:38 AM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Yes

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:42 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Hi Jeff,

To clarify, do you want me to edit?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:46 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 4:21 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>

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**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

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Sincerely,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

Center for Devices and Radiological Health
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**U.S. Food and Drug Administration**
Tel: 301-796-5900
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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 4:46:07 AM
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** Re: NYS Wadsworth

I should add that Wadsworth can begin testing once we announce our policy of enforcement discretion today. We will let them know once the announcement is made.

Also, we responded to all HHS comments on the guidance last night.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 28, 2020 at 10:10:00 PM EST
**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** NYS Wadsworth

Wadsworth sent us their EUA this afternoon. (b) (5) [redacted]

In addition, Wadsworth (b) (4), (b) (5) [redacted] That testing is premised on their ability to reference the CDC's data. We've asked if they would give a right of reference to Wadsworth as this is important not just for Wadsworth but some other test developers, as well. We asked that, if CDC agrees, they just email us that "The New York State Wadsworth Center can reference the data in the CDC 2019 nCoV EUA application".

We'll follow up but if we do not hear back from them tomorrow morning I may ask you to reach out to Redfield. This should be a no-brainer.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/25/2020 9:22:21 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: RE: RE: 2019 nCoV

Thank you.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 9:00 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: RE: RE: 2019 nCoV

Dan lives it and also loves it.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 25, 2020 at 8:59:31 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: RE: RE: 2019 nCoV

Dan lives it. Everyone else had left. Working on the rest of the team. Sent an email to them tonight giving them a heads up for a discussion in the morning. Uwe is on board too!

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 25, 2020 at 8:16:25 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: RE: RE: 2019 nCoV

Great. Was CDC on board with the N1/N2 interim approach?

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 8:12 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: RE: RE: 2019 nCoV

LabCorp is rolling along!

Best,
*Tim*

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**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*

*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Tuesday, February 25, 2020 8:02 PM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: RE: 2019 nCoV

Will do. We should be able to submit late next week or early the week after. (b) (4)

Thanks again for all of your help.

-Brian

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 7:58:51 PM
**To:** Krueger, Brian (b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Subject:** [External] RE: RE: 2019 nCoV

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Thanks Brian for the update. That is great news. If you wouldn't mind continuing to keep me informed of your progress that would be great!

Best,
***Tim***

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Tuesday, February 25, 2020 11:17 AM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019 nCoV

Hey Tim,

Thank you so much for the UTMB lead. (b) (4)

-Brian

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 9:07:13 PM
**To:** Krueger, Brian (b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Subject:** [External] RE: 2019 nCoV

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You are most welcome.

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Date:** February 24, 2020 at 9:06:28 PM EST
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019 nCoV

Ok, we will get in touch with utmb, thanks!

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 8:57:38 PM
**To:** Krueger, Brian (b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Subject:** [External] RE: 2019 nCoV

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Great to connect Brian. Also I just heard that UTMB has extracted RNA that is ready to ship.

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Date:** February 24, 2020 at 7:04:56 PM EST
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019 nCoV

Hey Tim,

Give me a call if you're still free to chat.

(b) (6)

-Brian

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:29:56 PM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Cc:** Krueger, Brian (b) (6) @LabCorp.com>
**Subject:** [External] RE: 2019 nCoV

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Thank you Marcia! Hi Brian,

Fantastic. I am at CDC HQ now and can talk. My cell is (b) (6)

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Sent:** Monday, February 24, 2020 5:51 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Krueger, Brian (b) (6) @LabCorp.com>
**Subject:** Re: 2019 nCoV

Hi Tim
So great to hear from you.
We have our submission number after a few exchanges with the agency via email on our validation design. I am copying Dr. Brian Krueger. He and I can be available and welcome your help.

On Feb 24, 2020, at 4:37 PM, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov> wrote:

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Hi Marcia,

I am told LabCorp is developing an assay. Could you put me in touch with the correct R&D leader to discuss? We want to do anything we can to help speed the development of an EUA.

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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**[Date]**

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**ATTN:** Division Director: Dr. Uwe Scherf**,** OHT7-OIR/OPEQ/CDRH/FDA

**RE:** Request for Pre-Emergency Use Authorization (Pre-EUA) of the [*Name of the Assay*]

**Dear Dr. Scherf,**

[***Name of the Company***] is submitting a Pre-Emergency Use (Pre-EUA) for the [***Name of the Medical Device Product***] so we can obtain feedback from FDA concerning the studies and/or testing outlined in our Pre-Emergency Use Authorization (Pre-EUA) submission package.

The [***Name of the Medical Device Product***] is [***brief description of the device***] and [***intended use***].

Attached to this letter is the first draft of our device EUA Interactive Review Template for FDA review as a Pre-EUA. One hard copy of the signed EUA Cover Letter and one electronic copy are enclosed. Also, these documents have been sent to you via email.

In case you should have any questions regarding the information provided and/or need additional information/data from us please contact me immediately either via email [_____] or phone [_____].

Sincerely,

[***Name***]

[***Signature block***]

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# EMERGENCY USE AUTHORIZATION (EUA)

## EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (2019-nCoV)

## GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow ***[Text]*** should be completed by the IVD developer (sponsor) as applicable to their specific test. Text in **bold** outlines the Food and Drug Administration (FDA) suggestions and clarifications for the sponsors' consideration when completing the required information in a specific section.

- This is a EUA interactive review template for Pre-EUA/EUA submissions concerning molecular-based single target tests for detection of 2019 Novel Coronavirus (2019-nCoV), Wuhan, China. If you are developing a multiplex molecular-based assay for the detection and differentiation of nucleic acids from a panel of microorganisms, please review Appendix A for FDA recommendations.

- This is a EUA interactive review template for Pre-EUA/EUA submissions and not a guidance document. The template is subject to change as we learn more about the 2019-nCoV disease and its risk-benefit profile. Recipients will receive notice and updated templates as they become available.

- This EUA interactive review template is an FDA internal document and any proprietary information provided within the template and during the interactive review process will remain confidential as it does in a regular FDA premarket submission.

- Feedback provided by FDA during the interactive review of your pre-EUA/EUA is subject to change as we learn more about the 2019-nCoV disease and the risk-benefit profile evolves to address unmet public health needs.

- Prior to a potential authorization FDA will require developers of molecular-based tests to assess traceability of their test to an FDA-recommended reference material panel if available at the time. Specific details about the traceability study and the FDA-recommended reference material panel will be provided by the Lead Reviewer assigned to the Pre-EUA submission once the analytical and clinical evaluation data has been reviewed and found to be acceptable.

- Please be reminded that tests for the detection of 2019-nCoV or 2019-nCoV infection must not be distributed and/or used for clinical diagnoses without premarket clearance, approval, or EUA by the FDA. Clinical samples for 2019-nCoV testing should be sent to the appropriate public health laboratories until the IVD device subject of this Pre-EUA submission has received authorization from the FDA.

- Clinical specimens may be required to support the EUA request. Furthermore, please note that applicable regulations for human subject protection do apply under the

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EUA. Please refer to the Clinical Evaluation section of this document for more details.

- If authorized, the EUA means that this 2019-nCoV IVD is temporarily authorized for use until the public health emergency is terminated or the EUA is revoked by the FDA.

    - FDA recommends that you consider registration and listing your EUA product once you have been issued an EUA. If this is problematic, please notify the Agency during your Pre-EUA.
    - The EUA is not a pathway to permanent marketing of your device. Therefore, we strongly recommend that you consider, in addition to an EUA, a traditional premarket submission for your IVD so that your device can still be legally marketed after termination of the emergency declaration. We recommend that you identify as soon as possible in the Pre-EUA review process any consideration of moving your product forward towards De Novo/510(k) clearance. If so some of our feedback to you may take such a long-term goal into consideration in order to prevent additional testing where it may not be needed. Therefore, please consider submitting a Pre-Submission to inquire what studies would be required for a premarket approval/ clearance of your 2019-nCoV IVD. Details on how to submit a Pre-Submission to the Agency are outlined in the FDA guidance document: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.* [ HYPERLINK "https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program" ]

## A. EXECUTIVE SUMMARY (as of X/XX/20XX)

## B. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the ***[test name]*** to ***[indicate labs, if applicable]*** for the *in vitro* qualitative detection of RNA from the 2019-nCoV in ***[add all claimed specimen types, e.g., nasopharyngeal/oropharyngeal swabs, sputa, BAL, stool, and serum, etc.]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated with 2019-nCoV infection) and CDC novel coronavirus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated) to aid in the diagnosis of 2019-nCoV infection.

## C. MEASURAND

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Specific nucleic acid sequences from the genome of the 2019-nCoV **[*please specify the targeted gene(s) of the pathogen*]**.

## D. APPLICANT

***[Official name, address and contact information of applicant]***

## E. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name - ***[test name]***
Established Name - ***[test name]***

## F. REGULATORY INFORMATION

***Approval/Clearance Status:***
The ***[test name]*** test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

***Product Code:***
[XXX – FDA will complete]

## G. PROPOSED INTENDED USE

***1) Intended Use:***
**The proposed IU will be finalized based on the data and recommendations from Public Health authorities at the time of authorization – example text is provided below for a qualitative molecular test that detects organism RNA but may be adapted according to the specific emergency situation addressed by the device.**

[***Test name***] is a [***specify test technology such as, real-time RT-PCR test***] intended for the qualitative detection of nucleic acid from the 2019-nCoV in [***describe all the specimen types***] from individuals meeting CDC 2019-nCoV clinical criteria (e.g., clinical signs and symptoms associated with 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated). Testing is limited to [***laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories***].

Results are for the identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in **[*name specimen type*]** during the acute phase of infection. Positive results

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are indicative of active infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The ***[test name]*** is intended for use by **[*include intended user, e.g., trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures*]**. The ***[test name]*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

***2) Special Conditions for Use Statements:***

For prescription use only
For in vitro diagnostic use only

***3) Special Instrument Requirements:***

The ***[test name]*** test is to be used with the [***list all RT-PCR Instruments, software requirements, automated extraction instruments***].

## H. DEVICE DESCRIPTION AND TEST PRINCIPLE

**Example text has been added under each of the sub-headings below for a fluorescence based rRT-PCR test for detection of organism RNA. If a different test principle is used by the test for the detection of a specific analyte please modify the description accordingly to capture the salient points in each of the sub-headings below. Please note that for new investigative technologies FDA may request additional detailed information so we can adequately assess the risks and benefits associated with the device.**

***1) Product Overview/Test Principle:***

**Describe the technology of the test and how this technology works to identify the measurand, the instruments employed/required to perform the test from sample collection to result (include all claimed extraction and PCR detection instruments), and the specimen types for which you claim to have specific performance characteristics as described below. If applicable, list all primer and probe sets and briefly describe what they detect. Please include the nucleic acid sequences for all primers and probes used in the test. Please indicate if the test uses biotin-Streptavidin/avidin chemistry in any of the steps for coupling reagents. Please note that an alignment with available reference genomes for different strains of the target pathogen is requested as part of the inclusivity evaluation (Section N).**

The ***[test name]*** is a real-time reverse transcription polymerase chain reaction (rRT - PCR) test. The 2019-nCoV primer and probe set(s) is designed to detect RNA from

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the 2019-nCoV in ***[list all the specimens]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated).

2) ***Description of Test Steps:***

**List and describe in detail all the steps of the test sequentially from specimen collection to detection.**

Nucleic acids are isolated and purified from ***[specimens]*** using ***[please describe the method(s) of extraction (please specify the specimen input volume for extraction and/or test, the nucleic acid elution volume and whether isolation/purification is manual and/or automated)].*** The purified nucleic acid is reverse transcribed using ***[enzyme mix/kits – please specify the input volume of purified nucleic acid added to the rRT-PCR reaction mix]*** into cDNA which is then subsequently amplified in ***[please describe the instrument(s) and enzyme mix]***. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by ***[please describe the detection instrument(s)]***.

3) ***Control Material(s) to be Used with [test name]:***

**List all control materials (provided with the test kit and/or required but not provided with the test kit and describe what they are, how they are expected to work, where in the testing process they are used, and the frequency of use. If a control is commercially available, provide supplier's name and catalog number or other identifier; if your device relies on external controls that are manufactured by a third party please note that these controls should also be validated within your analytical and clinical studies described below in Section (N).**

Controls that will be provided with the test kit include:

a) A "no template" (negative) control is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***

b) A positive template control is needed to ***[describe need]*** and is used ***[describe use – please specify the concentration of the positive control relative to the LoD of your test (note that ideally the positive control concentration should be such that it is close to the LoD of your test) and also specify frequency of use]***

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c) An extraction control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use].*** **Please note that if the no template control and positive control, are taken through the entire sample processing procedure, including the extraction, then a separate extraction control is not required**.

d) An internal control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use]***.

Controls that are required but not provided with the test kit include ***[describe control – provide recommended sources of the control materials – either a separate control kit for purchase that you the applicant develops or a control material that can be purchased from a third party].*** This/these control(s) is/are needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***.

**Please note that any control recommended to be used with your device (provided with the kit or not) needs to be validated in the context of your analytical and clinical study (i.e., you will need to run these controls as part of your studies). In instances where control material is not readily available through 3rd party vendors (which is often the case at the beginning of an outbreak) FDA may request that you include suitable control material with your device. Please note that external control materials are considered particularly important in the context of EUA devices because often GMP requirements for the manufacture of the EUA device are waived in emergency situations and reagent stability studies are limited. Hence the external controls offer some assurance of EUA test performance in the hands of the end user.**

## I. INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. **Please describe if a Ct cutoff is used as part of your testing algorithm and/or if the end user is required to review fluorescent curves for weakly positive samples before final interpretation. Although not typical for molecular-based tests, if the test result involves the use of an algorithm/calculation, for example a ratio value, when determining the final patient test result, please include a detailed description and any additional calibration materials that may be required.**

1) ***[Test name] Controls – Positive, Negative and Internal***

**Describe in detail the expected results generated, including acceptance criteria, for all the controls described in detail in Section H above. Describe the measured values (if applicable) for valid and invalid controls and outline the recommended actions the laboratory should take in the event of an invalid control result.**

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2) ***Examination and Interpretation of Patient Specimen Results:***

**Describe when clinical specimen test results should be assessed and outline the criteria for test validity**. **Example text**: Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

**Clearly indicate how to interpret numeric test values (if applicable) as positive or negative for presence of the 2019-nCoV. Indicate if the end user is required to review fluorescent curves for weakly positive samples before final interpretation and how to identify indeterminate/inconclusive results (if they exist) results and how the user should resolve them, e.g. if repeat testing may be required.**

**When applicable, provide a table clearly describing the possible combinations of test result values for each primer/probe set, and how they should be combined into a final interpretation of the result for your test. If the test produces result that will be used as part of a CDC recommended testing algorithm, please indicate what follow-up testing/process should be conducted, if applicable.**

## J. PRODUCT MANUFACTURING

**Please note that if you are developing a test for use at a single site (i.e., a laboratory developed test LDT), some of the information requested in this section may not be applicable. Please contact FDA for additional guidance for an emergency use LDT.**

The ***[test name]*** has been validated using only the components referenced in this submission and shall not be changed without prior concurrence from the FDA.

*1)* ***Overview of Manufacturing and Distribution:***

The product will be manufactured at [***manufacturer's name and FDA registration number (if applicable) or laboratory name if an LDT***] by [***manufacturer name, or laboratory name if an LDT***] personnel consistent with practices for the production of **[*types of devices*]** based on [***type of quality system****]. Material manufactured by [***manufacturer's name, or laboratory name if an LDT***] may be bottled and kitted by [***packager name***] manufacturing facility.

***Under the Emergency Use Authorization (EUA) most of the 21 CFR 820 Quality System Regulation (QSR) requirements can be waived for the duration of the EUA. FDA expects that developers follow comparable practices as much as possible and may consider previous compliance history when determining whether or not to waive certain QSR requirements for a specific product. Please note adverse events, as per 21 CFR Part 803, have to be reported for authorized devices (see Section R).**

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The current manufacturing capabilities include the ability to manufacture approximately **[*please insert the approximate number of units/products that can currently be manufactured per week at the manufacturing facility*]** products per week, however in the event of a surge in demand this could be increased to **[*please insert the approximate maximum number of units/products that could potentially be manufactured per week at the manufacturing facility if there was a surge in demand*]** product per week within a **[*please specify in weeks/months the expected timeframe required to increase product production if required*]** timeframe.

The product will be distributed by **[*please describe the distribution plan for the product and list all current distributors*]**.

2) ***Components Included with the Test***

Components manufactured by [***manufacturer's name and FDA registration number (if applicable)***] and supplied with the test include:
**List all components and reagents provided for your test, including a description of the primers and probes, volumes, concentrations, quantities, buffer components, etc.**

3) ***Components Required But Not Included with the Test***

Components required but not included with the test:
**List all components and reagents not included with the test that must be supplied by the user to perform the test, with specific supplier names and catalog numbers or other identifiers for obtaining these components and reagents. Please include here all specific consumables that were validated for use with your device, that are not interchangeable with other products and that are needed to guarantee device performance as established in the EUA validation studies listed in Section N below.**

4) ***Testing Capabilities***

**Briefly describe current sample throughput capacity, total time required to perform the test (from clinical specimen collection, specimen transport to result), and number of tests that can be performed per instrument run and per day.**

5) ***Reagent Stability:***

**Briefly describe stability test plan for *[test name]* reagents and include any accelerated stability information if available. Please note that reagent stability studies do not need to be completed at the time of EUA issuance, however the study design should be agreed upon during interactive review and the stability studies started immediately following authorization, if not before. When designing your stability study, we have some general recommendations that are outlined in Appendix B, for your consideration.**

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## K. PERFORMANCE EVALUATION

**If you plan to claim multiple target analytes to aid in differential diagnosis or you plan to claim multiple RT-PCR instruments and/or extraction methods, please refer to Appendix A and C, respectively, more information. Please note that any omission of a requested study in this document should be documented and justified.**

### *1) Analytical Sensitivity:*

a) *Limit of Detection (LoD):* **You should determine the LoD of the device utilizing the entire test system from sample preparation to detection for each clinical matrix claimed. Please note that claims for additional anticoagulants, for blood specimens, can be supported by a matrix equivalency study as outlined in Section N, subsection 3 below. The LoD is determined using dilutions of live propagated and titered 2019-nCoV stocks (CFU/mL or PFU/mL) spiked into a relevant clinical matrix. If wild-type virus is not available at the time of your validation studies, please contact FDA to discuss a potential alternative. Please note that if available please also provide Genomic Equivalent Copies (GEC)/mL units for the stock solutions used and include an explanation on how they were determined. Please note that LoD studies should be performed with live organisms, as described above. If you plan to use inactivated organism in your LoD determination you should describe how the material was inactivated and perform a study to determine whether the inactivation process impacted the LoD of the device.**

**First a tentative LoD must be established through limiting dilutions of the prepared material with 3-5 replicate measurements. Please note for all the analytical studies described in Section N that require replicate testing, one replicate equates to one independent extraction and PCR detection. Once a tentative LoD is established, the LoD should be confirmed by preparing at least 20 additional replicates at the LoD concentration and demonstrating that the organism was detected with a minimum 95% positivity (19/20). If this confirmatory study achieves a positivity of 100%, then a lower concentration needs to be tested (with 20 replicates) until <100% positivity is obtained.**

**Please use the following format when submitting LoD information and data:**

LoD studies determine the lowest detectable concentration of 2019-nCoV at which approximately 95% of all (true positive) replicates test positive. The LoD was determined by limiting dilution studies using characterized samples.

**List/describe the following in this section:**

- **Titers and strains of the 2019-nCoV stocks used for the LoD study and describe how the organism stocks were prepared and how the titers were determined.**

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- **The dilution factor and number of serial dilutions of the characterized 2019-nCoV that were tested to determine the LoD for each primer and probe set.**
- **The nucleic acid extraction/purification method.**
- **The real time PCR instrument.**

Serial dilutions of the characterized 2019-nCoV were then tested in **[*number of replicates (i.e., recommend that sample is extracted independently three-five times and each extraction tested once)*]** replicates. The lowest concentration at which all [***number of replicates***] replicates were positive was treated as the tentative LoD for each test. The LoD of each test was then confirmed by testing [***number of replicates (at least 20 recommended)***] with concentrations at the tentative limit of detection. The final LoD of each test was determined to be the lowest concentration resulting in positive detection of [***number of positive replicates (at least 19 out of 20 replicates)***]. [***Include analysis of LoD results, indicating the final LoD for each test***]

**Tentative LoD: [*Please provide a summary of the data for each strain tested]* example table 2019-nCoV stocks is provided below:**

| 2019-nCoV Strain Tested | Stock 2019-nCoV Titer | Serial 10-Fold Dilution Factor | Concentration in Dilution Tested [Include Units] | Replicate 1 $C_t$ | Replicate 2 $C_t$ | Replicate 3 $C_t$ | Replicate 4 $C_t$ | Replicate 5 $C_t$ | Call Rate | Lowest Concentration with Uniform Positivity per Analyte | Limit of Detection (LoD) per Virus Strain |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Example:*** *[analyte]* | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

b) FDA Sensitivity Evaluation: The analytical sensitivity of the test has to be further assessed by evaluating an FDA-recommended reference material using an FDA developed protocol if applicable and/or when available. Details will be provided during the Pre-EUA interactive review.

c) *Reactivity/Inclusivity:* Reactivity of the ***[test name]*** was evaluated for additional isolates of 2019-nCoV.

**Reactivity: *[test name]* example table below**

| 2019-nCoV Strain/Isolate | Source/Sample Type* | Concentration | Ct** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

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| | | | |
|---|---|---|---|
| | | | |

***Please list source of material used for wet testing and sample type tested (i.e., organism – live or inactivated, purified nucleic acid – whole genome etc.).**
**** If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**At a minimum, the strain used in your LoD evaluation should be listed here (multiple isolates of the same 2019-nCoV strain that was used for the LoD studies can also be included if available). If additional isolates are not available at the time of your validation studies, please discuss with FDA. Each isolate should be tested at or near the LoD (no more than 3x LOD) of the test, spiked into clinical matrix utilizing the entire test system, including extraction. If you plan to claim more than one type of clinical matrix, we recommend that you perform this study in the most challenging clinical matrix, testing a minimum of 3 replicates. In addition, the wet testing should be accompanied by extensive inclusivity *in silico* analysis of the test primer and probes with all known strains/isolates (past/present) of 2019-nCoV (including the strain/isolate used for wet testing).**

## 2) *Analytical Specificity:*

a) *Cross-Reactivity:* Cross-reactivity of the ***[test name]*** was evaluated using both *in silico* analysis and by testing whole organisms **[*pathogen*]** (concentration) or purified nucleic acid from other ***[describe organisms]*** (concentration/reaction).

**Cross-Reactivity: *[test name]* example table for wet tested organisms below**

| Virus/Bacteria/Parasite | Strain | Source/ Sample type | Concentration | Ct Values* |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

***If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**Cross-reactivity studies are preformed to demonstrate that the test does not react with related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen. The FDA Tables 1 and 2, below are intended to recommend simulate testing of patients having infections with organisms which cause similar symptoms to those observed at the onset of 2019-nCoV infection. The FDA Tables also include other organisms and strains which have significant genetic similarity and therefore a higher likelihood of cross-reacting with 2019-nCoV specific reagents. Also included in the FDA Tables are recommended unclaimed organisms/strains which are likely to be endemic to the currently affected area should be included in cross-reactivity testing since these organisms/strains will be an important aspect of the differential diagnosis of 2019-nCoV infection.**

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**FDA Table 1 Cross-Reactivity: List of Organisms to be wet-tested and analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens**

| Other high priority pathogens from the same genetic family | High priority organisms likely in the circulating area |
|---|---|
| Human coronavirus 229E | Adenovirus (e.g. C1 Ad. 71) |
| Human coronavirus OC43 | Human Metapneumovirus (hMPV) |
| Human coronavirus HKU1 | Parainfluenza virus 1-4 |
| Human coronavirus NL63 | Influenza A |
| SARS-coronavirus | Influenza B |
| MERS-coronavirus | Enterovirus (e.g. EV68) |
| | Respiratory syncytial virus |
| | Rhinovirus |
| | *Chlamydia pneumonia* |
| | *Haemophilus influenzae* |
| | *Legionella pneumophila* |
| | *Mycobacterium tuberculosis* |
| | *Streptococus pneumonia* |
| | *Streptococcus pyogenes* |
| | *Bordetella pertussis* |
| | *Mycoplasma pneumoniae* |
| | *Pneumocystis jirovecii* (PJP) |
| | Pooled human nasal wash - *to represent diverse microbial flora in the human respiratory tract* |
| | |

**FDA Table 2 Cross-Reactivity: List of Organisms to be analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens:**

| Other high priority pathogens from the same genetic family | High priority organisms, including organisms commonly found in the clinical matrix |
|---|---|
| | Influenza C |
| | Parechovirus |
| | *Candida albicans* |
| | *Corynebacterium diphtheriae* |
| | *Legionella non-pneumophila* |
| | *Bacillus anthracis* (Anthrax) |
| | *Moraxella catarrhalis* |
| | *Neisseria elongate and meningitidis* |
| | *Pseudomonas aeruginosa* |
| | *Staphylococcus epidermis* |
| | *Staphylococcus salivarius* |
| | *Leptospirosis* |

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| | |
|---|---|
| | *Chlamydia psittaci* |
| | *Coxiella burnetii (Q-Fever)* |
| | *Streptococcus aureus* |
| | |

***In silico*** **analysis should be performed on all potentially cross-reactive organisms outlined in the FDA Tables 1 and 2 above. You should provide the result summary of the *in silico* blast analysis (tabular format) evaluating whether there is any significant amplification of non-target sequences that could either result is cross-reactivity or potentially interfere with the detectability of the actual target analyte. As such we are asking that you provide individual blast results (non-truncated alignments) for each of the primers and probes used in your device with potential cross-reacting organisms. Please provide for our review the percent sequence homology for each organism relative to the target analyte primers/probes in your test. Please use the example table below when presenting the results of *in silico* analysis in your submission:**

**Results of *In Silico* Analysis**

| Pathogen | Strain | GenBank Acc# | % Homology Test FP (i.e. 0-100%) | % Homology Test RP | % Homology Test Probe |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**The analysis should include multiple representative strains from GenBank for each organism. If *in silico* analysis reveals other potential cross-reactants (i.e., ≥80% homology between one of your primers or the probe to any of the sequences of listed potential cross reactants), you should carefully review the alignments and determine based on the positions of the homologous stretches and mismatches if additional cross-reactivity and/or interference (please refer to item b below – microbial interference studies) wet testing will be required to rule out cross-reactivity or interference of that organism that may affect the performance of your device. In these circumstances if wet-testing is omitted you should include an explanation as to why *in silico* generated data is not clinically relevant (irrelevant isolate, location/extent of match within primer/probe, etc.), or why the performance of your test would not be impacted.**

**Organisms in FDA Table 1 should be wet tested in addition to the *in silico* analysis. Omissions from wet-testing should be discussed with FDA and supported by a well-documented justification that includes a due diligence attempt to obtain the live or inactivated organisms (and/or purified nucleic acid – which is acceptable for cross reactivity evaluation for an EUA).**

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**The wet testing evaluation should reflect test specimens prepared at the highest clinically relevant level of organism (i.e., a minimum of $10^6$ CFU/ml or higher for bacteria and $10^5$ $TCID_{50}$/mL or PFU/ml or higher for viruses) and should be tested with a minimum of three replicates per organism test specimen. Test specimens can be prepared by spiking cultured isolates/inactivated organisms/ purified nucleic acids (whole genome) into negative clinical matrix and determining cross reactivity based on triplicate replicates. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix.**

**If you plan to claim non-blood or non-respiratory clinical specimen types for diagnostic use with your device, e.g., stool specimens, etc., please consult FDA for more information on additional organisms that may be recommended for cross-reactivity testing, common examples are provided below for stool specimens (FDA Table 3):**

**FDA Table 3: Organisms to be analyzed for non-blood clinical specimens:**

| **Stool** |
|---|
| *Escherichia coli* |
| *Lactobacillus* |
| *Bacillus* spp. |
| *Clostridium* Spp. |
| *Enterobacter* |
| *Enterococcus* |
| Fusobacterium |
| Bacteroidetes |
| Bifidobacterium |
| Ruminococcus |
| |

b) *Microbial Interference Studies:* **If *in silico* analysis reveals ≥ 80% homology between the cross-reactivity microorganisms and your test primers/ probe(s), we recommend that you either perform (1) a microbial interference study with 2019-nCoV and the microorganisms that your test primers/ probe(s) have homology to, (2) as an alternative to the microbial interference study, you may provide justification as to why (e.g., amount of primer(s)/ probe(s) included in your master mix) the performance of your test would not be impacted by the presence of a causative agent of a clinically significant co-infection, or (3) explain why the *in silico* results are clinically irrelevant. In the case of the microbial interference study, interference should be evaluated using samples spiked at a low 2019-nCoV concentration, at 3x LoD, and a high interferent level (either microorganisms or nucleic acids purified from them), to represent the worst-case scenario, with a minimum of 3 replicates. If you plan to claim more than**

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**one type of blood clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix. If the LoDs are similar in the blood clinical matrices the study should be performed in the most challenging matrix, i.e., whole blood. In addition, if you are claiming blood and non-blood clinical specimens you may be required to perform this study in more than one clinical matrix. If interference is observed at the level tested, an additional titration study should be performed to determine the highest microorganism interferent level the 2019-nCoV test can tolerate.**

**c)** *Endogenous Interference Substances Studies*: **The extent of testing for endogenous interference substances depends on the matrix that is claimed for the device as well as on the technology of the device, e.g., if a nucleic extraction procedure is performed prior to testing or not. For EUA we do not typically ask for interference studies for tests that use conventional PCR and/or well-established extraction methods prior to testing (e.g., Boom method and column-based extraction methods).**

**For extraction procedures that are new or for nucleic acid-based technologies that are different from conventional PCR (e.g., various isothermal methods), we expect testing of potential interferents. The impact of interfering substances should be evaluated over the expected clinical range of the potentially interfering substance. Potential sources of endogenous interference include, but are not limited to, the ones listed in the tables below. It is important to note that the evaluation of interference and the generation of false negative results should be done using samples containing the analyte at or near the LoD and should not exceed 3x LoD. You should test a minimum of 3 replicates per substance. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed between the different clinical matrices this may warrant this study being performed in more than one clinical matrix. Biotin interference poses a risk to laboratory tests that incorporate the free biotin-streptavidin capture method. Therefore, please review this safety communication [ HYPERLINK "https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication" ] and the following [ HYPERLINK "onenote:http://sharepoint.fda.gov/orgs/CDRH-IVD/Orgs/DMD/DMD%20OneNotes/Language/Analytical%20Studies/Interference.one" \l "DRAFT%20guidance%20-%20Testing%20for%20Biotin%20Interference%20in%20In%20Vitro%20Diagnostic%20Devices&section-id={39D67316-5AE2-4791-958F-9387D384D6FA}&page-id={9298F00C-7C39-43CB-9EBA-29E5BC08BB6E}&end" ] ([ HYPERLINK "http://sharepoint.fda.gov/orgs/CDRH-IVD/Orgs/DMD/_layouts/OneNote.aspx?id=%2Forgs%2FCDRH-IVD%2FOrgs%2FDMD%2FDMD%20OneNotes%2FLanguage&wd=target%28Analytical%20Studies%2FInterference.one%7C39D67316-5AE2-4791-958F-**

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**9387D384D6FA%2FDRAFT%20guidance%20-%20Testing%20for%20Biotin%20Interference%20in%20In%20Vitro%7C9298F00C-7C39-43CB-9EBA-29E5BC08BB6E%2F%29" ]) to determine if biotin interference testing may be warranted for your device. We also recommend you consult with FDA prior to initiating biotin interference testing, if applicable.**

**The tables below indicate the potentially interfering substances that may be found in blood and respiratory specimens. For other non-blood specimen types, such as stool, the list of substances could be expanded – please consult with FDA.**

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *positive* results:**

| Potential Interfering Substance | Concentration | Results (Detected X/3) |
|---|---|---|
| **Respiratory Specimens** | | |
| Mucin: bovine submaxillary gland, type I-S | | |
| Blood (human) | | |
| Nasal sprays or drops | | |
| Nasal corticosteroids | | |
| Nasal gel | | |
| FluMist | | |
| Homeopathic allergy relief medicine | | |
| Throat lozenges, oral anesthetic and analgesic | | |
| Anti-viral drugs | | |
| Antibiotic, nasal ointment | | |
| Antibacterial, systemic | | |
| **Blood Specimens** | | |
| Hemoglobin | 10 mg/mL* | |
| Bilirubin Conjugated | 0.4 mg/mL* | |
| Bilirubin Unconjugated | 0.4 mg/mL* | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | |
| Triglycerides | 15 mg/mL* | |
| Cholesterol | 4 mg/mL* | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | |
| Rheumatoid Factor | 2000 IU/mL* | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *negative* results:**

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| Potential Interfering Substance | Concentration* | Viral Strain Level (In multiples of LoD) | Results (Detected X/3) |
|---|---|---|---|
| **Respiratory Specimens** | | | |
| Mucin: bovine submaxillary gland, type I-S | | | |
| Blood (human) | | | |
| Nasal sprays or drops | | | |
| Nasal corticosteroids | | | |
| Nasal gel | | | |
| FluMist | | | |
| Homeopathic allergy relief medicine | | | |
| Throat lozenges, oral anesthetic and analgesic | | | |
| Anti-viral drugs | | | |
| Antibiotic, nasal ointment | | | |
| Antibacterial, systemic | | | |
| **Blood Specimens** | | | |
| Hemoglobin | 10 mg/mL* | | |
| Bilirubin Conjugated | 0.4 mg/mL* | | |
| Bilirubin Unconjugated | 0.4 mg/mL* | | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | | |
| Triglycerides | 15 mg/mL* | | |
| Cholesterol | 4 mg/mL* | | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | | |
| Rheumatoid Factor | 2000 IU/mL* | | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

### 3) *Matrix Equivalency (if applicable):*

**A matrix equivalency study may be used to support certain specimen type claims that were not evaluated during the clinical study (e.g., serum versus plasma, use of different anticoagulants, use of difference swab types or viral transport media, etc.). Please note that LoD and clinical specificity studies are required for all claimed matrices. The matrix in which the clinical studies are conducted is the comparator. All other matrices are to be shown to be equivalent to the comparator matrix. We request a minimum of 40 paired samples each obtained from individual persons; negative (10 samples), low positive (1.5-2xLoD, 20 samples), and moderate positive (5-10xLoD, 10 samples) samples should be tested. Positive samples are prepared by spiking paired negative clinical matrix with the same amount of target analyte. Please note that individual (and not pooled) samples should be used in this study.**

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4) ***Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method:***

**A comparative LoD study may be required to support use of a comparator method in your clinical evaluation that has not been validated with a specific specimen type. The comparative LoD study should be conducted testing the same dilution series using both, your test and the comparator you chose in parallel (to dilution endpoints for both tests), 3-5 replicates per dilution level are sufficient for this study.**

5) ***Specimen Stability and Fresh-frozen Testing:***

**A specimen stability study may be required to support specimen stability claims in the instructions for use outside of those typically outlined in CSLI standards. A fresh/frozen and/or freeze/thaw study may be required to support the use of frozen specimens if they are used as part of the clinical evaluation. Please consult with FDA concerning an appropriate study design prior to initiating any studies.**

6) ***Clinical Evaluation:***

**This section should describe the clinical study used to evaluate the performance of your test. Please note that the exact requirements for the clinical evaluation will be very dependent on, access to 2019-nCoV disease clinical specimens at the time of the studies and the nature of the emergency. Our general clinical study evaluation recommendations for respiratory and serum clinical specimens are outlined below. If you are interested in claiming additional specimen types, for example, stool, please contact FDA for current recommendations. Please note these clinical study recommendations may be subject to change as we continue to learn about the 2019-nCoV disease or as the risk benefit analysis changes.**

**The clinical performance in general should be evaluated for each unique claimed clinical specimen type - with the exception of claims that can be supported by a matrix equivalency study (outlined in Section 3 above). The performance characteristics should ideally be established using a clinical study with a limited number of prospective samples. If a prospective study is not feasible, an acceptable alternative would be to test retrospectively collected 2019-nCoV nucleic acid negative and positive specimens from patients, accompanied by some basic information such as, the specimen collection date, date of onset of symptoms (if present/known), tests used to identify 2019-nCoV nucleic acid positive specimens, etc. Depending on the nature of the disease, if no prospective or retrospective specimens are**

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**available at the time of your pre-EUA submission for the 2019-nCoV disease we may accept a fully contrived clinical evaluation. The clinical evaluation should be comprised of a minimum of 100 negative individually collected specimens and 50 individual positive specimens (prospective, retrospective and/or contrived). Use of pooled specimens are not acceptable for the clinical evaluation of your test. Please see FDA Table 5 for more details. Please note that if a fully contrived clinical study is used to support your Pre-EUA submission, additional clinical testing of a limited number of natural clinical positive specimens and potentially negative specimens from the endemic region, if available, may be required at the time when this Pre-EUA transitions to an EUA as a result of an Emergency declaration for 2019-nCoV disease.**

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## FDA Table 5: Clinical study Recommendations:

| Details | Study Including Prospective/ Retrospective Specimens | Fully Contrived Sample Study |
|---|---|---|
| Minimum Number of Positive Specimens | 50<br><br>The number of natural (prospective/retrospective) positive clinical specimens should be at least 25 (collected from symptomatic patients in the 2019-nCoV disease endemic region(s)) and, if necessary, may be supplemented with contrived samples to generate the total of 50 positive specimens. Contrived samples should be prepared as described in the fully contrived sample study column. | 50<br><br>The contrived positive samples should be made in individual negative clinical matrix collected from subjects from a non-endemic population (pooled matrix is not acceptable for the clinical evaluation). Please note that the negative clinical matrix used for spiking should be confirmed negative by your test device prior to spiking. Half of the contrived positive samples can be prepared by spiking the 2019-nCoV at LoD and the remaining contrived positive samples should cover the range of the test up to and not higher than 5 x LoD.<br><br>Negative respiratory specimens: Can be archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection.<br><br>Negative blood specimens: Can be collected from healthy subjects from non-endemic areas. |
| Minimum Number of Negative Specimens | 100<br><br>Note: In general, for EUA the 100 individual negative samples can be collected from; (1) archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection for respiratory specimens, and (2) healthy subjects from non-endemic areas for blood specimens, that are "expected 2019-nCoV disease negative". Note these negative specimens can be used to also prepare any contrived positive specimens used in support of the clinical evaluation of the test.<br><br>Please note this recommendation is dependent on the current outbreak situation and is subject to change as we learn more about the 2019-nCoV disease/outbreak. If the outbreak situation for 2019-nCoV disease is primarily outside of the continental U.S. (OUS) it may be beneficial to consider collecting negative specimens that represent 50% endemic and 50% non-endemic regions. If negative specimens are collected from the endemic region of the 2019-nCoV disease these should be tested with the same comparator chosen for the positive specimens (more details provided below). For non-endemic collected specimens you can compare to the expected "negative" result. | |
| Recommended Comparator Method | Positive: Positive percent agreement should be calculated in comparison to a EUA PCR test (please see the following website for the most recent list of FDA authorized 2019-nCoV | Positive: Compare to expected result.<br><br>Negative: See Minimum Number of Negative Specimens row |

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| | | |
|---|---|---|
| for percent agreement performance calculations | tests: [ HYPERLINK "https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm" ]. If no EUA test available at the time of your EUA submission, please consult with FDA about your choice of comparator method – which ideally should be a well validated PCR test with comparable sensitivity to your subject device. Please note that a well validated PCR test should include evaluation of the tests LoD, inclusivity, exclusivity, interference and any clinical testing.<br><br>Negative: See Minimum Number of Negative Specimens row | |
| Comparator Method Note 1 | Please note when using natural clinical specimens, the comparator method must be validated for the specimen type claimed – if not you should perform a Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method study, as explained above (Section 4), to support its use as a comparator method in your clinical study. | N/A |
| Comparator Method Note 2 | Any occurrences of false results should be investigated with an additional validated PCR test and/or targeted sequencing, and the results of the discordant analysis can be footnoted in your final performance table but cannot be used to change the final performance calculations. | |
| Natural Clinical Specimens IRB/Informed Consent Note | For clinical specimens collected to support the EUA request, please note that sample collection needs to adhere to all applicable rules of human subject protection; as such, sample collection needs IRB approval, which includes review of the informed consent forms. Samples need to be collected with informed consent. If leftover de-identified samples are used, FDA exercises enforcement discretion regarding the informed consent requirement if the specimen collection meets the criteria described in the FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable ([ HYPERLINK "http://www.fda.gov/cdrh/oivd/guidance/1588.pdf" ]).<br>**Note that IRB approval is still required even if leftover de-identified samples are used in your study.** | |
| Additional Studies Warning | N/A | If fully contrived samples were used in your Pre-EUA submission, additional testing of natural clinical specimens may be requested, if available, to support transition of the Pre-EUA to EUA as a result of an Emergency declaration. |
| Testing Approach Note 1 | Please note all clinical specimens (natural and contrived) should be evaluated in accordance with your proposed diagnostic algorithm, including retesting when appropriate. We understand the limited nature of natural specimens may preclude retesting. In instances were retesting is indicated but not performed, for the purposed of performance evaluation, initial results will be analyzed for performance and equivocal/indeterminate results count against your final performance. | |
| Testing Approach Note 2 | Specimens should be tested in a blinded fashion, e.g., positive and negative samples should be mixed and blinded to the end user, end user should also be blinded to the results of any comparator method testing. | |

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**When you describe your clinical study please indicate/include:**

- **How the specimens were generated/collect/sourced**
- **If the study was fully prospective, mix of prospective, retrospective and/or contrived or fully contrived**
- **The rationale for the concentrations/specimens selected (if using contrived or 3-party sourced specimens)**
- **The total number of specimens tested**
- **The specimen types (clinical matrix)**
- **A summary of the study results**

**In the case of real-time PCR tests, please provide the line data in an Excel file as part of the Pre-EUA submission for each specimen (please indicate for each specimen if it was prospective, retrospective or contrived and the clinical matrix it represents); the data should include the $C_T$ values (for the specimen and the controls) and call/result for your device and, in the case of the natural clinical specimens, the comparator method results should be included as well.**

## L. UNMET NEED ADDRESSED BY THE PRODUCT

**This section will be finalized by FDA based on the state of the emergency at the time of authorization and based on recommendations from Public Health authorities at that time. Example text is provided below but may be adapted according to the specific emergency situation that is addressed by the device and the need at the specific time of the outbreak.**

[Outline background of pathogen, disease and current outbreak]

[Outline details of the disease such as the following:

- likely sources of transmission
- likely symptoms – if any
- Prevalence of symptomatic disease (what fraction of infection results in symptomatic disease)]

Laboratories in the United States are in need of diagnostic tools for use in the 2019-nCoV emergency for rapid diagnosis of acute 2019-nCoV infection.

A public health emergency has been declared by the Secretary of Health and Human Services (HHS) on [Month Day, YEAR] justifying the authorization of emergency use of *in vitro* diagnostic tests for detection of 2019-nCoV and/or diagnosis of 2019-nCoV infection.

The ***[test name]*** can augment clinically important laboratory evidence for individuals with active infection. The 2019-nCoV nucleic acid is generally detectable in [name

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specimen type] during the acute phase of infection (approximately [7] days following onset of symptoms, if present) [and possibly for longer in other specimen types].

Under emergency use authorization (EUA), ***[applicant name]*** plans to distribute the test or accept sample for testing with the ***[test name]*** for the detection of nucleic acid from 2019-nCoV in clinical specimens collected from individuals meeting CDC's 2019-nCoV clinical and/or epidemiological criteria. This EUA request for the ***[test name]*** is intended to expand domestic readiness within the United States and its territories by expanding diagnostic testing capabilities for 2019-nCoV during public health emergency.

FDA consulted with subject matter experts within HHS on the public health needs for diagnostic devices to detect 2019-nCoV nucleic acid. It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for 2019-nCoV detection during the public health emergency.

## M. APPROVED/CLEARED ALTERNATIVE PRODUCTS

Currently no methods for the detection of the 2019-nCoV have been approved/ cleared by FDA.

## N. RISKS AND BENEFITS:

**The Risks and Benefits section should be updated according to your specific device, some example language is given below but should be tailored to the device and the disease.**

Risks

The ***[test name]*** has been designed to minimize the likelihood of false test results. However, should false results occur, they may present risks to patients:

- False positive result:
  - A false positive 2019-nCoV result could [***update based on the pathogen***].
  - A false positive result in the context of the current public health emergency could lead to misallocation of resources used for surveillance and prevention.
  - A false positive result could delay correct diagnosis and initiation of appropriate treatment for the actual cause of patient illness.
- False negative result:
  - Although a negative result does not rule out 2019-nCoV infection, a false negative has the potential to result in initiation of inappropriate treatment and a delay in correct diagnosis.
  - A false negative result can trigger a waste of health care resources, as additional evaluations are pursued in the effort to establish the true diagnosis.
  - A false negative results can contribute to further spread of the disease.

Benefits

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The primary benefit of distributing the ***[test name]*** for clinical use is that it provides a relatively fast diagnostic method for symptomatic patients, which enables faster intervention.

- True positive test results provide support for the diagnosis of a 2019-nCoV infection. The results can be used in conjunction with clinical and epidemiological information to guide patient management.
- Distribution of the factsheets can help healthcare professionals and the public learn more about 2019-nCoV disease and how to avoid acquiring it.

Risk Assessment

- Negative results may not preclude a 2019-nCoV infection. It is emphasized that the ***[test name]*** should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure must be considered pivotal to making patient management decisions. A negative test should not be interpreted as definitive, if other aspects of the patient's clinical presentation or recent epidemiologic exposures indicate such is likely, and diagnostic tests for other diseases are negative.
- False negative results due to failure of PCR are minimized by the presence of controls that monitor nucleic acid extraction and PCR efficiency.
- Risk of patient discomfort or harm during sample collection is minimal.

Risk-Benefit Assessment

The risks posed by use of the ***[test name]*** are mitigated by:

- Use of the ***[test name]*** in conjunction with other laboratory, epidemiological, and clinical evaluation tools
- Distribution of Healthcare Provider and Patient fact sheets.
- Post-market studies/reporting or conditions of Authorization.

Based on these factors, the potential benefits from the use of the ***[test name]*** are expected to outweigh the risks.

## O. FACT SHEET FOR HEALTHCARE PROVIDERS AND PATIENTS:

**Include proposed Fact Sheets for Patients and Healthcare Providers**

## P. INSTRUCTIONS FOR USE/ PROPOSED LABELING/PACKAGE INSERT:

**Include Instructions for Use, Box Labels, Vial Labels and any other proposed labeling.**

## Q. RECORD KEEPING AND REPORTING INFORMATION TO FDA:

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[***Manufacturer name***] will track adverse events and report to FDA under 21 CFR Part 803. A website is available to report on adverse events, and this website is referenced in the Fact Sheet for Health Care providers as well as through the [***Manufacturer name***] Product Support website: [***Include link to Website***]. Each report of an adverse event will be processed according to [***Manufacturer name]***'s Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the FDA as required. Through a process of inventory control, [***Manufacturer name]*** will also maintain records of device usage/purchase. [***Manufacturer name]*** will collect information on the performance of the test, and report to FDA any suspected occurrence of false positive or false negative results of which [***Manufacturer name]*** becomes aware. [***Manufacturer name]*** will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

## R. ADMINISTRATIVE INFORMATION:

**Interactive Review Log:** Please use the table below to document interactive review with FDA and include interactions initiated by either FDA or yourself

| **Date** | **Type of Interaction** (phone/ email/ formal submission-DCC) | **Brief Description** (e.g., questions asked/ feedback from FDA received / any word documents included) |
|---|---|---|
| [X] | [X] | [X] |
| | | |
| | | |

## S. FDA ADMINISTRATIVE INFORMATION:

**This section will be finalized by the FDA Lead Reviewer upon completion of the review process and documents the interactive review of this submission and any conclusions resulting from the interactive review.**

1) **Summary of Interactive Review – Lead Reviewer to use this section to highlight any major issues solved during interactive review.**
2) **Final Conclusions for Interactive Review -** It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for [pathogen] detection during the public health emergency. **Conclusion should include an outline the unique features of the device compared to currently issued EUA's under the declaration, if applicable.**
3) **Upon competition of this section the Lead Reviewer should also sign this document and save the file as the final Decision Memorandum.**

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## APPENDIX A – Multiplex Panels Under EUA:

An emergency declaration by the HHS Secretary is typically specific for a pathogen/disease (i.e., there is a publicly declared health emergency involving a particular etiologic agent). Therefore, the EUA pathway is only applicable for testing patients with signs/symptoms/risk of exposure for that single agent in a given emergency. FDA has occasionally allowed limited additional target pathogens to be claimed for EUA devices, but panel members must be relevant to the event/disease outbreak subject of the specific emergency declaration. When determining whether to issue an EUA for a multiplex panel FDA takes into consideration the utility of the test (multiplex pathogen detection as an aid in differential diagnosis), clearance/approval status of IVDs for the other panel members, whether the proposed Intended Use fits within the HHS emergency declaration and the how the multiplex panel would fit into current public health authority patient testing algorithm recommendations. We recommend you contact FDA for specific feedback if you plan to claim multiple target analytes as part of your EUA test. If it is determined that a multiplex test is beneficial to the emergency response, please note that analytical and clinical evaluations for each of the target analytes will be required.

## APPENDIX B – General Study Design Recommendations for Reagent Stability:

- For EUAs you may follow the current FDA recognized CLSI Standard EP25 – Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline when evaluating the suitability of stability study designs. If you are planning to pursue a De Novo/510(k) for your device we recommend discussing in more detail your stability design to facilitate potential use of the EUA data in your regular premarket submission.
- Please note that use of only the positive controls is not acceptable for reagent stability evaluation because controls are usually formulated at a moderate positive level. For all the stability evaluations in addition to your external positive and negative controls and the no-template control you should include for the EUA evaluation at least one sample, that should be prepared by spiking negative clinical matrix at an analyte concentration of 3-5xLoD.
- If you are claiming multiple blood clinical specimen types in which similar LoDs are determined, you should use the most challenging clinical matrix for this study.
- Please note we typically recommend your stability study design includes the evaluation of at least 5 replicates. You should also evaluate, if available, 3 different lots of reagents.
- You should design your study to provide data for a timeframe that is about 10% longer than the one to be claimed – for example; a claim of 18 months should be supported by stability data out to 20 months and a claim of 7 days should include stability data out to 8 days.
- FDA considers 15-30°C to represent room temperature conditions. Ideally you should evaluate stability at both 15°C and 30°C, however, for the purposes of the EUA evaluation at 30°C is acceptable as the worse-case scenario.
- Shelf-Life Stability- Unopened kit:
    - You should evaluate real-time kit stability studies with unopened kits stored at the claimed storage temperature for your test.

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  - Accelerated stability evaluations for unopened kits is acceptable for EUA submissions while the real-time studies are on-going. However, please note real-time stability data is required to support regular pre-market submissions and for the final claim of an EUA.
- Shipping Stability - Unopened kit: Study should evaluate the anticipated handling and shipping times and temperatures expected for unopened kits.
- In-use/Opened Kit Stability: Depending on your device your stability study design should also support in-use stability of the kit reagents once the kit has been opened, e.g., storage at 2-8 $^{o}$C for 7 days. This includes on board stability once reagents have been placed on the instrument (if applicable).
- Inverted stability (if applicable): Study should support inverted stability for of kits.
- Freeze-thaw Stability: If you recommend aliquoting the reagents to meet the end-users needs following the initial thaw this recommendation should be supported by a freeze-thaw stability study, including the specific number of allowed freeze-thaw cycles.
- FDA analysis recommendations for real time stability studies are as follows:
  - Baseline of the study (t=0 of stability study) should not exceed a month from bottling
  - Clear baselines should be described (e.g., a month from bottling) for each stability claim under each study
  - Claims should be determined based on regression analysis. Any %change (%shift) from time zero (baseline) should be calculated between the target claim and the zero-time as (Ttest-Tbaseline)/ Tbaseline*100 with 95%CI using the regression equation obtained from plotting the mean values. When formulating your acceptance criteria for evaluating the shift from baseline you should consider the reproducibility of your device. However, generally, that the shift at the target claim due to storage cannot exceed 10-15%. The target stability is the next to last tested point that was within +/- 10% of time zero.
  - Acceptance criterion may be different, depending on the test samples analyte concentration distribution in the intended use population and the risk, in other words, the impact of false results to public health.

**APPENDIX C – Claiming Multiple Instruments and/or Extraction Methods:**

If you wish to claim multiple instruments and/or extraction methods for use with your test, please review the study recommendations provided below and contact FDA for any additional feedback. Please note that these analytical and clinical evaluation recommendations are based on the assumption that the elution volumes from the extraction methods and PCR volumes on the different RT-PCR instruments are identical.

- Limit of Detection (LoD): Please note that these studies should be repeated for each clinical matrix claimed in the Intended Use. Pick one RT-PCR instrument and determine the tentative LoD (using 5 replicates in 10-fold dilution) followed by the confirmatory LoD (20 replicates spiked at tentative LoD) for each extraction method on the chosen instrument. Note: If you detect 20/20 replicates in your confirmatory LOD study you should test the next lower concentration, using a 3-fold dilution, until

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you achieve a hit rate of <20/20.

- If the different extraction methods yield the same LoD (≤3xLOD) on the RT-PCR instrument chosen for initial testing, pick one extraction method for further LoD determination on the remaining RT-PCR instruments and follow the recommendations below.
- If the extraction methods do not yield the same LoD on the chosen RT-PCR instrument, please choose the extraction method with the worst LoD for further comparison of the LoD on all RT-PCR instruments.

For all other RT-PCR instruments you should use the following adaptive LoD study design:

- Please perform a refined tentative LoD study with 5 replicates at 0.5x, 1x, and 1.5 to 2x LoD. If you detect 4/5 replicates as positive at all the tested levels, you need to include the next higher concentration (i.e., 3x LoD). If you obtain 5/5 replicates at 0.5x LoD, you need to test the next lower concentration (i.e., 0.25x LoD). You will test in this manner until you find the lowest concentration that gives you 5/5 positive results for the tested RT-PCR instrument. This concentration should be used for a confirmatory LoD study for the given RT-PCR instrument using 20 replicates.

Final reported LoD: Please list all RT-PCR instruments with their respective LoDs if different LoDs are obtained. LoDs are considered comparable if they are between 1-3xLoD. These studies should be repeated for each clinical matrix claimed in the Intended Use.

- Interference Substances Studies (if applicable): Pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Inclusivity Testing: For the inclusivity testing, pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Exclusivity Testing: For exclusivity, you can perform this study using any extraction/instrument combination.

- Clinical study: If equivalency of the RT-PCR instruments is shown in an LoD study that tests and confirms that the LoD is the same or very similar for all of the RT-PCR instruments (between 2-3xLoD), then you can pick one RT-PCR instrument for your clinical study provided that the RT-PCR instruments in question are known to FDA for other *in vitro* diagnostic devices. If you find that one or more RT-PCR instruments machines has/have a different LoD, you should pick the extraction method / RT-PCR instrument combination with the worst LoD.

Note, if there are differences in the extraction input volume, extraction elution volume

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and PCR input volume (extracted nucleic acid) then the LoD should be confirmed, for each.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/28/2020 4:07:03 AM
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** NYS
**Attachments:** Draft cover letter for Sponsor 01212020.docx; EUA Review Template_NAT_Novel Coronavirus 1.19.2020.doc

Additional communication — as of February 25th Wadsworth hadn't finished validating their test.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 27, 2020 at 10:01:33 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Pre-EUA IVD template request

FYI

---

**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:03 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Pre-EUA IVD template request

FYI – see information in red in the email below and:

Wadsworth:

(b) (4), (b) (5)

Best regards
Kim

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:50 PM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** RE: Pre-EUA IVD template request

Dear Jill,

Thank you very much for reaching out to us about the test you have validated at Wadsworth Center, NYS Department of Health it was very nice to chat with you. As discussed please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [formally - 2019-novel coronavirus (2019-nCoV)]. I suggest the first step is to populate this draft template with the validation information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center). The Pre-EUA review is an interactive process, so we will provide feedback after receiving and reviewing the information provided. The draft review template is a shared "work-in-progress" document which you will populate with information and data as obtained and which we will review and provide feedback to you. **Please make sure to capture in the EUA review template that you performed the validation using the SIGMA primer/probes sets, sensitivity was evaluated with the positive control material provided in the CDC EUA test kit and that validation studies were performed used the commercial primer/probe materials using the CDC EUA Protocol (please be sure to include information the extraction method and instrument used).**

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I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of SARS-CoV-2 to FDA (it includes the address for the Document Control Center). Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under Section A (type of submission) please check "other" and specify Pre-EUA; please also complete Sections B, C, F and G. For G please use the information provided in this link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=3669.

One hard copy of the signed EUA Cover Letter and one electronic copy (CD or thumb drive) of you Pre-EUA submission package should be enclosed in your Pre-EUA submission package mailed to FDA (recommend FedEx). In addition to mailing your Pre-EUA package to FDA we also request that you submit the package to the review division via electronic mail (including the EUA Review Template in MS word) to myself Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;
- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please let me know if you have ANY questions I am happy to assist if you are not sure about certain sections in the template.

Best regards

Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Tuesday, February 25, 2020 1:08 PM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** Pre-EUA IVD template request

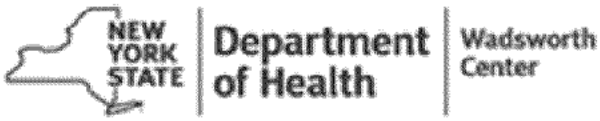
At your earliest convenience, I wish to request a copy of the most recent EUA review template relevant to an assay for the SARS-CoV-2 pathogen.

(b) (4)

Thank you,

**Jill Taylor, Ph.D.**
Director

Wadsworth Center, NYS Department of Health
Room E-260, Biggs Laboratory
(518) 474-3157 | jill.taylor@health.ny.gov
www.wadsworth.org




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AMERICAN SOCIETY FOR MICROBIOLOGY

February 28, 2020

The Honorable Stephen M. Hahn, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hahn:

On behalf of the American Society for Microbiology (ASM), we are writing to express concerns about the effects that current regulations under the FDA Emergency Use Authorization (EUA) are having on the use of diagnostic tests by clinical laboratories. Specifically, under the current EUA in place as a result of the COVID-19 outbreak, laboratory developed tests (LDTs) created outside the CDC and public health labs may not be performed in clinical settings.

We respectfully ask that you consider adjustments to the regulations to allow clinical laboratories to have access to the test assay from CDC **in addition to** the public health laboratories. Clinical laboratories follow a rigorous process for validation and implementation of laboratory-developed tests. If this pathway was considered during an outbreak, it would allow for a more rapid response to implementation of diagnostic testing. Many clinical laboratories have already validated high-complexity LDTs for SARS-CoV-2 and could begin testing tomorrow, but cannot do so due to the FDA EUA process. Testing is overseen by board-certified doctoral-level directors of clinical laboratories that are routinely inspected and certified to perform CLIA high-complexity testing. While we appreciate that the intent of the EUA is to safeguard the public and ensure tests are safe and effective early in outbreaks, the EUA process is proving a hindrance to rapid identification of potential COVID-19 infections. If we have tests that are safe and effective that cannot be used, this can put people at risk.

The regulatory process under the EUA is significantly more stringent than that required for other viral tests in CLIA-certified clinical laboratories. The current CDC test for COVID-19 remains the only test available with EUA status, and it has not been made available to hospital laboratories. This creates undue pressure on both the CDC and state public health labs to rapidly scale manufacturing and clinical testing. As a result, turnaround time may slow, which will present significant challenges should the number of infected individuals, or suspected infections, dramatically increase here in the United States.

Because COVID19 poses a major threat to the public health of the United States, diagnostic testing for the virus causing COVID19 (SARS-CoV-2) is an essential component of our nation's response to the current outbreak. In this situation, rapid identification of cases is critical. This is due to several factors, including the need to make appropriate patient management decisions and the need to curb further spread of the disease. The widespread availability of diagnostic testing enables rapid identification of infected individuals so they can be quickly isolated to prevent onward transmission of the virus and protect healthcare personnel. Furthermore, when patient is considered a "suspect" COVID-19 case, the healthcare providers and laboratories often manage the case differently than they normally would. This could include deferring or not performing certain procedures, which would have normally been done to diagnose, treat, or stabilize a patient. This alteration of the normal protocol is done to keep healthcare

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and laboratory staff safe, and to help prevent the spread of disease. However, it can have a negative impact on the patient's outcome.

ASM's membership includes clinical microbiologists working in all laboratory settings, from community hospitals, to academic medical centers, to public health labs, all of whom are on the front lines in addressing COVID-19 and other infectious diseases at the point of care. We recognize that this is a complex, rapidly evolving situation. While we believe the policies are well-intentioned, the regulations are creating significant barriers to patient care at this time.

We appreciate your consideration of our concerns, and we look forward to working with you to address these challenges with an eye toward the long-term, including considering what legislative changes may be necessary to improve our response to a future outbreak. If we can be of further assistance, please contact Allen Segal, ASM Director of Public Policy and Advocacy, at asegal@asmusa.org or 202-942-9294.

Sincerely,

Robin Patel, MD
President

Stefano Bertuzzi, PhD
Chief Executive Officer

Stacey L. Schultz-Cherry, PhD
Chair, ASM Public and Scientific Affairs Committee

Melissa Miller, PhD
Chair, ASM Clinical and Public Health Microbiology Committee

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 2:38:43 PM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]
**CC**: Tomasello, Jennifer (Jennifer.Tomasello@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=Jennifer.Tomasello]
**Subject**: FW: Letter from the American Society for Microbiology re COVID 19 EUA and clinical testing
**Attachments**: EUA Letter_to FDA on COVID_final.pdf

Another letter but a different ask.

Alicia – can you please include Mary Lee Watts/ASM on the invite for the stakeholder call? Thank you.

---

**From:** Watts, Mary Lee <mwatts@asmusa.org>
**Sent:** Friday, February 28, 2020 2:22 PM
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Varnado, Martina <Martina.Varnado@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** Letter from the American Society for Microbiology re COVID 19 EUA and clinical testing

Dear Dr. Hahn, Dr. Abernethy, and Dr. Shuren,

The American Society for Microbiology is one of the largest professional societies dedicated to the life sciences and is composed of 30,000 scientists and health practitioners, including clinical microbiologists and laboratory professionals. ASM's mission is to promote and advance the microbial sciences. We thank you for your leadership during this COVID-19 outbreak.

Attached is a letter from our leadership expressing our concerns about challenges that the current EUA is presenting to clinical labs and their ability to test for the virus. We appreciate your consideration of our views, and we look forward to working with you.

Best,

Mary Lee Watts, MPH, RD
Director, Federal Affairs
Public Policy and Advocacy
American Society for Microbiology
1752 N St., NW
Washington, DC 20036
Direct: (b) (6)
mwatts@asmusa.org

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NEW YORK STATE OF OPPORTUNITY. Department of Health

**ANDREW M. CUOMO**
Governor

**HOWARD A. ZUCKER, M.D., J.D.**
Commissioner

**SALLY DRESLIN, M.S., R.N.**
Executive Deputy Commissioner

February 25, 2020

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn,

As the New York State Commissioner of Health, I am very concerned that the lack of diagnostic testing outside of the labs of the Centers for Disease Control and Prevention places New York in an unacceptably vulnerable situation in light of the COVID-19 outbreak that is rapidly expanding to several other countries including South Korea, Iran and Italy. While CDC has worked diligently to provide select public health labs with the testing kits to allow for expanded lab capacity, we are now several weeks into the response, and manufacturing problems continue. While CDC works to provide a diagnostic assay to public health labs under the current Emergency Use Authorization (EUA), New York State has independently worked to develop and validate a diagnostic assay using the CDC protocol.

To address the current urgent situation, I am hereby requesting that FDA approve the New York State Public Health Laboratory, Wadsworth Center, and the New York City Public Health Laboratory to implement their own laboratory developed test (LDT) for the detection of the COVID-19 virus, SARS-CoV2, outside of the current EUA process. Wadsworth Center and the NYC Public Health Laboratory have already developed and validated a test, modeled after the CDC test, (b) (4)

Upon FDA approval, Wadsworth Center and the NYC Public Health Laboratory can quickly begin testing all specimens from persons under investigation in New York State and potentially other states in the northeast region in order to be responsive to the rapidly escalating public health crisis. In their role as reference laboratories, Wadsworth Center and the NYC Public Health Laboratory already have a tremendous amount of experience in the development and implementation of LDTs for the molecular detection of a wide range of microbial pathogens. Wadsworth Center is also an approved third-party reviewer for FDA for laboratory developed tests. In addition, LDTs developed for offering in New York State, including at Wadsworth Center and the NYC Public Health Laboratory, must be reviewed and approved by New York's Clinical Laboratory Evaluation Program, CLEP, before they can be implemented in the laboratory.

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New York State and New York City are eager to expand testing capacity to allow for sentinel surveillance and potentially testing of an expanded group of individuals with symptoms and a travel history to recently impacted countries. I look forward to discussing this request with you and your staff as soon as possible.

Sincerely,

Howard Zucker M.D.

Howard A. Zucker, M.D., J.D.
Commissioner of Health

cc:
Oxiris Barbot, M.D., Commissioner
NYC Department of Health and Mental Hygiene

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/28/2020 4:04:43 AM
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** NYS
**Attachments:** Letter to FDA Commissioner RE COVID-19.pdf
**Importance:** High

Here's the letter sent to you from Dr. Zucker emailed and dated February 25th. I don't know if there was any outreach from him beforehand.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Date:** February 25, 2020 at 3:10:48 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Fwd: COVID-19 Outbreak
**Importance:** High

Request from wadsworth similar to aphl

---

**From:** Zucker, Howard A (HEALTH) <howard.zucker@health.ny.gov>
**Date:** February 25, 2020 at 2:18:58 PM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** COVID-19 Outbreak

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/25/2020 1:02:40 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Deliberative/Predecisional

That's a good question.

Uwe, Kim — what do you think?

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 25, 2020 at 12:50:36 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Deliberative/PreDecisional

The CDC has not received kits from IDT yet, doesn't expect them for 2-3 weeks. CDC says they may be advertising kits but may not be able to ship. I or someone else can call IDT to find out for sure. I'm going into my last lab manufacture tour now.

If IDT can ship kits today, (b) (5)

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 25, 2020 at 12:11:07 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

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(b) (5)

[redacted]

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 25, 2020 at 11:24:51 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Tim, Ellen, Jeff,

Based on the attached information it looks like that the CDC primer is commercially available at IDT Integrated Technology:

# 2019-nCoV CDC qPCR Probe Assays

IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes. Three of the primer/probe sets in this panel target different locations on the 2019-nCoV/SARS-CoV-2 Nucleocapsid gene (N-gene). These 3 primer/probe sets must be run concurrently with the internal control (4th assay), which targets the human RNase P gene. Altogether, there are 4 qPCR assays per patient sample.

Components are premixed to the CDC recommended working concentration and delivered in IDTE, pH 7.5. Stocked kits are available in 3 reaction sizes of 50, 100, and 500 reactions, with custom sizes available (see section below. Kits are shipped within 1–2 business days at ambient temperature.

https://www.idtdna.com/pages/education/decoded/article/assays-and-sequences-for-2019-ncov-detection-and-vaccine-development

Uwe

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 12:43:27 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: IDT's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

I would confirm receipt from CDC and that they have no issue first before letting IDT know. Maybe a call to Dan. I agree you would not send the below email.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:35 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: IDT's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Ok to let IDT know? I don't think I should show them this letter. That would be CDC to do.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 29, 2020 at 12:25:40 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** IDT's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Dear Wendi,

Integrated DNA Technologies (IDT) developed a 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) using the CDC protocol and N1, N2, and N3 primers. CDC has generated data indicating that this panel may be effective in the detection of SARS-CoV-2, and CDC and FDA have worked interactively in connection with FDA's review of the data.

Given our understanding of the facts and the public health concerns at issue here: that there is currently limited national testing capability to detect SARS-CoV-2 to respond to this emergency; significant public health concerns are presented by the infectious disease; and the proposed testing may help to prevent the spread of the infectious disease COVID-19. Based on this understanding, at this time, FDA does not intend to object to the distribution of 2019-nCoV Kit to laboratories, once each lot is qualified by the CDC, with the condition that CDC will act promptly to submit a new or amended EUA to authorize the testing described above.

Jeff

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/28/2020 2:24:47 PM
**To:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** FW: Language consideration for expedited EUA process
**Importance:** High

---

**From:** Becker, Scott | APHL <Scott.Becker@aphl.org>
**Sent:** Friday, February 28, 2020 2:18 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Wroblewski, Kelly | APHL <kelly.wroblewski@aphl.org>; Emergency Center | APHL <eoc@aphl.org>
**Subject:** Language consideration for expedited EUA process
**Importance:** High

Dear Drs. Stenzel and Jernigan,

We appreciate your work on rolling out an expedited approach for laboratories interested in pursuing Emergency Use Authorization of tests developed in their laboratories. We think this is an important step in expanding testing capacity in the United States. We would like to put forward two points for you to consider as you are developing guidance on this process in case they have not already been considered.

1. Please consider including language on requiring rapid notification of positive results to public health agencies to assure appropriate public health steps are taken to mitigate spread of disease.
2. Consider limiting use of EUA assays made available through the expedited EUA process to individuals who meet CDC criteria for testing, as has been required in other public health emergencies.

We applaud your efforts to identify pathways to expand testing capacity more quickly and look forward to working with you on how to move forward.

Scott Becker

**Scott J. Becker** (he/him)
Chief Executive Officer
**P** +1 240.485.2747 | **M** +1 301.526.5704
scott.becker@aphl.org | @scottjbecker

Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
www.aphl.org | APHL Blog
Facebook | Twitter | LinkedIn | Instagram

ID Lab Con 2020 | APHL 2020 Why Attend? (video)

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/29/2020 10:44:20 AM
**To**: Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: IDT

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 10:28 AM
**To:** Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** IDT

Tim,

Below is a draft email not yet ready to be share but I wanted to get your feedback on whether it captures what would be

(b) (5)

Dear Wendi,

(b) (5)

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/29/2020 12:29:55 PM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; MacLennan, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e3684d6a36e4002bc07015b7506b803-Lori.MacLen]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]
**Subject**: RE: NYS

Yes, that is what he is doing.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS

Do they have sufficient validation to start running the test under the new policy? Perhaps he is conflating authorization with the ability to run the test clinically.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:28 PM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS

We have not granted it. We are still working with them. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:26 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** NYS

FYI—Governor Cuomo is telling folks we granted the EUA. I've gotten a couple pings from reporters. I'll hold off on responding and will flag EUA authorization link once online.

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/29/2020 12:29:31 PM
**To**: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; MacLennan, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e3684d6a36e4002bc07015b7506b803-Lori.MacLen]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]
**Subject**: RE: NYS

We have not granted their EUA. We told them they can proceed with testing under our new policy and conditions for proceeding with testing. Email trail is below.

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Saturday, February 29, 2020 11:11 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Two pre-EUA questions....advice please

Jeff,
Thank you so much. This is a great relief. I have to say that it has been a pleasure to work with your incredibly professional and responsive staff.
Jill

Sent from my iPhone

On Feb 29, 2020, at 10:58 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Jill,

I wanted to let you know that today we announced a policy that would allow appropriate laboratories that are certified to perform high-complexity testing consistent with requirements under CLIA develop, validate, and use SARS-CoV-2 tests if they notify FDA and submit an EUA request within 15 days of the notification. Other conditions are described in the

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guidance we posted on our website today. Our intent is to more quickly increase the national capability for testing while assuring accurate and reliable tests are being used.

Because you have already notified us, you can proceed with patient testing. Please see the guidance for additional details. If you have any questions or there is anything we can do to help, I, Uwe, or Tim would be happy to discuss. (Kim is currently out of the office.)

Our press release and guidance can be found at the following:
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia-prior

Best regards,

Jeff

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**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:26 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** NYS

FYI—Governor Cuomo is telling folks we granted the EUA. I've gotten a couple pings from reporters. I'll hold off on responding and will flag EUA authorization link once online.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 10:45:19 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Forgot to ask, did you or one of your folks connect with Co-Diagnostics or the other two test makers for South Korea and Germany?

TY

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 27, 2020 at 10:18:54 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Forgot to ask, did you or one of your folks connect with Co-Diagnostics or the other two test makers for South Korea and Germany?

Jeff,

From the data we have the South Korea device is not an established technology and is not sensitive. The same technology came in for Ebola and Zika and we did not authorize this deceive at the time either.

Could not connect the German companies due to the time zone or Co-Diagnostics yet, but got the following feedback for the rapid diagnostic test:

Charles is collaborating with Mammoth Biosciences (Jennifer Doudna) to develop a SARS-CoV-2 diagnostic assay using a CRISPR-based diagnostic platform. (Link to white paper)

- The assay has been validated with IVT material (CDC positive control; N gene fragment) and 2 patient samples
- The assay can use extracted RNA as input or direct from specimen (currently focused on NP swabs)
- Assay relies on an isothermal amplification (RT-LAMP) of template (using CDC and WHO primers and validated protocols) followed by CRISPR/Cas12 mediated detection (indirect fluorescent reporter)
- Targets:
  - N-gene (SARS-CoV-2 specific)
  - E-gene (SARS-CoV, bat-SARS-like-CoV, and SARS-CoV-2 coronavirus)
  - Human RNase P (human sample control)
- Detection currently uses a visually read lateral flow strip with 30 minute sample to result
- Also developing a higher throughput format (96-well fluorescent plate read) also working to develop into a cartridge format
- LoD (b) (4) copies stated on the phone, but the white paper states (b) (4) copies/ul input vs. CDC 5-15 copies
- Working with California Department of Public Health
- They appear to be focused on POCT

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- ***Current limiting factor is access to patient samples, extracted viral RNA, or inactivated virus
- FDA offered to provide extracted viral RNA

Uwe

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 8:51 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Forgot to ask, did you or one of your folks connect with Co-Diagnostics or the other two test makers for South Korea and Germany?

**Jeffrey Shuren, MD, JD**
*Director*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Email: jeff.shuren@fda.hhs.gov






Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: ***https://www.research.net/s/cdrhcustomerservice?ID=2000&S=E.***

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/25/2020 9:19:00 AM
**To:** Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
**Subject:** RE: Public health labs press FDA to allow homegrown coronavirus tests

I would highlight (b) (5) [redacted]

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 8:54 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Subject:** RE: Public health labs press FDA to allow homegrown coronavirus tests

Hey folks-
Just flagging that WSJ's Brianna Abbott reached out with similar questions as David, so I'll send the same response to her. Thanks!

**From:** Caccomo, Stephanie
**Sent:** Monday, February 24, 2020 8:38 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Subject:** RE: Public health labs press FDA to allow homegrown coronavirus tests

Updated story:

Public health laboratories urged the FDA on Monday to permit them to create their own tests for the coronavirus, after problems with a diagnostic developed by CDC prevented its widespread rollout.

FDA typically allows "laboratory developed tests" — which are designed, manufactured and used within a single lab — to be used without close regulatory scrutiny. But the agency requires labs to submit such tests for review during health emergencies to prevent harm from false or misleading results from compounding a crisis. The coronavirus does not appear to be an exception.

"No test should be used without being validated," FDA spokesperson Stephanie Caccomo said. "In the context of a public health emergency, false results can lead to significant adverse public health consequences."

The FDA has traditionally shied away from allowing the use of LDTs in emergency situations. In 2016, the agency sent a letter to two Houston hospitals that created an LDT to rapidly detect the Zika virus, expressing concern that the agency had not reviewed the "high-risk" test.

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But Association of Public Health Laboratories Executive Director Scott Becker said that the coronavirus requires a different approach. The virus is spreading in multiple countries, and the CDC's efforts to expand testing capability beyond its labs have run into trouble.

Only five state and local public health labs — in California, Nebraska, Illinois, Nevada and Tennessee — have verified the CDC diagnostic for use since the FDA approved it on an emergency basis on Feb. 4, he said.

APHL hopes to work with FDA to develop a policy that allows some labs to market a LDT without submitting it for FDA review, Becker told POLITICO — adding that it doesn't make sense for more than 100 labs to file individual emergency use authority applications.

"We believe a more expeditious route is needed at this time," Becker and Grace Kubin, director of the Laboratory Services Section at the Texas Department of State Health Services, wrote to FDA Commissioner Stephen Hahn on Monday.

"What we're suggesting is that public health labs be viewed as a group to do this," Becker told POLITICO. "It isn't every lab on their own — we would want to do this in a network sort of fashion. We could also enable confirmation at another public health laboratory to ensure confidence."

The letter says that labs could work together towards a standard protocol, purchase reagents and supplies from a common source and recommend a minimum standard approach for validating test results.

Caccomo says that the FDA is working with more than 70 test developers on products for the virus. The agency can complete reviews for such tests in as little as one day, she added — ensuring that it is effective and meets the minimum standards for emergency use.

The FDA said the statute's emergency provisions "establish a lower bar to market compared to conventional premarket pathways — namely that the test may be effective — but still requires a sufficient level of validation even in the context of the emergency."

Some major hospitals are also starting to develop LDTs for coronavirus screening, but are concerned that FDA rules do not permit them to actually start testing patients, according to Michael Mina, associate medical director of molecular diagnostics at Brigham and Women's Hospital.

"We're actually trying to get our test up and running, even though we don't know if we'll be able to use it," Mina said. "I know that Mass General Hospital is also thinking about doing something very similar. I presume all the major academic hospitals are at least considering it."

The American Clinical Laboratory Association, which represents large commercial labs like LabCorp and Quest Diagnostics, declined to comment on whether LDTs should be used to help increase the country's capacity to screen for the coronavirus. Historically, the lab industry trade lobby has maintained LDTs are not medical devices and subject to FDA regulation.

---

**From:** Caccomo, Stephanie
**Sent:** Monday, February 24, 2020 8:19 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Subject:** RE: Public health labs press FDA to allow homegrown coronavirus tests

I just spoke to David—he's going to add this part of what we sent him back into the story:

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The EUA provisions of the statute establish a lower bar to market compared to conventional premarket pathways – namely that the test may be effective - but still requires a sufficient level of validation even in the context of the emergency

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 7:41 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Subject:** Re: Public health labs press FDA to allow homegrown coronavirus tests

David totally missed that EUA authorization is a statutory requirement regardless of who makes it.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 24, 2020 at 7:31:12 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Subject:** FW: Public health labs press FDA to allow homegrown coronavirus tests
**Importance:** High

FYI – here is the piece from POLITICO below re public health labs and COVID-19 tests. I've highlighted several items of note. I've also attached the letter from APHL to FDA for anyone who has not seen it yet. APHL is advocating for enforcement discretion and that public health laboratories work together on utilizing a standard protocol, purchasing reagents from a common source, utilizing a standard validation panel, etc.

Note that the Grace Kubin, the Director of the Laboratory Services Section of the Texas Department of State Health Service, has cosigned with the CEO of APHL.

Also note that Brigham and Women's is saying they, Mass General, and other hospitals are developing tests but FDA's rules will not permit testing.

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>
**Sent:** Monday, February 24, 2020 7:16 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Public health labs press FDA to allow homegrown coronavirus tests

**Public health labs press FDA to allow homegrown coronavirus tests**

By David Lim

02/24/2020 07:15 PM EST

Public health laboratories urged the FDA on Monday to permit them to create their own tests for the coronavirus, after problems with a diagnostic developed by CDC prevented its widespread rollout.

FDA typically allows "laboratory developed tests" — which are designed, manufactured and used within a single lab — to be used without close regulatory scrutiny. But the agency requires labs to submit such tests for review during health emergencies to prevent harm from false or misleading results from compounding a crisis. The coronavirus does not appear to be an exception.

"No test should be used without being validated," FDA spokesperson Stephanie Caccomo said. "In the context of a public health emergency, false results can lead to significant adverse public health consequences."

The FDA has traditionally shied away from allowing the use of LDTs in emergency situations. In 2016, the agency sent a letter to two Houston hospitals that created an LDT to rapidly detect the Zika virus, expressing concern that the agency had not reviewed the "high-risk" test.

But Association of Public Health Laboratories Executive Director Scott Becker said that the coronavirus requires a different approach. The virus is spreading in multiple countries, and the CDC's efforts to expand testing capability beyond its labs have run into trouble.

Only five state and local public health labs — in California, Nebraska, Illinois, Nevada and Tennessee — have verified the CDC diagnostic for use since the FDA approved it on an emergency basis on Feb. 4, he said.

APHL hopes to work with FDA to develop a policy that allows some labs to market a LDT without submitting it for FDA review, Becker told POLITICO — adding that it doesn't make sense for more than 100 labs to file individual emergency use authority applications.

"We believe a more expeditious route is needed at this time," Becker and Grace Kubin, director of the Laboratory Services Section at the Texas Department of State Health Services, wrote to FDA Commissioner Stephen Hahn on Monday.

" What we're suggesting is that public health labs be viewed as a group to do this," Becker told POLITICO. "It isn't every lab on their own — we would want to do this in a network sort of fashion. We could also enable confirmation at another public health laboratory to ensure confidence."

The letter says that labs could work together towards a standard protocol, purchase reagents and supplies from a common source and recommend a minimum standard approach for validating test results.

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can complete reviews for such tests in as little as one day, she added — ensuring that it is effective and meets the minimum standards for emergency use.

Some major hospitals are also starting to develop LDTs for coronavirus screening, but are concerned that FDA rules do not permit them to actually start testing patients, according to Michael Mina, associate medical director of molecular diagnostics at Brigham and Women's Hospital.

"We're actually trying to get our test up and running, even though we don't know if we'll be able to use it," Mina said. "I know that Mass General Hospital is also thinking about doing something very similar. I presume all the major academic hospitals are at least considering it."

The American Clinical Laboratory Association, which represents large commercial labs like LabCorp and Quest Diagnostics, declined to comment on whether LDTs should be used to help increase the country's capacity to screen for the coronavirus. Historically, the lab industry trade lobby has maintained LDTs are not medical devices and subject to FDA regulation.

*To view online*:
https://subscriber.politicopro.com/health-care/article/2020/02/public-health-labs-press-fda-to-allow-homegrown-coronavirus-tests-1884096

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POLITICO, LLC
1000 Wilson Blvd.
Arlington, VA 22209
USA.

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/29/2020 7:43:57 AM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: NYS Wadsworth Center COVID-19 Test

TY

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:43 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Yes, see my next email. Our call was cut short by Redfield calling Dan so I didn't get to communicate the second part. Just put it in an email.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:38 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Tim,

Don't we need it for IDT, too? Also, did you ask him about QCing IDT lots, at least until IDT gets access to viral samples?

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:37 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>

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**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Hi Dan, Thanks for the quick call this morning. A simple email to the FDA/me stating "Yes, The New York State Wadsworth Center can reference the data in the CDC's 2019 nCoV EUA application" is sufficient for the FDA's review purposes that should lead to a quick EUA authorization for Wadworth's EUA, as early as this afternoon. Therefore, this is obviously an urgent matter.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Hi Dan and Wendi,

This right of reference is important to get this and additional assays based on the CDC through the EUA process quickly. The other two companies we discussed today will be similar.

I believe a simple email stating "Yes, The New York State Wadsworth Center can reference the data in the CDC 2019 nCoV EUA application".

Hope this helps.

Thanks in advance!

Best,
Tim

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 7:55:22 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Adding additional people.

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:50 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** NYS Wadsworth Center COVID-19 Test
**Importance:** High

Wendi, Dan, Laura,

NYS Wadsworth Center submitted an EUA request to us this afternoon for a test that uses the CDC protocol but only for N1/N2 (consistent with the CDC test currently subject to enforcement discretion). To support their EUA, Wadsworth conducted a bridging study that demonstrates performance similar to CDC's N1/N2 test. We know their performance is comparable because we have seen CDC's data but Wadsworth has not. **Would CDC allow Wadsworth to have a right of reference to its data, under which does not get access to the data but can reference it in support of their EUA?** Wadsworth has one more test to perform, which if it looks good, we would otherwise grant the EUA.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 8:30:24 AM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shearstone, Peter E. (b) (6) @thermofisher.com]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Press

Peter,

Thank you for the heads up. It's up to the company as to what it wants to say about developing/validating a test. You are welcome to say that you have been work with the FDA.

On that note, is there anything you need from us or anything we can do for Thermo Fisher to facilitate development/validation/EUA for a COVID-19 diagnostic?

Best regards,

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:25 AM
**To:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Press

Hi Peter, You texted, "Tim
We received an inquiry this morning from Bloomberg on whether we've got anything brewing for an EUA. Have FDA been advising companies on how to answer that question?
Thx
Peter"

Thanks for reaching out Peter, I defer to Jeff.

Thank!

Best,
Tim

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**[Date]**

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**ATTN:** Division Director: Dr. Uwe Scherf**,** OHT7-OIR/OPEQ/CDRH/FDA

**RE:** Request for Pre-Emergency Use Authorization (Pre-EUA) of the [*Name of the Assay*]

**Dear Dr. Scherf,**

[***Name of the Company***] is submitting a Pre-Emergency Use (Pre-EUA) for the [***Name of the Medical Device Product***] so we can obtain feedback from FDA concerning the studies and/or testing outlined in our Pre-Emergency Use Authorization (Pre-EUA) submission package.

The [***Name of the Medical Device Product***] is [***brief description of the device***] and [***intended use***].

Attached to this letter is the first draft of our device EUA Interactive Review Template for FDA review as a Pre-EUA. One hard copy of the signed EUA Cover Letter and one electronic copy are enclosed. Also, these documents have been sent to you via email.

In case you should have any questions regarding the information provided and/or need additional information/data from us please contact me immediately either via email [_____] or phone [_____].

Sincerely,

[***Name***]

[***Signature block***]

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# EMERGENCY USE AUTHORIZATION (EUA)

## EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (2019-nCoV)

## GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow *[Text]* should be completed by the IVD developer (sponsor) as applicable to their specific test. Text in **bold** outlines the Food and Drug Administration (FDA) suggestions and clarifications for the sponsors' consideration when completing the required information in a specific section.

- This is a EUA interactive review template for Pre-EUA/EUA submissions concerning molecular-based single target tests for detection of 2019 Novel Coronavirus (2019-nCoV), Wuhan, China. If you are developing a multiplex molecular-based assay for the detection and differentiation of nucleic acids from a panel of microorganisms, please review Appendix A for FDA recommendations.

- This is a EUA interactive review template for Pre-EUA/EUA submissions and not a guidance document. The template is subject to change as we learn more about the 2019-nCoV disease and its risk-benefit profile. Recipients will receive notice and updated templates as they become available.

- This EUA interactive review template is an FDA internal document and any proprietary information provided within the template and during the interactive review process will remain confidential as it does in a regular FDA premarket submission.

- Feedback provided by FDA during the interactive review of your pre-EUA/EUA is subject to change as we learn more about the 2019-nCoV disease and the risk-benefit profile evolves to address unmet public health needs.

- Prior to a potential authorization FDA will require developers of molecular-based tests to assess traceability of their test to an FDA-recommended reference material panel if available at the time. Specific details about the traceability study and the FDA-recommended reference material panel will be provided by the Lead Reviewer assigned to the Pre-EUA submission once the analytical and clinical evaluation data has been reviewed and found to be acceptable.

- Please be reminded that tests for the detection of 2019-nCoV or 2019-nCoV infection must not be distributed and/or used for clinical diagnoses without premarket clearance, approval, or EUA by the FDA. Clinical samples for 2019-nCoV testing should be sent to the appropriate public health laboratories until the IVD device subject of this Pre-EUA submission has received authorization from the FDA.

- Clinical specimens may be required to support the EUA request. Furthermore, please note that applicable regulations for human subject protection do apply under the

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EUA. Please refer to the Clinical Evaluation section of this document for more details.

- If authorized, the EUA means that this 2019-nCoV IVD is temporarily authorized for use until the public health emergency is terminated or the EUA is revoked by the FDA.

    - FDA recommends that you consider registration and listing your EUA product once you have been issued an EUA. If this is problematic, please notify the Agency during your Pre-EUA.
    - The EUA is not a pathway to permanent marketing of your device. Therefore, we strongly recommend that you consider, in addition to an EUA, a traditional premarket submission for your IVD so that your device can still be legally marketed after termination of the emergency declaration. We recommend that you identify as soon as possible in the Pre-EUA review process any consideration of moving your product forward towards De Novo/510(k) clearance. If so some of our feedback to you may take such a long-term goal into consideration in order to prevent additional testing where it may not be needed. Therefore, please consider submitting a Pre-Submission to inquire what studies would be required for a premarket approval/ clearance of your 2019-nCoV IVD. Details on how to submit a Pre-Submission to the Agency are outlined in the FDA guidance document: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

## A. EXECUTIVE SUMMARY (as of X/XX/20XX)

## B. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the ***[test name]*** to ***[indicate labs, if applicable]*** for the *in vitro* qualitative detection of RNA from the 2019-nCoV in ***[add all claimed specimen types, e.g., nasopharyngeal/oropharyngeal swabs, sputa, BAL, stool, and serum, etc.]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated with 2019-nCoV infection) and CDC novel coronavirus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated) to aid in the diagnosis of 2019-nCoV infection.

## C. MEASURAND

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Specific nucleic acid sequences from the genome of the 2019-nCoV **[*please specify the targeted gene(s) of the pathogen*]**.

## D. APPLICANT

***[Official name, address and contact information of applicant]***

## E. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name - ***[test name]***
Established Name - ***[test name]***

## F. REGULATORY INFORMATION

***Approval/Clearance Status:***
The ***[test name]*** test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

***Product Code:***
[XXX – FDA will complete]

## G. PROPOSED INTENDED USE

***1) Intended Use:***
**The proposed IU will be finalized based on the data and recommendations from Public Health authorities at the time of authorization – example text is provided below for a qualitative molecular test that detects organism RNA but may be adapted according to the specific emergency situation addressed by the device.**

[***Test name***] is a [***specify test technology such as, real-time RT-PCR test***] intended for the qualitative detection of nucleic acid from the 2019-nCoV in [***describe all the specimen types***] from individuals meeting CDC 2019-nCoV clinical criteria (e.g., clinical signs and symptoms associated with 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated). Testing is limited to [***laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories***].

Results are for the identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in **[*name specimen type*]** during the acute phase of infection. Positive results

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are indicative of active infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The ***[test name]*** is intended for use by **[*include intended user, e.g., trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures*]**. The ***[test name]*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

***2) Special Conditions for Use Statements:***

For prescription use only
For in vitro diagnostic use only

***3) Special Instrument Requirements:***

The ***[test name]*** test is to be used with the [***list all RT-PCR Instruments, software requirements, automated extraction instruments***].

## H. DEVICE DESCRIPTION AND TEST PRINCIPLE

**Example text has been added under each of the sub-headings below for a fluorescence based rRT-PCR test for detection of organism RNA. If a different test principle is used by the test for the detection of a specific analyte please modify the description accordingly to capture the salient points in each of the sub-headings below. Please note that for new investigative technologies FDA may request additional detailed information so we can adequately assess the risks and benefits associated with the device.**

***1) Product Overview/Test Principle:***

**Describe the technology of the test and how this technology works to identify the measurand, the instruments employed/required to perform the test from sample collection to result (include all claimed extraction and PCR detection instruments), and the specimen types for which you claim to have specific performance characteristics as described below. If applicable, list all primer and probe sets and briefly describe what they detect. Please include the nucleic acid sequences for all primers and probes used in the test. Please indicate if the test uses biotin-Streptavidin/avidin chemistry in any of the steps for coupling reagents. Please note that an alignment with available reference genomes for different strains of the target pathogen is requested as part of the inclusivity evaluation (Section N).**

The ***[test name]*** is a real-time reverse transcription polymerase chain reaction (rRT - PCR) test. The 2019-nCoV primer and probe set(s) is designed to detect RNA from

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the 2019-nCoV in ***[list all the specimens]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated).

2) ***Description of Test Steps:***

**List and describe in detail all the steps of the test sequentially from specimen collection to detection.**

Nucleic acids are isolated and purified from ***[specimens]*** using ***[please describe the method(s) of extraction (please specify the specimen input volume for extraction and/or test, the nucleic acid elution volume and whether isolation/purification is manual and/or automated)].*** The purified nucleic acid is reverse transcribed using ***[enzyme mix/kits – please specify the input volume of purified nucleic acid added to the rRT-PCR reaction mix]*** into cDNA which is then subsequently amplified in ***[please describe the instrument(s) and enzyme mix]***. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by ***[please describe the detection instrument(s)]***.

3) ***Control Material(s) to be Used with [test name]:***

**List all control materials (provided with the test kit and/or required but not provided with the test kit and describe what they are, how they are expected to work, where in the testing process they are used, and the frequency of use. If a control is commercially available, provide supplier's name and catalog number or other identifier; if your device relies on external controls that are manufactured by a third party please note that these controls should also be validated within your analytical and clinical studies described below in Section (N).**

Controls that will be provided with the test kit include:

a) A "no template" (negative) control is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***

b) A positive template control is needed to ***[describe need]*** and is used ***[describe use – please specify the concentration of the positive control relative to the LoD of your test (note that ideally the positive control concentration should be such that it is close to the LoD of your test) and also specify frequency of use]***

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c) An extraction control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use].*** **Please note that if the no template control and positive control, are taken through the entire sample processing procedure, including the extraction, then a separate extraction control is not required**.

d) An internal control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use]***.

Controls that are required but not provided with the test kit include ***[describe control – provide recommended sources of the control materials – either a separate control kit for purchase that you the applicant develops or a control material that can be purchased from a third party].*** This/these control(s) is/are needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***.

**Please note that any control recommended to be used with your device (provided with the kit or not) needs to be validated in the context of your analytical and clinical study (i.e., you will need to run these controls as part of your studies). In instances where control material is not readily available through 3rd party vendors (which is often the case at the beginning of an outbreak) FDA may request that you include suitable control material with your device. Please note that external control materials are considered particularly important in the context of EUA devices because often GMP requirements for the manufacture of the EUA device are waived in emergency situations and reagent stability studies are limited. Hence the external controls offer some assurance of EUA test performance in the hands of the end user.**

## I. INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. **Please describe if a Ct cutoff is used as part of your testing algorithm and/or if the end user is required to review fluorescent curves for weakly positive samples before final interpretation. Although not typical for molecular-based tests, if the test result involves the use of an algorithm/calculation, for example a ratio value, when determining the final patient test result, please include a detailed description and any additional calibration materials that may be required.**

1) ***[Test name] Controls – Positive, Negative and Internal***

**Describe in detail the expected results generated, including acceptance criteria, for all the controls described in detail in Section H above. Describe the measured values (if applicable) for valid and invalid controls and outline the recommended actions the laboratory should take in the event of an invalid control result.**

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2) ***Examination and Interpretation of Patient Specimen Results:***

**Describe when clinical specimen test results should be assessed and outline the criteria for test validity**. **Example text**: Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

**Clearly indicate how to interpret numeric test values (if applicable) as positive or negative for presence of the 2019-nCoV. Indicate if the end user is required to review fluorescent curves for weakly positive samples before final interpretation and how to identify indeterminate/inconclusive results (if they exist) results and how the user should resolve them, e.g. if repeat testing may be required.**

**When applicable, provide a table clearly describing the possible combinations of test result values for each primer/probe set, and how they should be combined into a final interpretation of the result for your test. If the test produces result that will be used as part of a CDC recommended testing algorithm, please indicate what follow-up testing/process should be conducted, if applicable.**

## J. PRODUCT MANUFACTURING

**Please note that if you are developing a test for use at a single site (i.e., a laboratory developed test LDT), some of the information requested in this section may not be applicable. Please contact FDA for additional guidance for an emergency use LDT.**

The ***[test name]*** has been validated using only the components referenced in this submission and shall not be changed without prior concurrence from the FDA.

*1)* ***Overview of Manufacturing and Distribution:***

The product will be manufactured at [***manufacturer's name and FDA registration number (if applicable) or laboratory name if an LDT***] by [***manufacturer name, or laboratory name if an LDT***] personnel consistent with practices for the production of **[*types of devices*]** based on [***type of quality system****]. Material manufactured by [***manufacturer's name, or laboratory name if an LDT***] may be bottled and kitted by [***packager name***] manufacturing facility.

***Under the Emergency Use Authorization (EUA) most of the 21 CFR 820 Quality System Regulation (QSR) requirements can be waived for the duration of the EUA. FDA expects that developers follow comparable practices as much as possible and may consider previous compliance history when determining whether or not to waive certain QSR requirements for a specific product. Please note adverse events, as per 21 CFR Part 803, have to be reported for authorized devices (see Section R).**

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The current manufacturing capabilities include the ability to manufacture approximately **[*please insert the approximate number of units/products that can currently be manufactured per week at the manufacturing facility*]** products per week, however in the event of a surge in demand this could be increased to **[*please insert the approximate maximum number of units/products that could potentially be manufactured per week at the manufacturing facility if there was a surge in demand*]** product per week within a **[*please specify in weeks/months the expected timeframe required to increase product production if required*]** timeframe.

The product will be distributed by **[*please describe the distribution plan for the product and list all current distributors*]**.

2) ***Components Included with the Test***

Components manufactured by [***manufacturer's name and FDA registration number (if applicable)***] and supplied with the test include:
**List all components and reagents provided for your test, including a description of the primers and probes, volumes, concentrations, quantities, buffer components, etc.**

3) ***Components Required But Not Included with the Test***

Components required but not included with the test:
**List all components and reagents not included with the test that must be supplied by the user to perform the test, with specific supplier names and catalog numbers or other identifiers for obtaining these components and reagents. Please include here all specific consumables that were validated for use with your device, that are not interchangeable with other products and that are needed to guarantee device performance as established in the EUA validation studies listed in Section N below.**

4) ***Testing Capabilities***

**Briefly describe current sample throughput capacity, total time required to perform the test (from clinical specimen collection, specimen transport to result), and number of tests that can be performed per instrument run and per day.**

5) ***Reagent Stability:***

**Briefly describe stability test plan for *[test name]* reagents and include any accelerated stability information if available. Please note that reagent stability studies do not need to be completed at the time of EUA issuance, however the study design should be agreed upon during interactive review and the stability studies started immediately following authorization, if not before. When designing your stability study, we have some general recommendations that are outlined in Appendix B, for your consideration.**

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## K. PERFORMANCE EVALUATION

**If you plan to claim multiple target analytes to aid in differential diagnosis or you plan to claim multiple RT-PCR instruments and/or extraction methods, please refer to Appendix A and C, respectively, more information. Please note that any omission of a requested study in this document should be documented and justified.**

### *1) Analytical Sensitivity:*

a) *Limit of Detection (LoD):* **You should determine the LoD of the device utilizing the entire test system from sample preparation to detection for each clinical matrix claimed. Please note that claims for additional anticoagulants, for blood specimens, can be supported by a matrix equivalency study as outlined in Section N, subsection 3 below. The LoD is determined using dilutions of live propagated and titered 2019-nCoV stocks (CFU/mL or PFU/mL) spiked into a relevant clinical matrix. If wild-type virus is not available at the time of your validation studies, please contact FDA to discuss a potential alternative. Please note that if available please also provide Genomic Equivalent Copies (GEC)/mL units for the stock solutions used and include an explanation on how they were determined. Please note that LoD studies should be performed with live organisms, as described above. If you plan to use inactivated organism in your LoD determination you should describe how the material was inactivated and perform a study to determine whether the inactivation process impacted the LoD of the device.**

**First a tentative LoD must be established through limiting dilutions of the prepared material with 3-5 replicate measurements. Please note for all the analytical studies described in Section N that require replicate testing, one replicate equates to one independent extraction and PCR detection. Once a tentative LoD is established, the LoD should be confirmed by preparing at least 20 additional replicates at the LoD concentration and demonstrating that the organism was detected with a minimum 95% positivity (19/20). If this confirmatory study achieves a positivity of 100%, then a lower concentration needs to be tested (with 20 replicates) until <100% positivity is obtained.**

**Please use the following format when submitting LoD information and data:**

LoD studies determine the lowest detectable concentration of 2019-nCoV at which approximately 95% of all (true positive) replicates test positive. The LoD was determined by limiting dilution studies using characterized samples.

**List/describe the following in this section:**

- **Titers and strains of the 2019-nCoV stocks used for the LoD study and describe how the organism stocks were prepared and how the titers were determined.**

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- **The dilution factor and number of serial dilutions of the characterized 2019-nCoV that were tested to determine the LoD for each primer and probe set.**
- **The nucleic acid extraction/purification method.**
- **The real time PCR instrument.**

Serial dilutions of the characterized 2019-nCoV were then tested in **[*number of replicates (i.e., recommend that sample is extracted independently three-five times and each extraction tested once)*]** replicates. The lowest concentration at which all [***number of replicates***] replicates were positive was treated as the tentative LoD for each test. The LoD of each test was then confirmed by testing [***number of replicates (at least 20 recommended)***] with concentrations at the tentative limit of detection. The final LoD of each test was determined to be the lowest concentration resulting in positive detection of [***number of positive replicates (at least 19 out of 20 replicates)***]. [***Include analysis of LoD results, indicating the final LoD for each test***]

**Tentative LoD: [*Please provide a summary of the data for each strain tested]* example table 2019-nCoV stocks is provided below:**

| 2019-nCoV Strain Tested | Stock 2019-nCoV Titer | Serial 10-Fold Dilution Factor | Concentration in Dilution Tested [Include Units] | Replicate 1 $C_t$ | Replicate 2 $C_t$ | Replicate 3 $C_t$ | Replicate 4 $C_t$ | Replicate 5 $C_t$ | Call Rate | Lowest Concentration with Uniform Positivity per Analyte | Limit of Detection (LoD) per Virus Strain |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Example:*** *[analyte]* | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

b) FDA Sensitivity Evaluation: The analytical sensitivity of the test has to be further assessed by evaluating an FDA-recommended reference material using an FDA developed protocol if applicable and/or when available. Details will be provided during the Pre-EUA interactive review.

c) *Reactivity/Inclusivity:* Reactivity of the ***[test name]*** was evaluated for additional isolates of 2019-nCoV.

**Reactivity: *[test name]* example table below**

| 2019-nCoV Strain/Isolate | Source/Sample Type* | Concentration | Ct** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

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| | | | |
|---|---|---|---|
| | | | |

***Please list source of material used for wet testing and sample type tested (i.e., organism – live or inactivated, purified nucleic acid – whole genome etc.).**
**** If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**At a minimum, the strain used in your LoD evaluation should be listed here (multiple isolates of the same 2019-nCoV strain that was used for the LoD studies can also be included if available). If additional isolates are not available at the time of your validation studies, please discuss with FDA. Each isolate should be tested at or near the LoD (no more than 3x LOD) of the test, spiked into clinical matrix utilizing the entire test system, including extraction. If you plan to claim more than one type of clinical matrix, we recommend that you perform this study in the most challenging clinical matrix, testing a minimum of 3 replicates. In addition, the wet testing should be accompanied by extensive inclusivity *in silico* analysis of the test primer and probes with all known strains/isolates (past/present) of 2019-nCoV (including the strain/isolate used for wet testing).**

## 2) *Analytical Specificity:*

a) *Cross-Reactivity:* Cross-reactivity of the ***[test name]*** was evaluated using both *in silico* analysis and by testing whole organisms **[*pathogen*]** (concentration) or purified nucleic acid from other ***[describe organisms]*** (concentration/reaction).

**Cross-Reactivity: *[test name]* example table for wet tested organisms below**

| Virus/Bacteria/Parasite | Strain | Source/ Sample type | Concentration | Ct Values* |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

***If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**Cross-reactivity studies are preformed to demonstrate that the test does not react with related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen. The FDA Tables 1 and 2, below are intended to recommend simulate testing of patients having infections with organisms which cause similar symptoms to those observed at the onset of 2019-nCoV infection. The FDA Tables also include other organisms and strains which have significant genetic similarity and therefore a higher likelihood of cross-reacting with 2019-nCoV specific reagents. Also included in the FDA Tables are recommended unclaimed organisms/strains which are likely to be endemic to the currently affected area should be included in cross-reactivity testing since these organisms/strains will be an important aspect of the differential diagnosis of 2019-nCoV infection.**

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**FDA Table 1 Cross-Reactivity: List of Organisms to be wet-tested and analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens**

| Other high priority pathogens from the same genetic family | High priority organisms likely in the circulating area |
|---|---|
| Human coronavirus 229E | Adenovirus (e.g. C1 Ad. 71) |
| Human coronavirus OC43 | Human Metapneumovirus (hMPV) |
| Human coronavirus HKU1 | Parainfluenza virus 1-4 |
| Human coronavirus NL63 | Influenza A |
| SARS-coronavirus | Influenza B |
| MERS-coronavirus | Enterovirus (e.g. EV68) |
| | Respiratory syncytial virus |
| | Rhinovirus |
| | *Chlamydia pneumonia* |
| | *Haemophilus influenzae* |
| | *Legionella pneumophila* |
| | *Mycobacterium tuberculosis* |
| | *Streptococus pneumonia* |
| | *Streptococcus pyogenes* |
| | *Bordetella pertussis* |
| | *Mycoplasma pneumoniae* |
| | *Pneumocystis jirovecii* (PJP) |
| | Pooled human nasal wash - *to represent diverse microbial flora in the human respiratory tract* |
| | |

**FDA Table 2 Cross-Reactivity: List of Organisms to be analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens:**

| Other high priority pathogens from the same genetic family | High priority organisms, including organisms commonly found in the clinical matrix |
|---|---|
| | Influenza C |
| | Parechovirus |
| | *Candida albicans* |
| | *Corynebacterium diphtheriae* |
| | *Legionella non-pneumophila* |
| | *Bacillus anthracis* (Anthrax) |
| | *Moraxella catarrhalis* |
| | *Neisseria elongate and meningitidis* |
| | *Pseudomonas aeruginosa* |
| | *Staphylococcus epidermis* |
| | *Staphylococcus salivarius* |
| | *Leptospirosis* |

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| | |
|---|---|
| | *Chlamydia psittaci* |
| | *Coxiella burnetii (Q-Fever)* |
| | *Streptococcus aureus* |
| | |

***In silico*** **analysis should be performed on all potentially cross-reactive organisms outlined in the FDA Tables 1 and 2 above. You should provide the result summary of the *in silico* blast analysis (tabular format) evaluating whether there is any significant amplification of non-target sequences that could either result is cross-reactivity or potentially interfere with the detectability of the actual target analyte. As such we are asking that you provide individual blast results (non-truncated alignments) for each of the primers and probes used in your device with potential cross-reacting organisms. Please provide for our review the percent sequence homology for each organism relative to the target analyte primers/probes in your test. Please use the example table below when presenting the results of *in silico* analysis in your submission:**

**Results of *In Silico* Analysis**

| Pathogen | Strain | GenBank Acc# | % Homology Test FP (i.e. 0-100%) | % Homology Test RP | % Homology Test Probe |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**The analysis should include multiple representative strains from GenBank for each organism. If *in silico* analysis reveals other potential cross-reactants (i.e., ≥80% homology between one of your primers or the probe to any of the sequences of listed potential cross reactants), you should carefully review the alignments and determine based on the positions of the homologous stretches and mismatches if additional cross-reactivity and/or interference (please refer to item b below – microbial interference studies) wet testing will be required to rule out cross-reactivity or interference of that organism that may affect the performance of your device. In these circumstances if wet-testing is omitted you should include an explanation as to why *in silico* generated data is not clinically relevant (irrelevant isolate, location/extent of match within primer/probe, etc.), or why the performance of your test would not be impacted.**

**Organisms in FDA Table 1 should be wet tested in addition to the *in silico* analysis. Omissions from wet-testing should be discussed with FDA and supported by a well-documented justification that includes a due diligence attempt to obtain the live or inactivated organisms (and/or purified nucleic acid – which is acceptable for cross reactivity evaluation for an EUA).**

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**The wet testing evaluation should reflect test specimens prepared at the highest clinically relevant level of organism (i.e., a minimum of $10^6$ CFU/ml or higher for bacteria and $10^5$ $TCID_{50}$/mL or PFU/ml or higher for viruses) and should be tested with a minimum of three replicates per organism test specimen. Test specimens can be prepared by spiking cultured isolates/inactivated organisms/ purified nucleic acids (whole genome) into negative clinical matrix and determining cross reactivity based on triplicate replicates. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix.**

**If you plan to claim non-blood or non-respiratory clinical specimen types for diagnostic use with your device, e.g., stool specimens, etc., please consult FDA for more information on additional organisms that may be recommended for cross-reactivity testing, common examples are provided below for stool specimens (FDA Table 3):**

**FDA Table 3: Organisms to be analyzed for non-blood clinical specimens:**

| **Stool** |
|---|
| *Escherichia coli* |
| *Lactobacillus* |
| *Bacillus* spp. |
| *Clostridium* Spp. |
| *Enterobacter* |
| *Enterococcus* |
| Fusobacterium |
| Bacteroidetes |
| Bifidobacterium |
| Ruminococcus |
| |

b) *Microbial Interference Studies:* **If *in silico* analysis reveals ≥ 80% homology between the cross-reactivity microorganisms and your test primers/ probe(s), we recommend that you either perform (1) a microbial interference study with 2019-nCoV and the microorganisms that your test primers/ probe(s) have homology to, (2) as an alternative to the microbial interference study, you may provide justification as to why (e.g., amount of primer(s)/ probe(s) included in your master mix) the performance of your test would not be impacted by the presence of a causative agent of a clinically significant co-infection, or (3) explain why the *in silico* results are clinically irrelevant. In the case of the microbial interference study, interference should be evaluated using samples spiked at a low 2019-nCoV concentration, at 3x LoD, and a high interferent level (either microorganisms or nucleic acids purified from them), to represent the worst-case scenario, with a minimum of 3 replicates. If you plan to claim more than**

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**one type of blood clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix. If the LoDs are similar in the blood clinical matrices the study should be performed in the most challenging matrix, i.e., whole blood. In addition, if you are claiming blood and non-blood clinical specimens you may be required to perform this study in more than one clinical matrix. If interference is observed at the level tested, an additional titration study should be performed to determine the highest microorganism interferent level the 2019-nCoV test can tolerate.**

**c)** *Endogenous Interference Substances Studies*: **The extent of testing for endogenous interference substances depends on the matrix that is claimed for the device as well as on the technology of the device, e.g., if a nucleic extraction procedure is performed prior to testing or not. For EUA we do not typically ask for interference studies for tests that use conventional PCR and/or well-established extraction methods prior to testing (e.g., Boom method and column-based extraction methods).**

**For extraction procedures that are new or for nucleic acid-based technologies that are different from conventional PCR (e.g., various isothermal methods), we expect testing of potential interferents. The impact of interfering substances should be evaluated over the expected clinical range of the potentially interfering substance. Potential sources of endogenous interference include, but are not limited to, the ones listed in the tables below. It is important to note that the evaluation of interference and the generation of false negative results should be done using samples containing the analyte at or near the LoD and should not exceed 3x LoD. You should test a minimum of 3 replicates per substance. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed between the different clinical matrices this may warrant this study being performed in more than one clinical matrix. Biotin interference poses a risk to laboratory tests that incorporate the free biotin-streptavidin capture method. Therefore, please review this safety communication https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication and the following DRAFT guidance - Testing for Biotin Interference in In Vitro Diagnostic Devices (Web view) to determine if biotin interference testing may be warranted for your device. We also recommend you consult with FDA prior to initiating biotin interference testing, if applicable.**

**The tables below indicate the potentially interfering substances that may be found in blood and respiratory specimens. For other non-blood specimen types, such as stool, the list of substances could be expanded – please consult with FDA.**

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *positive* results:**

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| Potential Interfering Substance | Concentration | Results (Detected X/3) |
|---|---|---|
| **Respiratory Specimens** | | |
| Mucin: bovine submaxillary gland, type I-S | | |
| Blood (human) | | |
| Nasal sprays or drops | | |
| Nasal corticosteroids | | |
| Nasal gel | | |
| FluMist | | |
| Homeopathic allergy relief medicine | | |
| Throat lozenges, oral anesthetic and analgesic | | |
| Anti-viral drugs | | |
| Antibiotic, nasal ointment | | |
| Antibacterial, systemic | | |
| **Blood Specimens** | | |
| Hemoglobin | 10 mg/mL* | |
| Bilirubin Conjugated | 0.4 mg/mL* | |
| Bilirubin Unconjugated | 0.4 mg/mL* | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | |
| Triglycerides | 15 mg/mL* | |
| Cholesterol | 4 mg/mL* | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | |
| Rheumatoid Factor | 2000 IU/mL* | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *negative* results:**

| Potential Interfering Substance | Concentration* | Viral Strain Level (In multiples of LoD) | Results (Detected X/3) |
|---|---|---|---|
| **Respiratory Specimens** | | | |
| Mucin: bovine submaxillary gland, type I-S | | | |
| Blood (human) | | | |
| Nasal sprays or drops | | | |
| Nasal corticosteroids | | | |
| Nasal gel | | | |
| FluMist | | | |
| Homeopathic allergy relief medicine | | | |
| Throat lozenges, oral anesthetic and analgesic | | | |

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| | | | |
|---|---|---|---|
| Anti-viral drugs | | | |
| Antibiotic, nasal ointment | | | |
| Antibacterial, systemic | | | |
| **Blood Specimens** | | | |
| Hemoglobin | 10 mg/mL* | | |
| Bilirubin Conjugated | 0.4 mg/mL* | | |
| Bilirubin Unconjugated | 0.4 mg/mL* | | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | | |
| Triglycerides | 15 mg/mL* | | |
| Cholesterol | 4 mg/mL* | | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | | |
| Rheumatoid Factor | 2000 IU/mL* | | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

### 3) *Matrix Equivalency (if applicable):*

**A matrix equivalency study may be used to support certain specimen type claims that were not evaluated during the clinical study (e.g., serum versus plasma, use of different anticoagulants, use of difference swab types or viral transport media, etc.). Please note that LoD and clinical specificity studies are required for all claimed matrices. The matrix in which the clinical studies are conducted is the comparator. All other matrices are to be shown to be equivalent to the comparator matrix. We request a minimum of 40 paired samples each obtained from individual persons; negative (10 samples), low positive (1.5-2xLoD, 20 samples), and moderate positive (5-10xLoD, 10 samples) samples should be tested. Positive samples are prepared by spiking paired negative clinical matrix with the same amount of target analyte. Please note that individual (and not pooled) samples should be used in this study.**

### 4) *Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method:*

**A comparative LoD study may be required to support use of a comparator method in your clinical evaluation that has not been validated with a specific specimen type. The comparative LoD study should be conducted testing the same dilution series using both, your test and the comparator you chose in parallel (to dilution endpoints for both tests), 3-5 replicates per dilution level are sufficient for this study.**

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5) ***Specimen Stability and Fresh-frozen Testing:***

**A specimen stability study may be required to support specimen stability claims in the instructions for use outside of those typically outlined in CSLI standards. A fresh/frozen and/or freeze/thaw study may be required to support the use of frozen specimens if they are used as part of the clinical evaluation. Please consult with FDA concerning an appropriate study design prior to initiating any studies.**

6) ***Clinical Evaluation:***

**This section should describe the clinical study used to evaluate the performance of your test. Please note that the exact requirements for the clinical evaluation will be very dependent on, access to 2019-nCoV disease clinical specimens at the time of the studies and the nature of the emergency. Our general clinical study evaluation recommendations for respiratory and serum clinical specimens are outlined below. If you are interested in claiming additional specimen types, for example, stool, please contact FDA for current recommendations. Please note these clinical study recommendations may be subject to change as we continue to learn about the 2019-nCoV disease or as the risk benefit analysis changes.**

**The clinical performance in general should be evaluated for each unique claimed clinical specimen type - with the exception of claims that can be supported by a matrix equivalency study (outlined in Section 3 above). The performance characteristics should ideally be established using a clinical study with a limited number of prospective samples. If a prospective study is not feasible, an acceptable alternative would be to test retrospectively collected 2019-nCoV nucleic acid negative and positive specimens from patients, accompanied by some basic information such as, the specimen collection date, date of onset of symptoms (if present/known), tests used to identify 2019-nCoV nucleic acid positive specimens, etc. Depending on the nature of the disease, if no prospective or retrospective specimens are available at the time of your pre-EUA submission for the 2019-nCoV disease we may accept a fully contrived clinical evaluation. The clinical evaluation should be comprised of a minimum of 100 negative individually collected specimens and 50 individual positive specimens (prospective, retrospective and/or contrived). Use of pooled specimens are not acceptable for the clinical evaluation of your test. Please see FDA Table 5 for more details. Please note that if a fully contrived clinical study is used to support your Pre-EUA submission, additional clinical testing of a limited number of natural clinical positive specimens and potentially negative specimens from the endemic region, if available, may be required at the time when this Pre-EUA transitions to an EUA as a result of an Emergency declaration for 2019-nCoV disease.**

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## FDA Table 5: Clinical study Recommendations:

| Details | Study Including Prospective/ Retrospective Specimens | Fully Contrived Sample Study |
|---|---|---|
| Minimum Number of Positive Specimens | 50<br><br>The number of natural (prospective/retrospective) positive clinical specimens should be at least 25 (collected from symptomatic patients in the 2019-nCoV disease endemic region(s)) and, if necessary, may be supplemented with contrived samples to generate the total of 50 positive specimens. Contrived samples should be prepared as described in the fully contrived sample study column. | 50<br><br>The contrived positive samples should be made in individual negative clinical matrix collected from subjects from a non-endemic population (pooled matrix is not acceptable for the clinical evaluation). Please note that the negative clinical matrix used for spiking should be confirmed negative by your test device prior to spiking. Half of the contrived positive samples can be prepared by spiking the 2019-nCoV at LoD and the remaining contrived positive samples should cover the range of the test up to and not higher than 5 x LoD.<br><br>Negative respiratory specimens: Can be archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection.<br><br>Negative blood specimens: Can be collected from healthy subjects from non-endemic areas. |
| Minimum Number of Negative Specimens | 100<br><br>Note: In general, for EUA the 100 individual negative samples can be collected from; (1) archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection for respiratory specimens, and (2) healthy subjects from non-endemic areas for blood specimens, that are "expected 2019-nCoV disease negative". Note these negative specimens can be used to also prepare any contrived positive specimens used in support of the clinical evaluation of the test.<br><br>Please note this recommendation is dependent on the current outbreak situation and is subject to change as we learn more about the 2019-nCoV disease/outbreak. If the outbreak situation for 2019-nCoV disease is primarily outside of the continental U.S. (OUS) it may be beneficial to consider collecting negative specimens that represent 50% endemic and 50% non-endemic regions. If negative specimens are collected from the endemic region of the 2019-nCoV disease these should be tested with the same comparator chosen for the positive specimens (more details provided below). For non-endemic collected specimens you can compare to the expected "negative" result. | |
| Recommended Comparator Method | Positive: Positive percent agreement should be calculated in comparison to a EUA PCR test (please see the following website for the most recent list of FDA authorized 2019-nCoV | Positive: Compare to expected result.<br><br>Negative: See Minimum Number of Negative Specimens row |

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| | | |
|---|---|---|
| for percent agreement performance calculations | tests: https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm. If no EUA test available at the time of your EUA submission, please consult with FDA about your choice of comparator method – which ideally should be a well validated PCR test with comparable sensitivity to your subject device. Please note that a well validated PCR test should include evaluation of the tests LoD, inclusivity, exclusivity, interference and any clinical testing.<br><br>Negative: See Minimum Number of Negative Specimens row | |
| Comparator Method Note 1 | Please note when using natural clinical specimens, the comparator method must be validated for the specimen type claimed – if not you should perform a Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method study, as explained above (Section 4), to support its use as a comparator method in your clinical study. | N/A |
| Comparator Method Note 2 | Any occurrences of false results should be investigated with an additional validated PCR test and/or targeted sequencing, and the results of the discordant analysis can be footnoted in your final performance table but cannot be used to change the final performance calculations. | |
| Natural Clinical Specimens IRB/Informed Consent Note | For clinical specimens collected to support the EUA request, please note that sample collection needs to adhere to all applicable rules of human subject protection; as such, sample collection needs IRB approval, which includes review of the informed consent forms. Samples need to be collected with informed consent. If leftover de-identified samples are used, FDA exercises enforcement discretion regarding the informed consent requirement if the specimen collection meets the criteria described in the FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable (http://www.fda.gov/cdrh/oivd/guidance/1588.pdf).<br>**Note that IRB approval is still required even if leftover de-identified samples are used in your study.** | |
| Additional Studies Warning | N/A | If fully contrived samples were used in your Pre-EUA submission, additional testing of natural clinical specimens may be requested, if available, to support transition of the Pre-EUA to EUA as a result of an Emergency declaration. |
| Testing Approach Note 1 | Please note all clinical specimens (natural and contrived) should be evaluated in accordance with your proposed diagnostic algorithm, including retesting when appropriate. We understand the limited nature of natural specimens may preclude retesting. In instances were retesting is indicated but not performed, for the purposed of performance evaluation, initial results will be analyzed for performance and equivocal/indeterminate results count against your final performance. | |
| Testing Approach Note 2 | Specimens should be tested in a blinded fashion, e.g., positive and negative samples should be mixed and blinded to the end user, end user should also be blinded to the results of any comparator method testing. | |

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**When you describe your clinical study please indicate/include:**

- **How the specimens were generated/collect/sourced**
- **If the study was fully prospective, mix of prospective, retrospective and/or contrived or fully contrived**
- **The rationale for the concentrations/specimens selected (if using contrived or 3-party sourced specimens)**
- **The total number of specimens tested**
- **The specimen types (clinical matrix)**
- **A summary of the study results**

**In the case of real-time PCR tests, please provide the line data in an Excel file as part of the Pre-EUA submission for each specimen (please indicate for each specimen if it was prospective, retrospective or contrived and the clinical matrix it represents); the data should include the $C_T$ values (for the specimen and the controls) and call/result for your device and, in the case of the natural clinical specimens, the comparator method results should be included as well.**

## L. UNMET NEED ADDRESSED BY THE PRODUCT

**This section will be finalized by FDA based on the state of the emergency at the time of authorization and based on recommendations from Public Health authorities at that time. Example text is provided below but may be adapted according to the specific emergency situation that is addressed by the device and the need at the specific time of the outbreak.**

[Outline background of pathogen, disease and current outbreak]

[Outline details of the disease such as the following:

- likely sources of transmission
- likely symptoms – if any
- Prevalence of symptomatic disease (what fraction of infection results in symptomatic disease)]

Laboratories in the United States are in need of diagnostic tools for use in the 2019-nCoV emergency for rapid diagnosis of acute 2019-nCoV infection.

A public health emergency has been declared by the Secretary of Health and Human Services (HHS) on [Month Day, YEAR] justifying the authorization of emergency use of *in vitro* diagnostic tests for detection of 2019-nCoV and/or diagnosis of 2019-nCoV infection.

The ***[test name]*** can augment clinically important laboratory evidence for individuals with active infection. The 2019-nCoV nucleic acid is generally detectable in [name

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specimen type] during the acute phase of infection (approximately [7] days following onset of symptoms, if present) [and possibly for longer in other specimen types].

Under emergency use authorization (EUA), ***[applicant name]*** plans to distribute the test or accept sample for testing with the ***[test name]*** for the detection of nucleic acid from 2019-nCoV in clinical specimens collected from individuals meeting CDC's 2019-nCoV clinical and/or epidemiological criteria. This EUA request for the ***[test name]*** is intended to expand domestic readiness within the United States and its territories by expanding diagnostic testing capabilities for 2019-nCoV during public health emergency.

FDA consulted with subject matter experts within HHS on the public health needs for diagnostic devices to detect 2019-nCoV nucleic acid. It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for 2019-nCoV detection during the public health emergency.

## M. APPROVED/CLEARED ALTERNATIVE PRODUCTS

Currently no methods for the detection of the 2019-nCoV have been approved/ cleared by FDA.

## N. RISKS AND BENEFITS:

**The Risks and Benefits section should be updated according to your specific device, some example language is given below but should be tailored to the device and the disease.**

Risks

The ***[test name]*** has been designed to minimize the likelihood of false test results. However, should false results occur, they may present risks to patients:

- False positive result:
  - A false positive 2019-nCoV result could [***update based on the pathogen***].
  - A false positive result in the context of the current public health emergency could lead to misallocation of resources used for surveillance and prevention.
  - A false positive result could delay correct diagnosis and initiation of appropriate treatment for the actual cause of patient illness.
- False negative result:
  - Although a negative result does not rule out 2019-nCoV infection, a false negative has the potential to result in initiation of inappropriate treatment and a delay in correct diagnosis.
  - A false negative result can trigger a waste of health care resources, as additional evaluations are pursued in the effort to establish the true diagnosis.
  - A false negative results can contribute to further spread of the disease.

Benefits

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The primary benefit of distributing the ***[test name]*** for clinical use is that it provides a relatively fast diagnostic method for symptomatic patients, which enables faster intervention.

- True positive test results provide support for the diagnosis of a 2019-nCoV infection. The results can be used in conjunction with clinical and epidemiological information to guide patient management.
- Distribution of the factsheets can help healthcare professionals and the public learn more about 2019-nCoV disease and how to avoid acquiring it.

Risk Assessment

- Negative results may not preclude a 2019-nCoV infection. It is emphasized that the ***[test name]*** should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure must be considered pivotal to making patient management decisions. A negative test should not be interpreted as definitive, if other aspects of the patient's clinical presentation or recent epidemiologic exposures indicate such is likely, and diagnostic tests for other diseases are negative.
- False negative results due to failure of PCR are minimized by the presence of controls that monitor nucleic acid extraction and PCR efficiency.
- Risk of patient discomfort or harm during sample collection is minimal.

Risk-Benefit Assessment

The risks posed by use of the ***[test name]*** are mitigated by:

- Use of the ***[test name]*** in conjunction with other laboratory, epidemiological, and clinical evaluation tools
- Distribution of Healthcare Provider and Patient fact sheets.
- Post-market studies/reporting or conditions of Authorization.

Based on these factors, the potential benefits from the use of the ***[test name]*** are expected to outweigh the risks.

## O. FACT SHEET FOR HEALTHCARE PROVIDERS AND PATIENTS:

**Include proposed Fact Sheets for Patients and Healthcare Providers**

## P. INSTRUCTIONS FOR USE/ PROPOSED LABELING/PACKAGE INSERT:

**Include Instructions for Use, Box Labels, Vial Labels and any other proposed labeling.**

## Q. RECORD KEEPING AND REPORTING INFORMATION TO FDA:

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[***Manufacturer name***] will track adverse events and report to FDA under 21 CFR Part 803. A website is available to report on adverse events, and this website is referenced in the Fact Sheet for Health Care providers as well as through the [***Manufacturer name***] Product Support website: [***Include link to Website***]. Each report of an adverse event will be processed according to [***Manufacturer name]***'s Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the FDA as required. Through a process of inventory control, [***Manufacturer name]*** will also maintain records of device usage/purchase. [***Manufacturer name]*** will collect information on the performance of the test, and report to FDA any suspected occurrence of false positive or false negative results of which [***Manufacturer name]*** becomes aware. [***Manufacturer name]*** will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

## R. ADMINISTRATIVE INFORMATION:

**Interactive Review Log:** Please use the table below to document interactive review with FDA and include interactions initiated by either FDA or yourself

| **Date** | **Type of Interaction** (phone/ email/ formal submission-DCC) | **Brief Description** (e.g., questions asked/ feedback from FDA received / any word documents included) |
|---|---|---|
| [X] | [X] | [X] |
| | | |
| | | |

## S. FDA ADMINISTRATIVE INFORMATION:

**This section will be finalized by the FDA Lead Reviewer upon completion of the review process and documents the interactive review of this submission and any conclusions resulting from the interactive review.**

1) **Summary of Interactive Review – Lead Reviewer to use this section to highlight any major issues solved during interactive review.**
2) **Final Conclusions for Interactive Review -** It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for [pathogen] detection during the public health emergency. **Conclusion should include an outline the unique features of the device compared to currently issued EUA's under the declaration, if applicable.**
3) **Upon competition of this section the Lead Reviewer should also sign this document and save the file as the final Decision Memorandum.**

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## APPENDIX A – Multiplex Panels Under EUA:

An emergency declaration by the HHS Secretary is typically specific for a pathogen/disease (i.e., there is a publicly declared health emergency involving a particular etiologic agent). Therefore, the EUA pathway is only applicable for testing patients with signs/symptoms/risk of exposure for that single agent in a given emergency. FDA has occasionally allowed limited additional target pathogens to be claimed for EUA devices, but panel members must be relevant to the event/disease outbreak subject of the specific emergency declaration. When determining whether to issue an EUA for a multiplex panel FDA takes into consideration the utility of the test (multiplex pathogen detection as an aid in differential diagnosis), clearance/approval status of IVDs for the other panel members, whether the proposed Intended Use fits within the HHS emergency declaration and the how the multiplex panel would fit into current public health authority patient testing algorithm recommendations. We recommend you contact FDA for specific feedback if you plan to claim multiple target analytes as part of your EUA test. If it is determined that a multiplex test is beneficial to the emergency response, please note that analytical and clinical evaluations for each of the target analytes will be required.

## APPENDIX B – General Study Design Recommendations for Reagent Stability:

- For EUAs you may follow the current FDA recognized CLSI Standard EP25 – Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline when evaluating the suitability of stability study designs. If you are planning to pursue a De Novo/510(k) for your device we recommend discussing in more detail your stability design to facilitate potential use of the EUA data in your regular premarket submission.
- Please note that use of only the positive controls is not acceptable for reagent stability evaluation because controls are usually formulated at a moderate positive level. For all the stability evaluations in addition to your external positive and negative controls and the no-template control you should include for the EUA evaluation at least one sample, that should be prepared by spiking negative clinical matrix at an analyte concentration of 3-5xLoD.
- If you are claiming multiple blood clinical specimen types in which similar LoDs are determined, you should use the most challenging clinical matrix for this study.
- Please note we typically recommend your stability study design includes the evaluation of at least 5 replicates. You should also evaluate, if available, 3 different lots of reagents.
- You should design your study to provide data for a timeframe that is about 10% longer than the one to be claimed – for example; a claim of 18 months should be supported by stability data out to 20 months and a claim of 7 days should include stability data out to 8 days.
- FDA considers 15-30°C to represent room temperature conditions. Ideally you should evaluate stability at both 15°C and 30°C, however, for the purposes of the EUA evaluation at 30°C is acceptable as the worse-case scenario.
- Shelf-Life Stability- Unopened kit:
    - You should evaluate real-time kit stability studies with unopened kits stored at the claimed storage temperature for your test.

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  - Accelerated stability evaluations for unopened kits is acceptable for EUA submissions while the real-time studies are on-going. However, please note real-time stability data is required to support regular pre-market submissions and for the final claim of an EUA.
- Shipping Stability - Unopened kit: Study should evaluate the anticipated handling and shipping times and temperatures expected for unopened kits.
- In-use/Opened Kit Stability: Depending on your device your stability study design should also support in-use stability of the kit reagents once the kit has been opened, e.g., storage at 2-8 $^{o}$C for 7 days. This includes on board stability once reagents have been placed on the instrument (if applicable).
- Inverted stability (if applicable): Study should support inverted stability for of kits.
- Freeze-thaw Stability: If you recommend aliquoting the reagents to meet the end-users needs following the initial thaw this recommendation should be supported by a freeze-thaw stability study, including the specific number of allowed freeze-thaw cycles.
- FDA analysis recommendations for real time stability studies are as follows:
  - Baseline of the study (t=0 of stability study) should not exceed a month from bottling
  - Clear baselines should be described (e.g., a month from bottling) for each stability claim under each study
  - Claims should be determined based on regression analysis. Any %change (%shift) from time zero (baseline) should be calculated between the target claim and the zero-time as (Ttest-Tbaseline)/ Tbaseline*100 with 95%CI using the regression equation obtained from plotting the mean values. When formulating your acceptance criteria for evaluating the shift from baseline you should consider the reproducibility of your device. However, generally, that the shift at the target claim due to storage cannot exceed 10-15%. The target stability is the next to last tested point that was within +/- 10% of time zero.
  - Acceptance criterion may be different, depending on the test samples analyte concentration distribution in the intended use population and the risk, in other words, the impact of false results to public health.

**APPENDIX C – Claiming Multiple Instruments and/or Extraction Methods:**

If you wish to claim multiple instruments and/or extraction methods for use with your test, please review the study recommendations provided below and contact FDA for any additional feedback. Please note that these analytical and clinical evaluation recommendations are based on the assumption that the elution volumes from the extraction methods and PCR volumes on the different RT-PCR instruments are identical.

- Limit of Detection (LoD): Please note that these studies should be repeated for each clinical matrix claimed in the Intended Use. Pick one RT-PCR instrument and determine the tentative LoD (using 5 replicates in 10-fold dilution) followed by the confirmatory LoD (20 replicates spiked at tentative LoD) for each extraction method on the chosen instrument. Note: If you detect 20/20 replicates in your confirmatory LOD study you should test the next lower concentration, using a 3-fold dilution, until

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you achieve a hit rate of <20/20.

- If the different extraction methods yield the same LoD (≤3xLOD) on the RT-PCR instrument chosen for initial testing, pick one extraction method for further LoD determination on the remaining RT-PCR instruments and follow the recommendations below.
- If the extraction methods do not yield the same LoD on the chosen RT-PCR instrument, please choose the extraction method with the worst LoD for further comparison of the LoD on all RT-PCR instruments.

For all other RT-PCR instruments you should use the following adaptive LoD study design:

- Please perform a refined tentative LoD study with 5 replicates at 0.5x, 1x, and 1.5 to 2x LoD. If you detect 4/5 replicates as positive at all the tested levels, you need to include the next higher concentration (i.e., 3x LoD). If you obtain 5/5 replicates at 0.5x LoD, you need to test the next lower concentration (i.e., 0.25x LoD). You will test in this manner until you find the lowest concentration that gives you 5/5 positive results for the tested RT-PCR instrument. This concentration should be used for a confirmatory LoD study for the given RT-PCR instrument using 20 replicates.

Final reported LoD: Please list all RT-PCR instruments with their respective LoDs if different LoDs are obtained. LoDs are considered comparable if they are between 1-3xLoD. These studies should be repeated for each clinical matrix claimed in the Intended Use.

- Interference Substances Studies (if applicable): Pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Inclusivity Testing: For the inclusivity testing, pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Exclusivity Testing: For exclusivity, you can perform this study using any extraction/instrument combination.

- Clinical study: If equivalency of the RT-PCR instruments is shown in an LoD study that tests and confirms that the LoD is the same or very similar for all of the RT-PCR instruments (between 2-3xLoD), then you can pick one RT-PCR instrument for your clinical study provided that the RT-PCR instruments in question are known to FDA for other *in vitro* diagnostic devices. If you find that one or more RT-PCR instruments machines has/have a different LoD, you should pick the extraction method / RT-PCR instrument combination with the worst LoD.

Note, if there are differences in the extraction input volume, extraction elution volume

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and PCR input volume (extracted nucleic acid) then the LoD should be confirmed, for each.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 10:03:12 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** FW: Pre-EUA IVD template request
**Attachments:** Draft cover letter for Sponsor 01212020.docx; EUA Review Template_NAT_Novel Coronavirus 1.19.2020.doc

Additional communication — as of February 25th Wadsworth hadn't finished validating their test.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 27, 2020 at 10:01:33 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Pre-EUA IVD template request

FYI

---

**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:03 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Pre-EUA IVD template request

FYI – see information in red in the email below and:

Wadsworth:

(b) (5), (b) (4)

[redacted]

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
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Kim.Sapsford@fda.hhs.gov

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**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:50 PM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** RE: Pre-EUA IVD template request

Dear Jill,

Thank you very much for reaching out to us about the test you have validated at Wadsworth Center, NYS Department of Health it was very nice to chat with you. As discussed please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [formally - 2019-novel coronavirus (2019-nCoV)]. I suggest the first step is to populate this draft template with the validation information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center). The Pre-EUA review is an interactive process, so we will provide feedback after receiving and reviewing the information provided. The draft review template is a shared "work-in-progress" document which you will populate with information and data as obtained and which we will review and provide feedback to you. **Please make sure to capture in the EUA review template that you performed the validation using the SIGMA primer/probes sets, sensitivity was evaluated with the positive control material provided in the CDC EUA test kit and that validation studies were performed used the commercial primer/probe materials using the CDC EUA Protocol (please be sure to include information the extraction method and instrument used).**

I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of SARS-CoV-2 to FDA (it includes the address for the Document Control Center). Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under Section A (type of submission) please check "other" and specify Pre-EUA; please also complete Sections B, C, F and G. For G please use the information provided in this link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=3669.

One hard copy of the signed EUA Cover Letter and one electronic copy (CD or thumb drive) of you Pre-EUA submission package should be enclosed in your Pre-EUA submission package mailed to FDA (recommend FedEx). In addition to mailing your Pre-EUA package to FDA we also request that you submit the package to the review division via electronic mail (including the EUA Review Template in MS word) to myself Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;
- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please let me know if you have ANY questions I am happy to assist if you are not sure about certain sections in the template.
Best regards
Kim

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Tuesday, February 25, 2020 1:08 PM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** Pre-EUA IVD template request

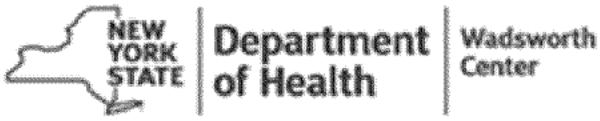
At your earliest convenience, I wish to request a copy of the most recent EUA review template relevant to an assay for the SARS-CoV-2 pathogen.

(b) (4)

Thank you,

**Jill Taylor, Ph.D.**
Director

Wadsworth Center, NYS Department of Health
Room E-260, Biggs Laboratory
(518) 474-3157 | jill.taylor@health.ny.gov
www.wadsworth.org




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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/29/2020 12:20:01 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: IDT No Objection Language

Thank you

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:20 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: IDT No Objection Language

(b) (5)

[redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 29, 2020 at 12:15:44 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: IDT No Objection Language

(b) (5)

[redacted]

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 11:46 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: IDT No Objection Language

Got it

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:38 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: IDT No Objection Language

(b) (5)

[redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 29, 2020 at 11:35:58 AM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: IDT No Objection Language

(b) (5)

[redacted]

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**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:26 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: IDT No Objection Language

Only suggestion (b) (5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 29, 2020 at 11:17:59 AM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** IDT No Objection Language

Here is the draft language I would send to CDC about the IDT test kit.

(b) (5) [redacted]

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/28/2020 7:55:43 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

TY!

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:55 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Adding additional people.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:50 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** NYS Wadsworth Center COVID-19 Test
**Importance:** High

Wendi, Dan, Laura,

NYS Wadsworth Center submitted an EUA request to us this afternoon for a test that uses the CDC protocol but only for N1/N2 (consistent with the CDC test currently subject to enforcement discretion). To support their EUA, Wadsworth conducted a bridging study that demonstrates performance similar to CDC's N1/N2 test. We know their performance is comparable because we have seen CDC's data but Wadsworth has not. **Would CDC allow Wadsworth to have a right of reference to its data, under which does not get access to the data but can reference it in support of their EUA?** Wadsworth has one more test to perform, which if it looks good, we would otherwise grant the EUA.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 5:52:17 PM
**To**: Stephanie Caccomo (Stephanie.Caccomo@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]
**CC**: Schwartz, Suzanne (Suzanne.Schwartz@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Suzanne.Schwartz]
**Subject**: FW: Coronavirus testing: 3 Marylanders meet CDC criteria for testing

Stephanie,

Sharing the below news report saying there are now three individuals in Maryland who have met CDC criteria for testing for COVID-19. It may generate questions from staff. I don't know if any internal comms for the Agency are being planned or contemplated but wanted to make sure folks were aware, if not already.

Jeff

3 Marylanders meet CDC criteria for testing of coronavirus

WBAL
Updated: 10:00 AM EST Feb 28, 2020

Lowell Melser

News Reporter, Meteorologist

REISTERSTOWN, Md. –
Three Marylanders have met the Centers for Disease Control and Prevention criteria for testing of the coronavirus.

Gov. Larry Hogan announced two cases met the criteria for testing Thursday.

A state Health Department spokesman confirmed Friday that a third Maryland resident has met criteria for CDC testing for the novel coronavirus.

State health officials said the samples are being flown to the CDC in Atlanta for testing.

Two other cases that were tested earlier in the year came back negative.

In an all-hands on deck news conference Thursday, the governor and state emergency officials addressed the concerns over coronavirus and how it might affect Marylanders.

The governor and state health officials made it clear that Maryland is currently considered a "low-level risk." Hogan said there is no immediate health threat in Maryland but that the state is taking every precaution to address the coronavirus.

"While we are hoping for the best, we are also actively planning for the worst," Hogan said.

The governor said he spoke with Vice President Mike Pence before Thursday afternoon's news conference. Pence was put in charge by the president to oversee the preparedness around the country.

Hogan also met with his top cabinet officials and state agency officials, and will do so in the coming days and weeks.

The state will be putting surveillance protocols in place with daily briefings from the CDC. State health officials said they are also able to use their labs to test for coronavirus -- that just needs to be cleared by the CDC.

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State officials are also telling people to start preparing just in case they need to be quarantined at home for a short or long period of time.

The governor said he will add $10 million in a supplemental budget for emergency preparedness and preventable measures.

Marylanders can also call 211 for more information.

-----Original Message-----
From: Peat, Raquel <Raquel.Peat@fda.hhs.gov>
Sent: Friday, February 28, 2020 5:03 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: FW: Coronavirus testing: 3 Marylanders meet CDC criteria for testing

Jeff:

Not sure if you saw the below in the news but this is being circulated. I am sure staff may want to have a update...
https://www.wbaltv.com/article/coronavirus-2-marylanders-meet-cdc-criteria-for-testing/31139631

Thank you,
Raquel

CAPT Raquel Peat, PhD, MPH
301-796-6218
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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/28/2020 7:52:35 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

If okay with you, I'd take the email you sent, hit "Reply All" and add the rest of us and just say you are adding other people. That way when folks reply we can all see it.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:51 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Did sent it. Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:45 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** NYS Wadsworth Center COVID-19 Test

Here's the draft email:

Wendi, Dan, Laura,

NYS Wadsworth Center submitted an EUA request to us this afternoon for a test that uses the CDC protocol but only for N1/N2 (consistent with the CDC test currently subject to enforcement discretion). To support their EUA, Wadsworth conducted a bridging study that demonstrates performance similar to CDC's N1/N2 test. We know their performance is comparable because we have seen CDC's data but Wadsworth has not. **Would CDC allow Wadsworth to have a right of reference to its data, under which does not get access to the data but can reference it in support of their EUA?** Wadsworth has one more test to perform, which if it looks good, we would otherwise grant the EUA.

Jeff

**Jeffrey Shuren, MD, JD**
*Director*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Email: jeff.shuren@fda.hhs.gov






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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/25/2020 8:39:07 AM
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**Subject:** RE: Two items re COVID-19 Hill Briefing

Jennifer,

Thank you. I'm all set.

Jeff

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 8:35 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Two items re COVID-19 Hill Briefing

Jeff,

Below is the information we provided to OC re EUAs for IVDs. Other than any updates between now and tomorrow, do you need additional details re IVDs?

Diagnostic Tests

- Granted 1 Emergency Use Authorization (EUA), to the CDC, as of 2/21/20
- This test was developed and validated within about a month.

- CDC submitted validation data interactively throughout the process and the EUA package was submitted to FDA on 2/3/2020; on 2/4/2020, FDA issued an EUA to enable emergency use of the test.

- Provided the EUA template to 70 developers of diagnostics for this outbreak as of 2/21/20
- 13 developers have submitted pre-EUA documents for FDA feedback as of 2/21/20

(b) (5)

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/28/2020 7:50:29 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Thank you. Please cc Tim, Elizabeth, Marcy and me.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:49 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Thanks, I send it now. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:45 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** NYS Wadsworth Center COVID-19 Test

Here's the draft email:

Wendi, Dan, Laura,

NYS Wadsworth Center submitted an EUA request to us this afternoon for a test that uses the CDC protocol but only for N1/N2 (consistent with the CDC test currently subject to enforcement discretion). To support their EUA, Wadsworth conducted a bridging study that demonstrates performance similar to CDC's N1/N2 test. We know their performance is comparable because we have seen CDC's data but Wadsworth has not. **Would CDC allow Wadsworth to have a right of reference to its data, under which does not get access to the data but can reference it in support of their EUA?** Wadsworth has one more test to perform, which if it looks good, we would otherwise grant the EUA.

Jeff

**Jeffrey Shuren, MD, JD**
*Director*

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**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Email: jeff.shuren@fda.hhs.gov

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 9:37:18 PM
**To:** 'Hahn, Stephen' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** COVID-19 Test Update

The IDT N1/N2 primers/probes plus CDC developed control were shipped today to 7 public health labs for verification. If all goes well a total of 50 kits (including the first 7) of the newly made primers/probes plus control will be shipped to public health labs; goal is by (b) (5) . Since public labs who verified the original N1 and N2 probes for the CDC test can use the current test and reagents, CDC will decide which other public health labs should receive the newly manufactured reagents. The IDT test, which is the same as the CDC test but manufactured by IDT, passed the QC assessment. A decision will be made in the morning whether the (b) (5) CDC agreed to keep this test under its EUA, which still need to be reauthorized but there is no hold up on IDT shipping out tests.

We hammered out the high level details for the one pager. Fine tuning the language. CDRH is working on the validation criteria, which won't need to be in the one-pager but need to have before communicating with the labs and the public.

Jeff

**Jeffrey Shuren, MD, JD**
*Director*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Email: jeff.shuren@fda.hhs.gov






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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/26/2020 3:41:09 PM
**To:** Schwartz, Suzanne (Suzanne.Schwartz@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Suzanne.Schwartz]
**Subject:** FW: AdvaMinute | Coronavirus Update

Give us a minute. We'll give you MedTech!

Good Morning, AdvaMed Nation—

Since the onset of the coronavirus (COVID-19) outbreak, at least 31 **AdvaMed member companies have donated medical products worth approximately $26.8 million and made cash donations worth $4.1 million** to the China Red Cross Foundation and other medical institutions, such as hospitals and clinics in Hubei Province. Donations

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and the medtech community's work will only grow in the coming weeks as the threat continues to elevate.

In a press release issued this morning, AdvaMed President and CEO Scott Whitaker said:

"At AdvaMed, we help industry and government work together to solve problems on behalf of the patients we serve, and that collaboration has never been more important than it is now in the face of this global health emergency. We're doing everything we can to help stop the spread of the coronavirus. For the medtech industry, that means donating key medical technologies, providing on-the-ground medical support, and developing new diagnostics, treatments, and vaccines. For AdvaMed, it means connecting industry to public officials and those who are on the front lines fighting this disease. The medical technology community has always stepped up during times of crisis, and AdvaMed is proud of the tremendous work and charity the industry has committed so far."

## AdvaMed Working With Key U.S. Government Agencies

AdvaMed has been working daily with key U.S. government agencies – including HHS, FDA, CDC, and ASPR – and the Chinese government to identify ways the industry can help ensure that providers and patients have access to the medical technologies they need to prevent, diagnose, and treat the coronavirus. This close coordination has facilitated information sharing; anticipated, identified, and reconciled supply-chain challenges; and prompted strategic product and capital donations.

## Coronavirus Task Force

The association has also assembled a coronavirus task force focused on personnel, transportation, and supply, among other needs. The task force meets regularly to receive government, industry, and member-company status updates, and to coordinate industry response. AdvaMed has also distributed to its membership a list of personal protective equipment (PPEs) identified by the Chinese government as essential to the emergency response (e.g., protective clothing, masks, gloves, and gowns; non-contact infrared thermometers; etc.), and is partnering with authorities to increase access to those medtech products.

## Member Company Response Effort

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Below is a collection of some of the efforts undertaken recently by AdvaMed member companies:

**3M** is continuing to increase the production of respirators at their facilities around the globe. 3M has also donated respirators, surgical masks, and hand sanitizer to affected areas in China. View the press release here.

**Bayer** is donating medicine and money with a total value of approximately EUR 1.5 million. View the press release here.

**BD** has donated medical devices such as catheters, syringes, sharps, blood collection tubes, and flush products valued at approximately $300,000 to the local Red Cross in Wuhan. In addition, BD has donated $50,000 that will be used to supply personal protective equipment (PPE) to frontline health workers. Read more here.

**Cepheid** is developing an automated molecular test for the qualitative detection of COVID-19 with the ability to deliver point-of-care results in about 30 minutes. View the press release here.

**Danaher Corporation:** Five Danaher operating companies donated RMB 10 million ($1.4 million) of diagnostic equipment, reagents and other products to hospitals in Wuhan, China to combat COVID-19. Included in the donation is: Beckman Coulter Diagnostics' hematology analyzers, Beckman Coulter Life Sciences' flow cytometers, Radiometer's blood gas analyzers, Cepheid's Xpert® Xpress Flu/RSV assay, and Hach's UV-Vis spectrometers.

**GE** Healthcare CEO Kieran Murphy shared here that the company has prioritized and fulfilled hundreds of medical technology installations – including CT, ultrasound, digital x-ray, respirators and patient monitors – in China and other impacted regions. Additionally, GE Healthcare has donated $2.8 million worth of medical equipment in Wuhan, and has accelerated its global supply chain to help cut production times for its new Revolution Maxima CT from around one week to only three days. More details here.

**Johnson & Johnson** has donated one million surgical masks to China and $1 million RMB to the Chinese Red Cross Foundation. They have also donated thermometers, respirators, an electrosurgical generator, 50,000 bottles of isopropyl alcohol, and PPE including goggles and protective suits. Additionally, Johnson & Johnson is diligently

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working with partners around the globe to develop a vaccine. Read more here.

**Medtronic** and the Medtronic Foundation are committing $1.5 million to coronavirus relief efforts across the globe. Product donations to Wuhan Huoshenshan Hospital include ventilators, respiratory filters, pulse oximeters, sensors, and centrifugal blood pump systems. View the press release here.

**Olympus** installed endoscope systems into the Wuhan Huo Shen Shan Hospital within 10 days to treat infected patients. In addition to monetary donations to the Red Cross Society of China Huanggang, Olympus has donated 15 sets of laryngoscopes to the China Social Welfare Foundation, and 25 biological microscopes to the Chinese Center for Disease Control and Prevention, totaling approximately $500,000 in donations.

**QIAGEN** has sent the first group of 200 QIAstat-Dx cartridges for syndromic detection of respiratory pathogens – including COVID-19 –to China; they're now being validated at four hospitals. This comes as an evaluation was also successfully completed at the Bichat-Claude Bernard Hospital in Paris. The use of QIAstat-Dx is increasingly important for detection of the COVID-19 infections, as well as to provide differential diagnostics involving the more than 20 other respiratory pathogens included in this syndromic test.

**ResMed** CEO Mick Farrell stated that the company has sent more than 100 ventilators from ResMed's facility near Shanghai to Wuhan. He also stated they will send hundreds more ventilators and thousands of masks. Read more here.

**Roche** is working with Chinese health authorities and the government to ensure people can access screening and healthcare. Roche is also working to support the government and local health officials and hospitals in Hubei Province in dealing with the coronavirus. Recently, Roche has donated diagnostic tests, medical supplies, and financial support for the affected region. View the press release here.

**Varian** has donated 1 million RMB to the China Red Cross. View the press release here.

**For more information, contact Jim Jeffries.**

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U.S. FOOD & DRUG ADMINISTRATION

February 26, 2020

Grace Kubin, Ph.D.
Director, Laboratory Services Section
Texas Department of State Health Services
1100 West 49th Street
Austin, TX 78756

Scott J. Becker, MS
Chief Executive Officer
Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910

Dear Dr. Kubin and Mr. Becker,

Thank you for your letter to the Food and Drug Administration (FDA or the Agency). FDA appreciates the critical role of state and local public health laboratories in our nation's response to public health emergencies, as well as the severity of the current situation with the 2019 novel coronavirus disease (COVID-19).

In the context of a public health emergency, false diagnostic test results can lead to significant adverse public health consequences—not only serious implications for individual patient care but also serious implications for the analyses of disease progression and for public health decision-making. The Emergency Use Authorization (EUA) statutory provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act) help ensure that FDA has appropriate oversight over the emergency use of certain unapproved products, as well as over unapproved uses of approved products, including diagnostic tests, regardless of who makes them. In certain emergency circumstances, FDA may issue an EUA if it determines, among other things, that the product "may be effective" in the diagnosis, treatment, or prevention of a disease or condition and that the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product.

In your letter, you propose developing and implementing a laboratory-developed test for COVID-19 that could be used across multiple public health laboratories with a standard protocol, common sources of reagents, and a standard validation panel and approach. You claim that such a test could be reviewed and, with supporting validation, authorized under a single EUA for use across multiple public health laboratories. In fact, FDA has developed a template to streamline the process to facilitate the protocol that you propose while ensuring FDA's appropriate oversight. Enclosed please find a template to help guide your development and validation of this protocol.

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U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

FDA welcomes the review of submissions of diagnostic test information on a rolling basis and is committed to a prompt and interactive review of them. Once you have developed your protocol, the Agency will coordinate closely with the Association of Public Health Laboratories (APHL) to facilitate access to appropriate materials for validation of your test protocol. In past experiences with these rolling reviews, FDA has been able to authorize tests for public health emergencies within as little as 1 day upon receipt of the complete validation. The Agency would be happy to talk with you about options for the timely availability of such tests.

The Agency is currently supporting over 70 developers in the diagnostic space, including some public health laboratories, and FDA looks forward to collaboration with APHL and/or additional member laboratories as well. We welcome dialogue on opportunities to support the development and implementation of validated tests for COVID-19.

Sincerely,

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs

Enclosure

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/26/2020 2:23:05 PM
**To:** Becker, Scott | APHL [Scott.Becker@aphl.org]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**CC:** Kyriacopoulos, Peter | APHL [Peter.Kyriacopoulos@aphl.org]; Kubin, Grace [Grace.Kubin@dshs.texas.gov]
**Subject:** RE: enforcement discretion request for COVID-19 for PHLs final.pdf
**Attachments:** APHL Final Response Letter.pdf

Scott,

I wanted to share FDA's response to APHL's letter. We can further discuss when we all talk today at 3:00 PM and then again at 4:30 PM.

We look forward to providing you and others with some updates and to working with you to best address the COVID-19 outbreak.

Best regards,

Jeff

---

**From:** Becker, Scott | APHL <Scott.Becker@aphl.org>
**Sent:** Monday, February 24, 2020 6:29 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Cc:** Kyriacopoulos, Peter | APHL <Peter.Kyriacopoulos@aphl.org>; Kubin, Grace <Grace.Kubin@dshs.texas.gov>
**Subject:** RE: enforcement discretion request for COVID-19 for PHLs final.pdf

Thanks Jeff, we appreciate it.

Scott

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:27 PM
**To:** Becker, Scott | APHL <Scott.Becker@aphl.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Cc:** Kyriacopoulos, Peter | APHL <Peter.Kyriacopoulos@aphl.org>; Kubin, Grace <Grace.Kubin@dshs.texas.gov>
**Subject:** RE: enforcement discretion request for COVID-19 for PHLs final.pdf

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Dear Mr. Becker,

Thank you for sharing APHL's letter. The Commissioner's Office is in receipt of it and we are working through them.

Best regards,

Jeff

---

**From:** Becker, Scott | APHL <Scott.Becker@aphl.org>
**Sent:** Monday, February 24, 2020 6:01 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>

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**Cc:** Kyriacopoulos, Peter | APHL <Peter.Kyriacopoulos@aphl.org>; Kubin, Grace <Grace.Kubin@dshs.texas.gov>
**Subject:** FW: enforcement discretion request for COVID-19 for PHLs final.pdf

Dear Drs. Shuren and Hillebrenner,

I wanted to be sure you also received this letter since I'm never certain how long it takes to make its way within each agency. We do recognize that the below is an unusual request and hope that we can have a productive dialogue to somehow gain greater diagnostic capacity across the state and local public health laboratory system as soon as possible.

Thank you,

Scott Becker

---

**From:** Becker, Scott | APHL
**Sent:** Monday, February 24, 2020 10:39 AM
**To:** 'Stephen.Hahn@fda.hhs.gov' <Stephen.Hahn@fda.hhs.gov>
**Cc:** 'Keagan.Lenihan@fda.hhs.gov' <Keagan.Lenihan@fda.hhs.gov>; 'olx1@cdc.gov' <olx1@cdc.gov>; Kubin, Grace <Grace.Kubin@dshs.texas.gov>; dbj0@cdc.gov
**Subject:** enforcement discretion request for COVID-19 for PHLs final.pdf

Dear Commissioner Hahn,

On behalf of our nation's state and local public health laboratories (PHLs), we are writing to urge you to consider enforcement discretion to allow this select group of governmental laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request. The letter attached details our request.

Please contact me for any follow up or questions you may have at 301-526-5704 or scott.becker@aphl.org

Sincerely,

Scott Becker

**Scott J. Becker** (he/him)
Chief Executive Officer
**P** +1 240.485.2747 | **M** +1 301.526.5704
scott.becker@aphl.org | @scottjbecker

Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
www.aphl.org | APHL Blog
Facebook | Twitter | LinkedIn | Instagram

ID Lab Con 2020 | APHL 2020 Why Attend? (video)

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 5:38:38 PM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject**: RE: Minimal Criteria for test validation

Thank you

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 5:14 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

Uwe and I discussed and agree with the reductions below.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Stenzel, Timothy
**Sent:** Friday, February 28, 2020 5:13 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Elizabeth J Hillebrenner (Elizabeth.Hillebrenner@fda.hhs.gov) <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

See updates.

Best,

AMERICAN OVERSIGHT

*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 4:49 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

See edits

(b) (5)



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(b) (5)

[redacted]

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 4:43 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

Hi Uwe, Jeff and I (b) (5)

[redacted]

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Jennifer.Campbell@fda.hhs.gov

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---

**From:** Stenzel, Timothy
**Sent:** Friday, February 28, 2020 11:22 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

Giving further thought it looks good. Jeff, Can I share with the CDC?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:48 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Minimal Criteria for test validation

Hi Uwe,

This is wonderful. Can we change (b) (5) [redacted]

Thanks in advance Uwe! :)

Best,
Tim

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 10:41:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

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**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Minimal Criteria for test validation

Jeff and Tim,

(b) (5)



Let me know if you have any questions.

Uwe

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 9:50:34 PM
**To**: Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) [gky2@cdc.gov]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject**: RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Steve,

Don't worry, worked it all out. All, get your well deserved test. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Tuesday, February 4, 2020 9:49 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

I apologize, did not see the previous email. I am happy to hear that arrangements have already been made.

Regards,
Steve

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 9:30:41 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

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Steve, issue resolved. Got in contact with Dr. Odle, she will hand over the package to me tomorrow morning at 8:30 AM.
Uwe

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 4, 2020 at 8:28:08 PM EST
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Steve,
We are arranging to assure that when the package comes will be accepted. I heard the name of the CDC individual is Bryan Tayler. Do you have his phone number so I can call him.
Thanks, Uwe

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Date:** February 4, 2020 at 6:54:47 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

We are making arrangements to have it delivered in the morning.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 6:44:24 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

I would arrange for him to come back tomorrow morning now

Best regards
Kim

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Date:** February 4, 2020 at 6:27:01 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>

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**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Our courier is at FDA right now attempting to deliver the hard copy is there a security department or some other way for the courier to deliver the package or do we need to make arrangements for delivery tomorrow morning?

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 5:57:06 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

FYI - Documents are live on our website:

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Let me know if you see any issues
Best regards
Kim

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Date:** February 4, 2020 at 4:25:06 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Wonderful, thank you and the FDA team so much for all the support!!!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

**Battelle**
2987 Clairmont Road
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Atlanta, GA 30329
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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 4:11 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Julie and CDC Team,

Just wanted to give you the authorized copies of your documents – FYI. They should be posted on our website hopefully soon – I will update you as soon as I hear. Please note that there was a minor edit made to the HCP fact sheet during final review at the Commissioners Office so please use the documents attached going forward. The Final Label package document includes the IFU, Product Information Sheet and Verification requirements in 1 -bundle – no changes were made to these.

Congratulations again, and thank you

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 3:52 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Burke, Stephen A (CDC)

AMERICAN OVERSIGHT

<gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Uwe,

Once again, we had the great pleasure of collaborating with you and your team on another successful public health initiative. Thank you for everything – looking forward to the first amendment (but not this week)!

All of the very best,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 3:38 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Julie, Steve, and Steve,

CONGRATULATIONS! Your EUA has just been authorized by FDA! Please see attached the signed letter!

This is an incredible accomplishment! You can be extremely proud of your accomplishments and contributions to public health.

It has been an absolute pleasure to work with you.

Very kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 4, 2020 2:32 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>

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**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

The pdf of the updated instructions for use.

THANK YOU!
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:40 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

This works thank Julie

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:37 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

(b) (5)

Are you OK with that addition?

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:33 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Sounds good can you just add a footnote to (b) (5)
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:28 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

(b) (5)

Does this help?

Thanks,
Julie

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:25 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>;

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Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

**Dear Julie and Steve**

**Li has these numbers - please just check**

**Thanks**
**Kim**

**Table 4. Limit of Detection Confirmation of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with QIAGEN EZ1 DSP**

| Targets | 2019-nCoV_N1 | 2019-nCoV_N2 | (b) (5) |
|---|---|---|---|
| RNA Concentration[1] | (b) (5) | | |
| Positives/Total | | | |
| Mean Ct[2] | | | |
| Standard Deviation (Ct) | | | |

[1] Concentration is presented in RNA copies/µL
[2] Mean Ct reported for dilutions that are ≥95% positive
NA not applicable

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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AMERICAN OVERSIGHT

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:17 PM

**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Fantastic – thank you! We will accept the edits and will send a clean version with doc and rev numbers.
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:14 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

We concur

Thank you all

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

AMERICAN OVERSIGHT

Hi Kim,

We have made a few edits to the table and have found a few numbers that we've highlighted that we'd like you to double check. Happy to discuss again if needed.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 11:34 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Julie,

Please find attached our suggested edits – let us know if you concur ASAP.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 9:34 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

Hi Kim,

AMERICAN OVERSIGHT

Attached are our edits to the instructions for use. We appreciate the edits on the other documents, but unfortunately those documents have been printed and are with the kits at ATCC. We will update the typos in future versions and will send to you for approval. Please let me know if you have any questions.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 8:53 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Julie,

Please find attached some minor edits to the verification requirements, PIS and IFU,

Please let us know if you have any questions

Please send revised ASAP

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Monday, February 03, 2020 10:42 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

AMERICAN OVERSIGHT

**Subject:** CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

Hi Uwe,

Attached are the following for the CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission:

- CDC 2019 Novel Coronavirus Real-Time RT-PCR Diagnostic Panel EUA Request Letter
- EUA Template CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Executive Summary
- Appendix A_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers
- Appendix B_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Patients
- Appendix C_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Vial_Control Vial_Package Labeling_Final
- Appendix D_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Product Information Sheet
- Appendix E_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Instructions for Use
- Appendix F_CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Verification Requirements
- Appendix G_CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Analytical Performance Data
- Appendix H_ CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Sequence Alignment and In Silico Analysis
- Appendix I_ CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Clinical Performance Data

We cannot thank you enough for all of your assistance with this. We cannot do our jobs without you.

Best regards,
Julie

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/5/2020 8:34:12 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Odle, Bonnie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04e7ddabc0f64f0da75502341736f9ef-HHS-bbo9-cd]
**CC:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Julie,

I confirm that FDA received the hard copies of your EUA submissions. Marcella Odle just handed it over to me and, we are taking it to the document center now.

Thanks for getting it to us so quickly.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 4, 2020 7:25 PM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Odle, Bonnie M (CDC) <bbo9@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

AMERICAN OVERSIGHT

Hi Kim - we tried to have the hard copies delivered today but it was rejected. Long story short, Marcella Odle from my team is in Silver Spring for an APHL meeting and has the package. How do we arrange delivery to the doc control center?

Thanks,
Julie

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Tuesday, February 4, 2020 7:20:42 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Thanks Kim.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 7:04:37 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Great thanks Steve - it doesn't impact the EUA though so don't worry - the EUA is signed and issued

Best regards
Kim

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Date:** February 4, 2020 at 6:54:48 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

We are making arrangements to have it delivered in the morning.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 6:44:24 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

I would arrange for him to come back tomorrow morning now

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Best regards
Kim

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Date:** February 4, 2020 at 6:27:01 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Our courier is at FDA right now attempting to deliver the hard copy is there a security department or some other way for the courier to deliver the package or do we need to make arrangements for delivery tomorrow morning?

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 5:57:06 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

FYI - Documents are live on our website:

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Let me know if you see any issues
Best regards
Kim

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Date:** February 4, 2020 at 4:25:06 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Wonderful, thank you and the FDA team so much for all the support!!!

Regards,
Steve

AMERICAN OVERSIGHT

Steve Burke, Ph.D., RAC
*Program Manager*

*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

**Battelle**
2987 Clairmont Road
Suite 450
Atlanta, GA 30329
http://www.battelle.org

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 4:11 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Julie and CDC Team,

Just wanted to give you the authorized copies of your documents – FYI. They should be posted on our website hopefully soon – I will update you as soon as I hear. Please note that there was a minor edit made to the HCP fact sheet during final review at the Commissioners Office so please use the documents attached going forward. The Final Label package document includes the IFU, Product Information Sheet and Verification requirements in 1 -bundle – no changes were made to these.

Congratulations again, and thank you

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 3:52 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Uwe,

Once again, we had the great pleasure of collaborating with you and your team on another successful public health initiative. Thank you for everything – looking forward to the first amendment (but not this week)!

All of the very best,
Julie

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 3:38 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Julie, Steve, and Steve,

CONGRATULATIONS! Your EUA has just been authorized by FDA! Please see attached the signed letter!

This is an incredible accomplishment! You can be extremely proud of your accomplishments and contributions to public health.

It has been an absolute pleasure to work with you.

Very kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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uwe.scherf@fda.hhs.gov

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 4, 2020 2:32 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

The pdf of the updated instructions for use.

THANK YOU!
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:40 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

This works thank Julie

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:37 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>

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**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

We added this to footnote 2: (b) (5) .

Are you OK with that addition?

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:33 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Sounds good can you just add a footnote to (b) (5) .
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:28 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

(b) (5)

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Does this help?

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:25 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

**Dear Julie and Steve**

**Li has these numbers - please just check**

**Thanks**
**Kim**

**Table 4. Limit of Detection Confirmation of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with QIAGEN EZ1 DSP**

| Targets | 2019-nCoV_N1 | 2019-nCoV_N2 |
|---|---|---|
| RNA Concentration[1] | $10^{0.5}$ | (b) (5) |
| Positives/Total | 20/20 | |
| Mean Ct[2] | 32.5 | |
| Standard Deviation (Ct) | 0.5 | |

[1] Concentration is presented in RNA

[2] Mean Ct reported for dilutions that are ≥95% positive

NA not applicable

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Fantastic – thank you! We will accept the edits and will send a clean version with doc and rev numbers.
Julie

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:14 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

We concur

Thank you all

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov






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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:07 PM

**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Hi Kim,

We have made a few edits to the table and have found a few numbers that we've highlighted that we'd like you to double check. Happy to discuss again if needed.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 11:34 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Julie,

Please find attached our suggested edits – let us know if you concur ASAP.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov






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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 9:34 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

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**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

Hi Kim,

Attached are our edits to the instructions for use. We appreciate the edits on the other documents, but unfortunately those documents have been printed and are with the kits at ATCC. We will update the typos in future versions and will send to you for approval. Please let me know if you have any questions.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 8:53 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Julie,

Please find attached some minor edits to the verification requirements, PIS and IFU,

Please let us know if you have any questions

Please send revised ASAP

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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AMERICAN OVERSIGHT

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Monday, February 03, 2020 10:42 PM

**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

Hi Uwe,

Attached are the following for the CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission:

- CDC 2019 Novel Coronavirus Real-Time RT-PCR Diagnostic Panel EUA Request Letter
- EUA Template CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Executive Summary
- Appendix A_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers
- Appendix B_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Patients
- Appendix C_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Vial_Control Vial_Package Labeling_Final
- Appendix D_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Product Information Sheet
- Appendix E_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Instructions for Use
- Appendix F_CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Verification Requirements
- Appendix G_CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Analytical Performance Data
- Appendix H_ CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Sequence Alignment and In Silico Analysis
- Appendix I_ CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Clinical Performance Data

We cannot thank you enough for all of your assistance with this. We cannot do our jobs without you.

Best regards,
Julie

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/5/2020 9:19:45 AM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Odle, Bonnie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04e7ddabc0f64f0da75502341736f9ef-HHS-bbo9-cd]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Odle, Bonnie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04e7ddabc0f64f0da75502341736f9ef-HHS-bbo9-cd]
**Subject**: RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Very much apricated. ☺

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Wednesday, February 5, 2020 9:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Odle, Bonnie M (CDC) <bbo9@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Odle, Bonnie M (CDC) <bbo9@cdc.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Hi all,

There's nothing like the white glove, personal delivery service – only the best for you!

Thank you so much again!
Julie

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 5, 2020 8:34 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Odle, Marcella (CDC/DDID/NCEZID/DPEI) <bbo9@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Julie,

I confirm that FDA received the hard copies of your EUA submissions. Marcella Odle just handed it over to me and, we are taking it to the document center now.

Thanks for getting it to us so quickly.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 4, 2020 7:25 PM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Odle, Bonnie M (CDC) <bbo9@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Hi Kim - we tried to have the hard copies delivered today but it was rejected. Long story short, Marcella Odle from my team is in Silver Spring for an APHL meeting and has the package. How do we arrange delivery to the doc control center?

Thanks,
Julie

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Tuesday, February 4, 2020 7:20:42 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>

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**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Thanks Kim.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 7:04:37 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Great thanks Steve - it doesn't impact the EUA though so don't worry - the EUA is signed and issued

Best regards
Kim

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Date:** February 4, 2020 at 6:54:48 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

We are making arrangements to have it delivered in the morning.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 6:44:24 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

I would arrange for him to come back tomorrow morning now

Best regards
Kim

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Date:** February 4, 2020 at 6:27:01 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>

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**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Our courier is at FDA right now attempting to deliver the hard copy is there a security department or some other way for the courier to deliver the package or do we need to make arrangements for delivery tomorrow morning?

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 5:57:06 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

FYI - Documents are live on our website:

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Let me know if you see any issues
Best regards
Kim

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Date:** February 4, 2020 at 4:25:06 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Wonderful, thank you and the FDA team so much for all the support!!!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

**Battelle**
2987 Clairmont Road
Suite 450
Atlanta, GA 30329
http://www.battelle.org

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 4:11 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Julie and CDC Team,

Just wanted to give you the authorized copies of your documents – FYI. They should be posted on our website hopefully soon – I will update you as soon as I hear. Please note that there was a minor edit made to the HCP fact sheet during final review at the Commissioners Office so please use the documents attached going forward. The Final Label package document includes the IFU, Product Information Sheet and Verification requirements in 1 -bundle – no changes were made to these.

Congratulations again, and thank you

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 3:52 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Burke, Stephen A (CDC)

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<gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Uwe,

Once again, we had the great pleasure of collaborating with you and your team on another successful public health initiative. Thank you for everything – looking forward to the first amendment (but not this week)!

All of the very best,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 3:38 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Julie, Steve, and Steve,

CONGRATULATIONS! Your EUA has just been authorized by FDA! Please see attached the signed letter!

This is an incredible accomplishment! You can be extremely proud of your accomplishments and contributions to public health.

It has been an absolute pleasure to work with you.

Very kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 4, 2020 2:32 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>

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**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

The pdf of the updated instructions for use.

THANK YOU!
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:40 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

This works thank Julie

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:37 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

(b) (5)

Are you OK with that addition?

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:33 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Sounds good can you just add a footnote to (b) (5) [redacted]
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:28 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

(b) (5) [redacted]

Does this help?

Thanks,
Julie

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:25 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>;

AMERICAN OVERSIGHT

Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

**Dear Julie and Steve**

**Li has these numbers - please just check**

**Thanks**
**Kim**

**Table 4. Limit of Detection Confirmation of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with QIAGEN EZ1 DSP**

| Targets | 2019-nCoV_N1 | 2019-nCoV_N2 | (b) (5) |
|---|---|---|---|
| RNA Concentration[1] | $10^{0.5}$ | (b) (5) | |
| Positives/Total | 20/20 | | |
| Mean Ct[2] | 32.5 | | |
| Standard Deviation (Ct) | 0.5 | | |

[1] Concentration is presented in RNA copies/µL
[2] Mean Ct reported for dilutions that are ≥95% positive
NA not applicable

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:17 PM

**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Fantastic – thank you! We will accept the edits and will send a clean version with doc and rev numbers.
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 12:14 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

We concur

Thank you all

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 12:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

AMERICAN OVERSIGHT

Hi Kim,

We have made a few edits to the table and have found a few numbers that we've highlighted that we'd like you to double check. Happy to discuss again if needed.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 11:34 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Dear Julie,

Please find attached our suggested edits – let us know if you concur ASAP.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 04, 2020 9:34 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

Hi Kim,

AMERICAN OVERSIGHT

Attached are our edits to the instructions for use. We appreciate the edits on the other documents, but unfortunately those documents have been printed and are with the kits at ATCC. We will update the typos in future versions and will send to you for approval. Please let me know if you have any questions.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 8:53 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Julie,

Please find attached some minor edits to the verification requirements, PIS and IFU,

Please let us know if you have any questions

Please send revised ASAP

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
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Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Monday, February 03, 2020 10:42 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

AMERICAN OVERSIGHT

**Subject:** CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission
**Importance:** High

Hi Uwe,

Attached are the following for the CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission:

- CDC 2019 Novel Coronavirus Real-Time RT-PCR Diagnostic Panel EUA Request Letter
- EUA Template CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Executive Summary
- Appendix A_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers
- Appendix B_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Patients
- Appendix C_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Vial_Control Vial_Package Labeling_Final
- Appendix D_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Product Information Sheet
- Appendix E_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Instructions for Use
- Appendix F_CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Verification Requirements
- Appendix G_CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Analytical Performance Data
- Appendix H_ CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Sequence Alignment and In Silico Analysis
- Appendix I_ CDC_2019-nCoV Real_Time RT-PCR Diagnostic Panel Clinical Performance Data

We cannot thank you enough for all of your assistance with this. We cannot do our jobs without you.

Best regards,
Julie

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/26/2020 9:03:46 PM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**CC:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**Subject:** Re: N95 EUA for COVID19

(b) (5)

Jeff

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 26, 2020 at 8:51:44 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Fwd: N95 EUA for COVID19

(b) (5)

We'll have to pursue this further with them.

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile(b) (6)

---

**From:** D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
**Date:** February 26, 2020 at 8:46:43 PM EST
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Pillai, Satish K (CDC) <vig8@cdc.gov>, Yu, Yon C (CDC) <fkb8@cdc.gov>, Patel, Anita (CDC) <bop1@cdc.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Delaney, Lisa (CDC) <lkd2@cdc.gov>, Dowell, Chad (CDC) <crd7@cdc.gov>
**Cc:** Miller, Colleen S (CDC) <hku6@cdc.gov>, Peterson, Jeffrey A (CDC) <jap3@cdc.gov>
**Subject:** RE: N95 EUA for COVID19

AMERICAN OVERSIGHT

Dear FDA Colleagues,

CDC/NIOSH appreciates the opportunity to discuss the Emergency Use Authorization to permit the use of NIOSH-approved filtering facepiece respirators currently not cleared by the FDA in healthcare settings.

(b) (5)

[redacted]

Please copy all CDC folks on this message when submitting the draft to us for review.

Thank you,

Maryann

**Maryann M. D'Alessandro, PhD**
Director
HHS/Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety & Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
626 Cochrans Mill Rd
Building 141, Rm 105
Pittsburgh, PA 15236

Office: (412) 386-4033
Mobile: (412) 760-3449
bpj5@cdc.gov

-----Original Appointment-----
**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 7:45 AM
**To:** Schwartz, Suzanne; Flannery, Ellen (FDA/CDRH); Ross, Aftin (FDA/CDRH); Tomasello, Jennifer (FDA/CDRH); Pillai, Satish K. (CDC/DDID/NCEZID/DPEI); Yu, Yon C. (CDC/DDID/NCEZID/DPEI); D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL); Patel, Anita (CDC/DDID/NCIRD/OD); Courtney, Brooke (FDA/OC); Delaney, Lisa (CDC/NIOSH/OD); Dowell, Chad (CDC/NIOSH/OD)
**Subject:** N95 EUA for COVID19

AMERICAN OVERSIGHT

**When:** Wednesday, February 26, 2020 2:30 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** Suzanne's Office/ WebEx below

**When it's time, join your Webex meeting here.**

Meeting number (access code): (b) (6)
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If you are a host, go here to view host information.

Need help? Go to http://help.webex.com

**From:** D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
**Date:** February 26, 2020 at 7:08:46 AM EST
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Patel, Anita (CDC) <bop1@cdc.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Pillai, Satish K (CDC) <vig8@cdc.gov>, Yu, Yon C (CDC) <fkb8@cdc.gov>, Delaney, Lisa (CDC) <lkd2@cdc.gov>, Dowell, Chad (CDC) <crd7@cdc.gov>
**Subject:** RE: N95 EUA

+ Lisa Delaney
+ Chad Dowell

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 12:13 AM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Cc:** Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Ross, Aftin (FDA/CDRH) <Aftin.Ross@fda.hhs.gov>; Tomasello, Jennifer (FDA/CDRH) <Jennifer.Tomasello@fda.hhs.gov>; Pillai, Satish K. (CDC/DDID/NCEZID/DPEI) <vig8@cdc.gov>; Yu, Yon C. (CDC/DDID/NCEZID/DPEI) <fkb8@cdc.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL)

AMERICAN OVERSIGHT

<bpj5@cdc.gov>
**Subject:** RE: N95 EUA

That works on our end. We'll provide an invite with a call-in.
TY! get some rest…

Suzanne

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell: (b) (6)
Suzanne.Schwartz@fda.hhs.gov




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**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Wednesday, February 26, 2020 12:12 AM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Pillai, Satish K (CDC) <vig8@cdc.gov>; Yu, Yon C (CDC) <fkb8@cdc.gov>; D'alessandro, Maryann M (CDC) <bpj5@cdc.gov>
**Subject:** RE: N95 EUA

How about 2:30?
+ Yon from CDC reg affairs

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 11:52 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Cc:** Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Ross, Aftin (FDA/CDRH) <Aftin.Ross@fda.hhs.gov>; Tomasello, Jennifer (FDA/CDRH) <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** N95 EUA
**Importance:** High

Anita,

In follow up to our FDA-CDC-ASPR call this afternoon regarding N95 EUA for COVID19, we (CDRH) had some additional questions to get the ball rolling.

Can you spare 30 minutes tomorrow for us to discuss?
I will do my best to accommodate to your availability as I'm sure your time is overcommitted.
The only times I absolutely cannot get on a call tomorrow (Wednesday) is 9-9:30 and noon to 1pm.

AMERICAN OVERSIGHT

Suzanne

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell (b) (6)
Suzanne.Schwartz@fda.hhs.gov




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-- Do not delete or change any of the following text. --

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/16/2020 7:28:56 PM
**To**: Kuhnert-Tallman, Wendi (CDC/DDID/OD) [wdk1@cdc.gov]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: Request for enforcement discretion

Wendi,

We have worked through your request with the FDA attorneys. Given the limitations you describe and under the specific circumstances for which the testing will be performed, we will forgo requiring that CDC submit an application for a new EUA or a request to modify its existing EUA to include testing of asymptomatic individuals at CDC's headquarters in Atlanta, GA.

Kind regards,

Jeff

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Sunday, February 16, 2020 7:08 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: Request for enforcement discretion

Jeff and others, we appreciate the response and will continue with our testing plan as discussed for this one set of samples.

Thanks, Wendi.

Get Outlook for iOS

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 6:54:14 AM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Kuhnert-Tallman,

AMERICA OVERSIGHT

Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Subject:** RE: Request for enforcement discretion

Wendi,

We are still working with the FDA attorneys to address your request. In the interim, CDC should proceed with its plans for testing the returning travelers from the Princess Diamond cruise ship. There should be no delay in the actions you need to take.

Kind regards,

Jeff

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Date:** February 15, 2020 at 7:12:25 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** RE: Request for enforcement discretion

Dear Uwe,

We wish to thank you and your colleagues at FDA for the rapid response to our urgent request for FDA enforcement discretion. We appreciate your willingness to allow our testing of returning US travelers from the Diamond Princess cruise ship, as required of CDC by HHS. CDC agrees to restrict testing to CDC's headquarters in Atlanta, GA and will agree to share data generated in this repatriation testing activity. (b) (5)

[redacted]

CDC would welcome the opportunity to discuss further.

We greatly appreciate FDA's partnership in this response.

Warm regards,
Wendi

**Wendi Kuhnert-Tallman**
**Office - 404-639-3103**
**Mobile – 678-576-2121**

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 5:29 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Cc:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion
**Importance:** High

Dear Dr. Kuhnert-Tallman,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

On February 15, 2020, CDC submitted to FDA a request for enforcement discretion from FDA for the testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Asymptomatic individuals do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC has stated that testing will be conducted at CDC's headquarters in Atlanta, GA. Specimens are expected to arrive at CDC for testing during this holiday weekend.

Our understanding of the facts and the public health concerns at issue here are that there is currently no other test available to respond to this emergency, significant public health concerns are presented by the infectious disease, and the proposed testing may help to prevent the spread of the infectious disease. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the following conditions: (b) (5)

(b) (5)

Regards,

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 15, 2020 12:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC)

AMERICAN OVERSIGHT

<dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Request for enforcement discretion

Good afternoon Dr. Scherf,

CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. (b) (5) [redacted]

Laura Rose, Regulatory Affairs Activity Lead for OLSS, is the primary point of contact at CDC to facilitate communications about this request. She may be reached at 404-639-1084 or LERose@cdc.gov.

Warm regards,
Wendi

Wendi Kuhnert-Tallman
ADIM
Mobile – 678-576-2121
CDC IMS LAB TF
2019 nCoV Response
eocevent177@cdc.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/21/2020 6:11:46 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Cut-off change - lot release testing criteria

Uwe,

Thank you. That is encouraging.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 6:04 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: Cut-off change - lot release testing criteria

Jeff,

We received the QC testing data for N1 & N2 following the heightened QC protocol. This data show that the new N1 and N2 lots are clean.
(b) (5)

Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 3:37 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hello Uwe,
We would like to share with you our bulk QC data summary for oligo sets N1, N2 and RP for your review. (b) (5)

Please be aware there are two tab in the excel file.
Please let us know if you have questions.
Do you and your colleagues have a time tomorrow that you would like to arrange a call to discuss?
Thank you very much.
Steve

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>

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**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,

(b) (5)

[redacted]

We hope this helps to clarify the data presented and addresses your request.
Thank you very much.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 10:07 AM
**To:** 'Scherf, Uwe' <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,

(b) (5)

[redacted]

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Thank you very much.
Steve

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing the (b) (5)

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

(b) (5)

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Steve,

Thank you for the update, when will you send us (b) (5) [redacted]

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

(b) (5) [redacted]

Please let us know if you have any additional questions.
Thank you very much!
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5) [redacted]

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5)



If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

AMERICAN OVERSIGHT

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts in (b) (5), please provide information regarding the (b) (5)

Thanks,
Uwe

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.

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4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) [redacted]

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) [redacted], is that correct?

Thank you for your feedback.

Uwe

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/16/2020 7:23:09 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** Re: Request for enforcement discretion

Thank you. I'll let CDC know (b) (5) [redacted]

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 16, 2020 at 7:20:23 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: Request for enforcement discretion

They said (b) (5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 16, 2020 at 4:41:36 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: Request for enforcement discretion

Any word yet from OCC?

Jeff

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 16, 2020 at 7:17:00 AM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: Request for enforcement discretion

(b) (5) [redacted]

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 16, 2020 at 7:03:51 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: Request for enforcement discretion

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Confidential communication from OCC counsel

Jeff,

This is the only OCC response so far. (b) (5) [redacted]

Ellen

---

**From:** Beers, Donald <Donald.Beers@fda.hhs.gov>
**Date:** February 15, 2020 at 10:48:40 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** Re: Request for enforcement discretion

(b) (5) [redacted]

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 15, 2020 at 8:59:04 PM EST
**To:** Raza, Mark <Mark.Raza@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** FW: Request for enforcement discretion
**Importance:** High

Dear OCC,

CDRH is requesting your further assistance on this matter.

(b) (5) [redacted]

Thanks,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration

AMERICAN OVERSIGHT

Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

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---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 15, 2020 7:12 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** RE: Request for enforcement discretion

Dear Uwe,

We wish to thank you and your colleagues at FDA for the rapid response to our urgent request for FDA enforcement discretion. We appreciate your willingness to allow our testing of returning US travelers from the Diamond Princess cruise ship, as required of CDC by HHS. CDC agrees to restrict testing to CDC's headquarters in Atlanta, GA and will agree to share data generated in this repatriation testing activity. (b) (5) [redacted]

[redacted]

CDC would welcome the opportunity to discuss further.

We greatly appreciate FDA's partnership in this response.

Warm regards,
Wendi

**Wendi Kuhnert-Tallman**
**Office - 404-639-3103**
**Mobile – 678-576-2121**

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 5:29 PM

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**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Cc:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion
**Importance:** High

Dear Dr. Kuhnert-Tallman,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

On February 15, 2020, CDC submitted to FDA a request for enforcement discretion from FDA for the testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Asymptomatic individuals do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC has stated that testing will be conducted at CDC's headquarters in Atlanta, GA. Specimens are expected to arrive at CDC for testing during this holiday weekend.

Our understanding of the facts and the public health concerns at issue here are that there is currently no other test available to respond to this emergency, significant public health concerns are presented by the infectious disease, and the proposed testing may help to prevent the spread of the infectious disease. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the following conditions: (b) (5)

[redacted]

Regards,

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 15, 2020 12:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Request for enforcement discretion

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Good afternoon Dr. Scherf,

CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. (b) (5)

Laura Rose, Regulatory Affairs Activity Lead for OLSS, is the primary point of contact at CDC to facilitate communications about this request. She may be reached at 404-639-1084 or LERose@cdc.gov.

Warm regards,
Wendi

Wendi Kuhnert-Tallman
ADIM
Mobile – 678-576-2121
CDC IMS LAB TF
2019 nCoV Response
eocevent177@cdc.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/23/2020 1:06:36 PM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**Subject:** RE: N95 decon and reuse -- preparatory to 3M call

No worries

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 23, 2020 at 1:03:53 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 decon and reuse -- preparatory to 3M call

I'm a little short on time at the moment, trying to complete review of a few other items for Heather and Aftin, so I will defer. But if I can help clarify anything, I can hop on as needed.

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
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Tel: 301-796-6937
Cell: (b) (6)
Suzanne.Schwartz@fda.hhs.gov




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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 12:56 PM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** RE: N95 decon and reuse -- preparatory to 3M call

Thank you. Let me know if you want to be on this call but you don't need to.

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 12:46 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 decon and reuse -- preparatory to 3M call

More-
The pandemic PHE modeling that was done by BARDA as part of its assignment in the RPD WG and is described in great detail in the appendix of the document I shared with you, (b) (5)
(b) (5)

AMERICAN OVERSIGHT

This should be mentioned

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
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Office of Strategic Partnerships and Technology Innovation (OST)
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Cell: (b) (6)
Suzanne.Schwartz@fda.hhs.gov




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---

**From:** Schwartz, Suzanne
**Sent:** Sunday, February 23, 2020 12:32 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 decon and reuse -- preparatory to 3M call

Postscript-
Kevin Yeskey was one of the signatories on the 2015 PHEMCE document. I note he is on the thread below.

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
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Cell: (b) (6)
Suzanne.Schwartz@fda.hhs.gov




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---

**From:** Schwartz, Suzanne
**Sent:** Sunday, February 23, 2020 12:31 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 decon and reuse -- preparatory to 3M call
**Importance:** High

Jeff,
First, we are aware of the 2006 IOM Report and recommendations. Yesterday, I mentioned the work product that the HHS OpDivs put out under PHEMCE in 2015 as part of a year long coordinated effort through the RPD WorkGroup, that CDRH and OCET participated in on behalf of FDA. I am attaching that full chapter here as it should be serving as a foundational reference document and guidance for COVID19. This was a well thought out effort that included FDA, CDC,

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NIOSH, OSHA, ASPR, BARDA, VA modeled primarily om influenza pandemic. CDC's guidances to healthcare workers and general public today for COVID 19 draw upon this important document (b) (5)
(b) (5)

I'm selecting specific sections and highlighting them below as important background for your HHS discussion since the use objective for the intended wearer of N95 respirators (known as filtering face piece respirators or FFRs) in pandemic scenarios needs to be clearly distinguished from use of masks by potentially infected individual(s) to limit transmission.

See these sections:

(b) (5)

Regarding making the most of a single disposable N95 respirator, we included discussion of 'extended use' and 'reuse'. Yesterday, I used with you the term 'reuse' by a single healthcare worker somewhat loosely, intending 'extended use'.
(b) (5)

(b) (5)

Recommend that you look at (b) (5)
(b) (5)

Happy to discuss further but wanted you to have this in your backpocket for your call ASAP

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:45 AM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** Fwd: N95 decon and reuse -- preparatory to 3M call

Suzanne,

Please see below about the IOM's finding. I thought you mentioned that a disposable N95 could be reused if used by the same individual (although that would not stop that individual from infecting others)?

FYI — I'll be on a call with HHS, CDC, and possibly 3M at 1 PM (although that may get pushed to 2 PM) to discuss use of standard N95s.

Jeff

---

**From:** Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>
**Date:** February 23, 2020 at 11:39:27 AM EST
**To:** Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Ford-Barnes, Arwenthia (OS) <Arwenthia.FordBarnes@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Brady, William (OS) <William.Brady@hhs.gov>, Austin, Meredith (uscg.mil) <Meredith.L.Austin@uscg.mil>, Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>
**Cc:** Hahn, Stephen (b) (6)@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** N95 decon and reuse -- preparatory to 3M call

Dr Kadlec—

(b) (5)



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(b) (5)

[redacted]

Chris

D. Christian Hassell, PhD
Senior Science Advisor
Assistant Secretary for Preparedness and Response (ASPR)
Department of Health and Human Services (HHS)
Washington, DC 20201

David.Hassell@hhs.gov
+1-202 (b) (6) office)
+1-202 mobile)

-----Original Appointment-----
**From:** Ford-Barnes, Arwenthia (OS/ASPR/IO) <Arwenthia.FordBarnes@hhs.gov> **On Behalf Of** Kadlec, Robert (OS/ASPR/IO)
**Sent:** Sunday, February 23, 2020 11:17 AM
**To:** Shuy, Bryan (OS/ASPR/IO); Ford-Barnes, Arwenthia (OS/ASPR/IO); Adams, Steven A. (CDC/SNS/DSNS); Callahan, Victoria (OS/ASPR/IO) (CTR); Brady, Will (HHS/IOS); Austin, Meredith (uscg.mil); Hassell, David (Chris) (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO)
**Cc:** (b) (6) @fda.hhs.gov; Shuren, Jeff (FDA/CDRH); (b) (6) @mmm.com
**Subject:** 3M
**When:** Sunday, February 23, 2020 2:00 PM-2:45 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** Dial in: (b) (6)

**HOLD: 3M**
Scheduled: Sunday, Feb 23, 2020 from 1:00 PM to 1:45 PM
Location: TBD
Invitees: Steve Hahn, Shuy, Bryan (OS/ASPR/IO), Callahan, Victoria (OS/ASPR/IO) (CTR), Jeffrey Shuren, Kadlec, Robert (OS/ASPR/IO), Ford-Barnes, Arwenthia (OS/ASPR/IO), Adams, Steven A. (CDC/SNS/DSNS)

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/23/2020 12:55:38 PM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**Subject:** RE: N95 decon and reuse -- preparatory to 3M call

Thank you. Let me know if you want to be on this call but you don't need to.

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(b) (5)

This should be mentioned

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*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
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Suzanne.Schwartz@fda.hhs.gov




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**From:** Schwartz, Suzanne
**Sent:** Sunday, February 23, 2020 12:32 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 decon and reuse -- preparatory to 3M call

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*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
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U.S. Food and Drug Administration
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Cell: (b) (6)
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FDA U.S. FOOD & DRUG ADMINISTRATION

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---

**From:** Schwartz, Suzanne
**Sent:** Sunday, February 23, 2020 12:31 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 decon and reuse -- preparatory to 3M call
**Importance:** High

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See these sections:

(b) (5)

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(b) (5)

(b) (5)

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(b) (5)

Recommend that you look at (b) (5)
(b) (5)

Happy to discuss further but wanted you to have this in your backpocket for your call ASAP

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:45 AM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** Fwd: N95 decon and reuse -- preparatory to 3M call

Suzanne,

Please see below about the IOM's finding. I thought you mentioned that a disposable N95 could be reused if used by the same individual (although that would not stop that individual from infecting others)?

FYI — I'll be on a call with HHS, CDC, and possibly 3M at 1 PM (although that may get pushed to 2 PM) to discuss use of standard N95s.

Jeff

---

**From:** Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>
**Date:** February 23, 2020 at 11:39:27 AM EST
**To:** Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Ford-Barnes, Arwenthia (OS) <Arwenthia.FordBarnes@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Brady, William (OS) <William.Brady@hhs.gov>, Austin, Meredith (uscg.mil) <Meredith.L.Austin@uscg.mil>, Yeskey, Kevin (OS)

AMERICAN OVERSIGHT

<Kevin.Yeskey@hhs.gov>
**Cc:** Hahn, Stephen (b) (6)@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** N95 decon and reuse -- preparatory to 3M call

Dr Kadlec—

(b) (5)

Chris

D. Christian Hassell, PhD
Senior Science Advisor
Assistant Secretary for Preparedness and Response (ASPR)
Department of Health and Human Services (HHS)
Washington, DC 20201

David.Hassell@hhs.gov
+1-202 (b) (6) (office)
+1-202 (mobile)

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-----Original Appointment-----
**From:** Ford-Barnes, Arwenthia (OS/ASPR/IO) <Arwenthia.FordBarnes@hhs.gov> **On Behalf Of** Kadlec, Robert (OS/ASPR/IO)
**Sent:** Sunday, February 23, 2020 11:17 AM
**To:** Shuy, Bryan (OS/ASPR/IO); Ford-Barnes, Arwenthia (OS/ASPR/IO); Adams, Steven A. (CDC/SNS/DSNS); Callahan, Victoria (OS/ASPR/IO) (CTR); Brady, Will (HHS/IOS); Austin, Meredith (uscg.mil); Hassell, David (Chris) (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO)
**Cc:** (b) (6)@fda.hhs.gov; Shuren, Jeff (FDA/CDRH); (b) (6) @mmm.com
**Subject:** 3M
**When:** Sunday, February 23, 2020 2:00 PM-2:45 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** Dial in: (b) (6)

**HOLD: 3M**
Scheduled: Sunday, Feb 23, 2020 from 1:00 PM to 1:45 PM
Location: TBD
Invitees: Steve Hahn, Shuy, Bryan (OS/ASPR/IO), Callahan, Victoria (OS/ASPR/IO) (CTR), Jeffrey Shuren, Kadlec, Robert (OS/ASPR/IO), Ford-Barnes, Arwenthia (OS/ASPR/IO), Adams, Steven A. (CDC/SNS/DSNS)

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/14/2020 5:10:49 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
**Subject:** RE: two quick read items to flag--

We didn't go into details on the history of morcellators other than to say (b) (5) [redacted]. I can go into more detail.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 5:07 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** RE: two quick read items to flag--

(b) (5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 4:54 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** RE: two quick read items to flag--

Yes, happy to update him on (b) (5) [redacted]

Jeff

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 14, 2020 at 4:35:24 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** RE: two quick read items to flag--

Thanks for flagging.

On another note – Lauren R mentioned (b) (5) [redacted] today to me. (b) (5) [redacted] pls.

(b) (5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 4:28 PM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: two quick read items to flag--

AMERICAN OVERSIGHT

FYI – I wanted to provide some follow up (b) (5), (b) (4) [redacted]

Jeff

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 5:56 PM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
**Subject:** FW: two quick read items to flag--

See ETO below from aspr

---

**From:** Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
**Sent:** Wednesday, February 12, 2020 4:28 PM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** two quick read items to flag--

Hey Anna,

Two quick things. One, presume this is on your radar https://www.fiercepharma.com/pharma-asia/chinese-firm-copies-gilead-s-remdesivir-most-promising-drug-against-new-coronavirus ? (b) (5) [redacted]

Best,
Bryan

Deputy Assistant Secretary and Chief of Staff
Immediate Office, Assistant Secretary for Preparedness and Response (ASPR)
US Dept. Health and Human Services (HHS)
Desk: 202-(b) (6) [redacted]
Mobile: 20
bryan.shuy@hhs.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/13/2020 1:50:23 PM
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
**Subject:** RE: N95 Respirators - internal confidential

You can use the following. Let me know if you have questions or need anything else.

(b) (5)

[redacted]

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 1:27 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 Respirators - internal confidential

(b) (5) [redacted] Thanks so much. What's the top 3 things I need to know if he asks. Thanks so much.

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 12:49 PM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Hahn, Stephen (b) (6) [redacted] @fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: N95 Respirators - internal confidential

Yes, we would engage in pre-EUA discussions with CDC and any of the manufacturers. We will also develop an EUA template. Same drill as we've done for tests.

(b) (5)

[redacted]

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 13, 2020 at 12:41:17 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hahn, Stephen (b) (6) [redacted] @fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: N95 Respirators - internal confidential

AMERICAN OVERSIGHT

Jeff, (b) (5) [redacted]

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 12:39 PM
**To:** Hahn, Stephen (b) (6) [redacted]@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Re: N95 Respirators

(b) (4), (b) (5) [redacted]

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**From:** Hahn, Stephen (b) (6) [redacted]@fda.hhs.gov>
**Date:** February 13, 2020 at 12:33:06 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Thanks, Jeff. (b) (5) [redacted]
Steve

---

**From:** Jeffrey Shuren <Jeff.Shuren@fda.hhs.gov>
**Date:** Thursday, February 13, 2020 at 12:32 PM
**To:** Stephen Hahn (b) (6) [redacted]@fda.hhs.gov>, Anna Abram <Anna.Abram@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** N95 Respirators

Confidential/Deliberative/Privileged

(b) (5) [redacted]

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/15/2020 4:06:31 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]
**Subject**: RE: Request for enforcement discretion

Thank you, Ellen.

Uwe – when you send the email to CDC please cc Ellen and me.

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 4:05 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion

OCC has cleared us for enforcement discretion. They did not modify my draft language. Below is the language for Uwe to use to respond to CDC, which includes the change to Uwe's language about the data we are requesting.

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

On February 15, 2020, CDC submitted to FDA a request for enforcement discretion from FDA for the testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Asymptomatic individuals do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC has stated that testing will be conducted at CDC's headquarters in Atlanta, GA. Specimens are expected to arrive at CDC for testing during this holiday weekend.

Our understanding of the facts and the public health concerns at issue here are that there is currently no other test available to respond to this emergency, significant public health concerns are presented by the infectious disease, and the proposed testing may help to prevent the spread of the infectious disease. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the following conditions: that the testing will be conducted only at CDC's headquarters in Atlanta, GA, that CDC will submit data to FDA on the number of asymptomatic cases identified as being positive during the testing, and that CDC will act promptly to submit an application for a new EUA or a request to modify its existing EUA to include testing of asymptomatic individuals at CDC's headquarters in Atlanta, GA.

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 2:18 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Subject:** FW: Request for enforcement discretion
**Importance:** High

Jeff and Ellen,

See below the official request from CDC.

As stated in my previous email, based on our knowledge of the device, DMD would not have objections allowing CDC to test asymptomatic individuals using the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship. Provided that testing be conducted at CDC's headquarters in Atlanta, GA.

Ellen, per my phone conversation with Jeff, he agrees but would like your input on FDA's intend to not object to the use of the 2019-Novel Coronavirus (2019-nCoV). Please let me know if your thoughts on CDC's request.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 15, 2020 12:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Request for enforcement discretion

Good afternoon Dr. Scherf,

CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. (b) (5)

AMERICAN OVERSIGHT

Laura Rose, Regulatory Affairs Activity Lead for OLSS, is the primary point of contact at CDC to facilitate communications about this request. She may be reached at 404-639-1084 or LERose@cdc.gov.

Warm regards,
Wendi

Wendi Kuhnert-Tallman
ADIM
Mobile – 678-576-2121
CDC IMS LAB TF
2019 nCoV Response
eocevent177@cdc.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/17/2020 1:05:25 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: BY noon tomorrow

Thank you.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 17, 2020 at 12:40:22 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Uwe, My POC thoughts below. Copying Jeff for his awareness.

REALLLY need help from FDA and CDC to find a coordinated approach to communicate around Dx capacity, Dx testing development and DX utilization.
Need today -

(b) (5)

Dear Rosemary,

Here are my thoughts.

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 17, 2020 at 9:59:06 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: BY noon tomorrow

Tim,

I need your help on this request, since I will not find time to provide feedback to Rosemary.

I am working with CDC on their change in cut-off proposal.

Thanks,
Uwe

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 8:36 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** BY noon tomorrow

Uwe and Wendi,
We have been asked to put together a one-pager (b) (5)

(b) (5)

Need today -

(b) (5)

Thanks very much,
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA

AMERICAN OVERSIGHT

202
Cel (b) (6)

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/15/2020 3:42:05 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Request for enforcement discretion

Yes, let's use Uwe's highlighted language. I also learned that these individuals will continue to be quarantined so I added that in green highlight below. Otherwise, looks good to me.

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 3:38 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion

Uwe and Jeff,

I had already sent a draft to OCC – see below -- and they are reviewing it now. We just had a call so I could explain this request and the one still to come. I can change the request for data in my draft to the more specific language that Uwe yellow-highlighted in his draft.

Thanks,
Ellen

Privileged and Confidential Draft / Deliberative / Predecisional

(b) (5)



AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 3:32 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion

Jeff & Ellen,

Here suggested language for the asymptomatic individual testing for consideration:

(b) (5)

Regarding the request for a change in cut-off, I am still waiting for CDC's email describing their proposal in more detail.

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 3:25 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion

Uwe,

Ellen is working with OCC on the "no objection" language, and to include that we don't object if this use on asymptomatic individuals if it is subsequently included under the EUA.

Please let me know when the team has made a decision on the cut off request. (b) (5)
(b) (5) . If there's any information Ellen can use to start on that language now so we can wrap this up today, please let us know.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 2:18 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>

AMERICAN OVERSIGHT

**Subject:** FW: Request for enforcement discretion
**Importance:** High

Jeff and Ellen,

See below the official request from CDC.

As stated in my previous email, based on our knowledge of the device, DMD would not have objections allowing CDC to test asymptomatic individuals using the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship. Provided that testing be conducted at CDC's headquarters in Atlanta, GA.

Ellen, per my phone conversation with Jeff, he agrees but would like your input on FDA's intend to not object to the use of the 2019-Novel Coronavirus (2019-nCoV). Please let me know if your thoughts on CDC's request.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 15, 2020 12:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Request for enforcement discretion

Good afternoon Dr. Scherf,

CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. (b) (5)

Laura Rose, Regulatory Affairs Activity Lead for OLSS, is the primary point of contact at CDC to facilitate communications about this request. She may be reached at 404-639-1084 or LERose@cdc.gov.

Warm regards,
Wendi

AMERICAN OVERSIGHT
Wendi Kuhnert-Tallman

ADIM
Mobile – 678-576-2121
CDC IMS LAB TF
2019 nCoV Response
eocevent177@cdc.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/23/2020 11:45:22 AM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**Subject:** Fwd: N95 decon and reuse -- preparatory to 3M call

Suzanne,

Please see below about the IOM's finding. I thought (b) (5)
(b) (5)

FYI — I'll be on a call with HHS, CDC, and possibly 3M at 1 PM (although that may get pushed to 2 PM) to discuss use of standard N95s.

Jeff

---

**From:** Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>
**Date:** February 23, 2020 at 11:39:27 AM EST
**To:** Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Ford-Barnes, Arwenthia (OS) <Arwenthia.FordBarnes@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Brady, William (OS) <William.Brady@hhs.gov>, Austin, Meredith (uscg.mil) <Meredith.L.Austin@uscg.mil>, Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>
**Cc:** Hahn, Stephen (b) (6)@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** N95 decon and reuse -- preparatory to 3M call

Dr Kadlec—
(b) (5)

AMERICAN OVERSIGHT

(b) (5)

Chris

D. Christian Hassell, PhD
Senior Science Advisor
Assistant Secretary for Preparedness and Response (ASPR)
Department of Health and Human Services (HHS)
Washington, DC 20201

David.Hassell@hhs.gov
+1-202(b) (6) (office)
+1-202 (mobile)

-----Original Appointment-----
**From:** Ford-Barnes, Arwenthia (OS/ASPR/IO) <Arwenthia.FordBarnes@hhs.gov> **On Behalf Of** Kadlec, Robert (OS/ASPR/IO)
**Sent:** Sunday, February 23, 2020 11:17 AM
**To:** Shuy, Bryan (OS/ASPR/IO); Ford-Barnes, Arwenthia (OS/ASPR/IO); Adams, Steven A. (CDC/SNS/DSNS); Callahan, Victoria (OS/ASPR/IO) (CTR); Brady, Will (HHS/IOS); Austin, Meredith (uscg.mil); Hassell, David (Chris) (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO)
**Cc:** (b) (6) @fda.hhs.gov; Shuren, Jeff (FDA/CDRH); (b) (6) @mmm.com
**Subject:** 3M
**When:** Sunday, February 23, 2020 2:00 PM-2:45 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** Dial in: (b) (6)

**HOLD: 3M**
Scheduled: Sunday, Feb 23, 2020 from 1:00 PM to 1:45 PM
Location: TBD
Invitees: Steve Hahn, Shuy, Bryan (OS/ASPR/IO), Callahan, Victoria (OS/ASPR/IO) (CTR), Jeffrey Shuren, Kadlec, Robert (OS/ASPR/IO), Ford-Barnes, Arwenthia (OS/ASPR/IO), Adams, Steven A. (CDC/SNS/DSNS)

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/14/2020 4:43:35 PM
**To:** Lloyd, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338a759166e74b13a5c9b385cde90eb9-Lindsay.Llo]
**Subject:** Fwd: two quick read items to flag--

Well, you were right about the WH briefing. It may get moved from Wednesday.

Jeff

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 14, 2020 at 4:35:24 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** RE: two quick read items to flag--

Thanks for flagging.

On another note – Lauren R mentioned (b) (5) today to me. (b) (5)

(b) (5)

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 4:28 PM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: two quick read items to flag--

FYI – I wanted to provide some follow up (b) (4), (b) (5)

Jeff

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**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 5:56 PM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
**Subject:** FW: two quick read items to flag--

See ETO below from aspr

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**From:** Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>

**Sent:** Wednesday, February 12, 2020 4:28 PM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** two quick read items to flag--

Hey Anna,

Two quick things. One, presume this is on your radar https://www.fiercepharma.com/pharma-asia/chinese-firm-copies-gilead-s-remdesivir-most-promising-drug-against-new-coronavirus ? Two, (b) (5) [redacted]

Best,
Bryan

Deputy Assistant Secretary and Chief of Staff
Immediate Office, Assistant Secretary for Preparedness and Response (ASPR)
US Dept. Health and Human Services (HHS)
Desk: 202-(b) (6) [redacted]
Mobile: 20 [redacted]
bryan.shuy@hhs.gov

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/23/2020 3:11:45 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Tim,

That's terrific. I think your presence at CDC will make a big difference. TY!

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 3:09 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Jeff,

Yes, they are. We expect more updates perhaps later today. We are exploring under a new EUA, could we allow the (b)(5) labs that only failed N3 to move forward with existing reagents using N1 and N2 only.

I have received a very warm welcome.

I have met with the Lab Task in the EOC lead by Wendi, I attending the daily briefing attended by Dr. Redfield, then went to see Steve and Julie in the Coronavirus testing lab. I am going to meet with the chief of staff, the surveillance lead and the Coronavirus Incidence Manager later today.

I have requested a tour of the core lab that does the manufacturing, hopefully today but latest tomorrow.

The briefing went well, I shared last night's ED green light on the Surveillance testing program and today's FDA response to the Surveillance EUA. Dr. Redfield and the rest were very pleased with both developments and thanked us.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 2:32 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Thank you. Hopefully, CDC follows up on their initial outreach to the labs so that they hear back from all of those labs who received their test.

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 2:07 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Cut-off change - Number of public health labs that verified CDC panel for use

(b)(5) labs of(b)(5) who received the kits have responded. The remainder have not.

(b)(5)labs verified.

(b)(5)labs failed verification. All (b)(5)failed N3 while only (b) failed N1.

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 22, 2020 at 8:12:02 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Cut-off change - Number of public health labs that verified CDC panel for use

Tim,

Thank you. Do you know the total number of labs CDC has heard back from out of the (b)(5) labs who received the test?

Jeff

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 22, 2020 at 8:07:13 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Fwd: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Jeff,

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The CDC now reports (b)(5)labs besides the CDC lab have been successful with verification.

Best,
Tim

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Date:** February 22, 2020 at 8:01:42 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
Our request for response from labs that were able to successfully verify the test went out yesterday afternoon. As of now, (b) (5) We will keep you updated on the status of responses.
I hope this is useful.
Thank you
Steve

Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30329
Phone: 404-639-1587

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 5:17:02 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Steve and Julie,

Do you have any updates on the labs that successfully validated your assay and are ready to run clinical samples? Did any lab respond?

Thanks,
Uwe

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 11:22 AM

**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
Notifications that CDC received from public health laboratories regarding the reactivity of the N1 and N3 assay as well as those that notified CDC of successful verification are below:

(b) (5) notified CDC of issues with N3 assay
(b) (5) notified CDC of issues with N1 assay (these labs are included in those that also saw issues with N3)
(b) (5) reported that they successfully verified the test in their laboratories

We are reaching out to labs today to notify CDC if they have successfully verified the test and will update if this number changes.

Thank you very much.
Steve

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Friday, February 21, 2020 10:59 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
I just wanted to follow up with you to let you know that we are now working to compile the numbers we have and will get these to you shortly. Also, we will be sending a request to all labs that have received the reagents to please notify CDC if they successfully verified the test in their lab, so the number of verified labs may change from the numbers we initially report to you.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use
**Importance:** High

Julie & Steve,

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As requested earlier, please clarify the number of labs that have successfully verified the CDC test panel for use asap.

You communicated earlier that (b) (5) labs received your test and that (b) (5) PHL informed you that they could not verify the test.

The question is in the context of a statement by APHL today that only 3 out of 100 public health labs have verified the CDC test for use. Can you confirm that?
"Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.'

See article below:

The article also states, according to CDC, that CDC will distribute a second test and will need it approved by the FDA first.

- Please clarify what that means: Are we talking about the new lot that is being manufactured or the change in cut-off?

Thanks,
Uwe

**Problems with CDC coronavirus test delay expanded US screening**

By David Lim

02/20/2020 05:03 PM EST

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current

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version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

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**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.

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- Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

There are laboratories that have not had any problems and are testing. We will need to work to find more detailed information for you.

Thanks,
Julie

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) [redacted] is that correct?

Thank you for your feedback.

Uwe

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/17/2020 5:10:16 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**CC:** Hahn, Stephen (b) (6) (b) (6) (b) (6) Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
**Subject:** Re: CDC 2019-nCoV Test Update

Okay

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 17, 2020 at 5:09:04 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Hahn, Stephen (b) (6)@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
**Subject:** Re: CDC 2019-nCoV Test Update

Thanks Jeff. (b) (5)

Sent from my iPhone

On Feb 17, 2020, at 3:37 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

I have an update. It might be better to discuss by phone if folks are available.

Also, below I'm sharing for your awareness an email sent to CDC/FDA/NIH from Rosemary Humes at BARDA regarding interest in point-of-care testing and the development of a one-pager and slides.

Jeff

Internal confidential

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**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 2:04 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Beanan, Maureen J (NIH) <beananm@mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Marston, Hilary D (NIH)

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<hilary.marston@nih.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>

**Subject:** Dx development status and RNA prioritization

Dear Dx WG members,

Thanks to all who participated in the call on Friday. I know that everyone is swamped.

A couple of follow up items:

1. (b) (5)

a. Please reply ASAP: (b) (5)

2. Point-of-Care diagnostics

b. (b) (5)

c. we are putting together a one pager and slide deck to try again to address some questions and reality set. Our (b) (5)

d. (b) (5)

e. Work-group membership - please let me know if there are others we should add to the WG for future calls and input.

f. If anyone has ideas for another approach we welcome suggestions.

Thanks to all for your help and support.

Rosemary

(b) (5)

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Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202(b) (6)
Cell: 202(b) (6)

**From:** Shuren, Jeff
**Sent:** Sunday, February 16, 2020 11:05 PM
**To:** Hahn, Stephen (b) (6)@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
**Subject:** CDC 2019-nCoV Test Update

CDC submitted their request for a new cut-off this evening. The CDRH team finished their review. (b) (5)

(b) (5)

The team and CDC will discuss on a phone call that will take place tomorrow, likely at 1 or 2 PM, during which we anticipate CDC will provide verbal feedback to the CDRH team's questions.

Jeff

Internal confidential

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/15/2020 8:42:13 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: Request for enforcement discretion

Yes, go ahead and check with OCC.

(b) (5) [redacted]

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 15, 2020 at 8:25:54 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Request for enforcement discretion

We gave the option of (b) (5) [redacted]

I'd want to check with OCC (b) (5) [redacted]

(b) (5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 7:24:24 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Fwd: Request for enforcement discretion

Do you have any concerns (b) (5) [redacted] ?

Jeff

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Date:** February 15, 2020 at 7:12:25 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Flannery, Ellen

AMERICAN OVERSIGHT

<Ellen.Flannery@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** RE: Request for enforcement discretion

Dear Uwe,

We wish to thank you and your colleagues at FDA for the rapid response to our urgent request for FDA enforcement discretion. We appreciate your willingness to allow our testing of returning US travelers from the Diamond Princess cruise ship, as required of CDC by HHS. CDC agrees to restrict testing to CDC's headquarters in Atlanta, GA and will agree to share data generated in this repatriation testing activity. (b) (5)

CDC would welcome the opportunity to discuss further.

We greatly appreciate FDA's partnership in this response.

Warm regards,
Wendi

**Wendi Kuhnert-Tallman**
**Office - 404-639-3103**
**Mobile – 678-576-2121**

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 5:29 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Cc:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion
**Importance:** High

Dear Dr. Kuhnert-Tallman,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

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On February 15, 2020, CDC submitted to FDA a request for enforcement discretion from FDA for the testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Asymptomatic individuals do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC has stated that testing will be conducted at CDC's headquarters in Atlanta, GA. Specimens are expected to arrive at CDC for testing during this holiday weekend.

Our understanding of the facts and the public health concerns at issue here are that there is currently no other test available to respond to this emergency, significant public health concerns are presented by the infectious disease, and the proposed testing may help to prevent the spread of the infectious disease. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the following conditions: (b) (5) [redacted]

Regards,

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 15, 2020 12:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Request for enforcement discretion

Good afternoon Dr. Scherf,

CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. (b) (5) [redacted]

Laura Rose, Regulatory Affairs Activity Lead for OLSS, is the primary point of contact at CDC to facilitate communications about this request. She may be reached at 404-639-1084 or LERose@cdc.gov.

Warm regards,
Wendi

Wendi Kuhnert-Tallman
ADIM
Mobile – 678-576-2121

AMERICAN OVERSIGHT

CDC IMS LAB TF
2019 nCoV Response
eocevent177@cdc.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/17/2020 3:37:47 PM
**To:** Hahn, Stephen (b) (6) Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
**Subject:** RE: CDC 2019-nCoV Test Update

I have an update. It might be better to discuss by phone if folks are available.

Also, below I'm sharing for your awareness an email sent to CDC/FDA/NIH from Rosemary Humes at BARDA regarding interest in point-of-care testing and the development of a one-pager and slides.

Jeff

Internal confidential

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 2:04 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Beanan, Maureen J (NIH) <beananm@mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>
**Subject:** Dx development status and RNA prioritization

Dear Dx WG members,
Thanks to all who participated in the call on Friday. I know that everyone is swamped.
A couple of follow up items:

1. (b) (5)

a. Please reply ASAP: (b) (5)

2. Point-of-Care diagnostics

b. (b) (5)

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c. we are putting together a one pager and slide deck to try again to address some questions and reality set. Our (b) (5) [redacted]

d. (b) (5) [redacted]

e. Work-group membership - please let me know if there are others we should add to the WG for future calls and input.

f. If anyone has ideas for another approach we welcome suggestions.

Thanks to all for your help and support.
Rosemary

(b) (5) [redacted]

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-(b) (6) [redacted]
Cell: 202(b) (6) [redacted]

**From:** Shuren, Jeff
**Sent:** Sunday, February 16, 2020 11:05 PM
**To:** Hahn, Stephen (b) (6)@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
**Subject:** CDC 2019-nCoV Test Update

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CDC submitted their request for a new cut-off this evening. The CDRH team finished their review. (b) (5) [redacted] The team and CDC will discuss on a phone call that will take place tomorrow, likely at 1 or 2 PM, during which we anticipate CDC will provide verbal feedback to the CDRH team's questions.

Jeff

Internal confidential

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/15/2020 6:02:03 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: Request for enforcement discretion

And I would add, as Ellen noted before, the EUA application is supposed to identify all manufacturing sites, the controls they will use, and their GMP status. If possible, it would be helpful to pull that information tomorrow.

Jeff

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 15, 2020 5:52 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion

Uwe,

Thank you, and understood. I'll give the Commissioner's Office an update, as well.

On a related note, I looked at the instructions that CDC provided to the public health labs under the EUA and it identifies CDC as the manufacturer. They do not identify a contract manufacturer, at least in that document. Maybe in material submitted to support the original EUA they identify an entity other than CDC as the manufacturer of the primers and probes CDC uses when testing is performed at their headquarters.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 5:42 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion

Jeff,

No, they have not send anything yet. I spoke with Steve Lindstrom at 4 PM again, they are discussing their internal data before they send it to us.

My team needs to see the proposal before we can agree on any cut-off change. We discussed a concept of testing 2 different specimen types and working out the details tonight.

We will need to have a conference call with CDC to come to an agreement which will realistically happen tomorrow. I will you keep you posted at every step.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 5:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion

Thank you. Have you received the email from CDC with the request for a new cut off?

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 5:29 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion
**Importance:** High

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Regards,

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-5456
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 15, 2020 12:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Request for enforcement discretion

Good afternoon Dr. Scherf,

CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC respectfully requests enforcement discretion from FDA for the testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Testing will be conducted at CDC's headquarters in Atlanta, GA. Specimens are expected to arrive at CDC for testing during this holiday weekend.

Laura Rose, Regulatory Affairs Activity Lead for OLSS, is the primary point of contact at CDC to facilitate communications about this request. She may be reached at 404-639-1084 or LERose@cdc.gov.

Warm regards,
Wendi

Wendi Kuhnert-Tallman
ADIM
Mobile – 678-576-2121
CDC IMS LAB TF
2019 nCoV Response
eocevent177@cdc.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/8/2020 3:38:29 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]
**CC:** Patel, Bakul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ce7d58d8b9c473c8ba4d6fcb8b02b5a-BYP]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Krueger, Angela C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96c8f1f9d6a8481195be2aa3147e0b4f-ACS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: (b) (4) [redacted]

Thank you, Uwe.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 8, 2020 at 2:59:49 PM EST
**To:** Maisel, William <William.Maisel@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Krueger, Angela C <Angela.Krueger@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: (b) (4) [redacted]

Bill, Jeff,
I confirm this belongs to DMD. We had similar (b) (4) [redacted] for the Zika outbreak and will find out how those request were handled. It is likely not to git the EUA approach since the emergency declaration was specifically for the detection of nCoV. DMD will follow up with a phone call to the sponsor.
Uwe

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Date:** February 8, 2020 at 2:10:54 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Krueger, Angela C <Angela.Krueger@fda.hhs.gov>
**Subject:** Re: (b) (4) [redacted]

Jeff,
I think this would be in OHT7's DMD. Looping in Tim and Uwe to confirm.
Bill

AMERICAN OVERSIGHT

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 8, 2020 at 12:35:19 PM EST
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** Fwd: (b) (4) [redacted]

Bill,

A small start up is looking to create (b) (4) [redacted]. The inputs it may use are described in Q3 below but it seems they are still figuring out what they want/will develop. Is there an appropriate person in OPEQ who can speak with them about FDA expectations, depending on what they specifically want to claim, including the merits of a Qsub? They may modify what they do based on the feedback.

I'm including Bakul and Suzanne for awareness.

Jeff

---

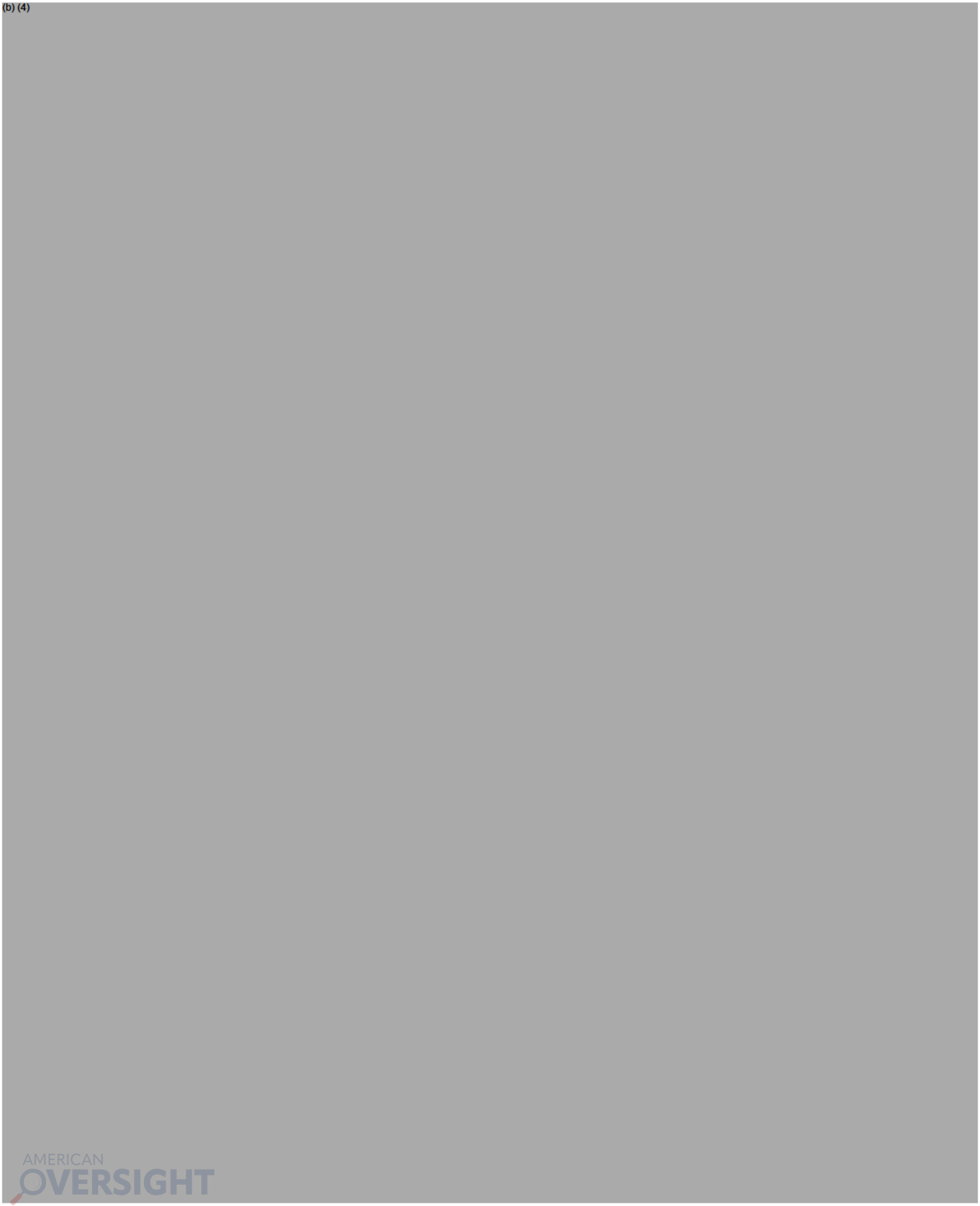
**From:** (b) (6) [redacted]
**Date:** February 8, 2020 at 11:18:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** (b) (4) [redacted]

Hi Jeff,

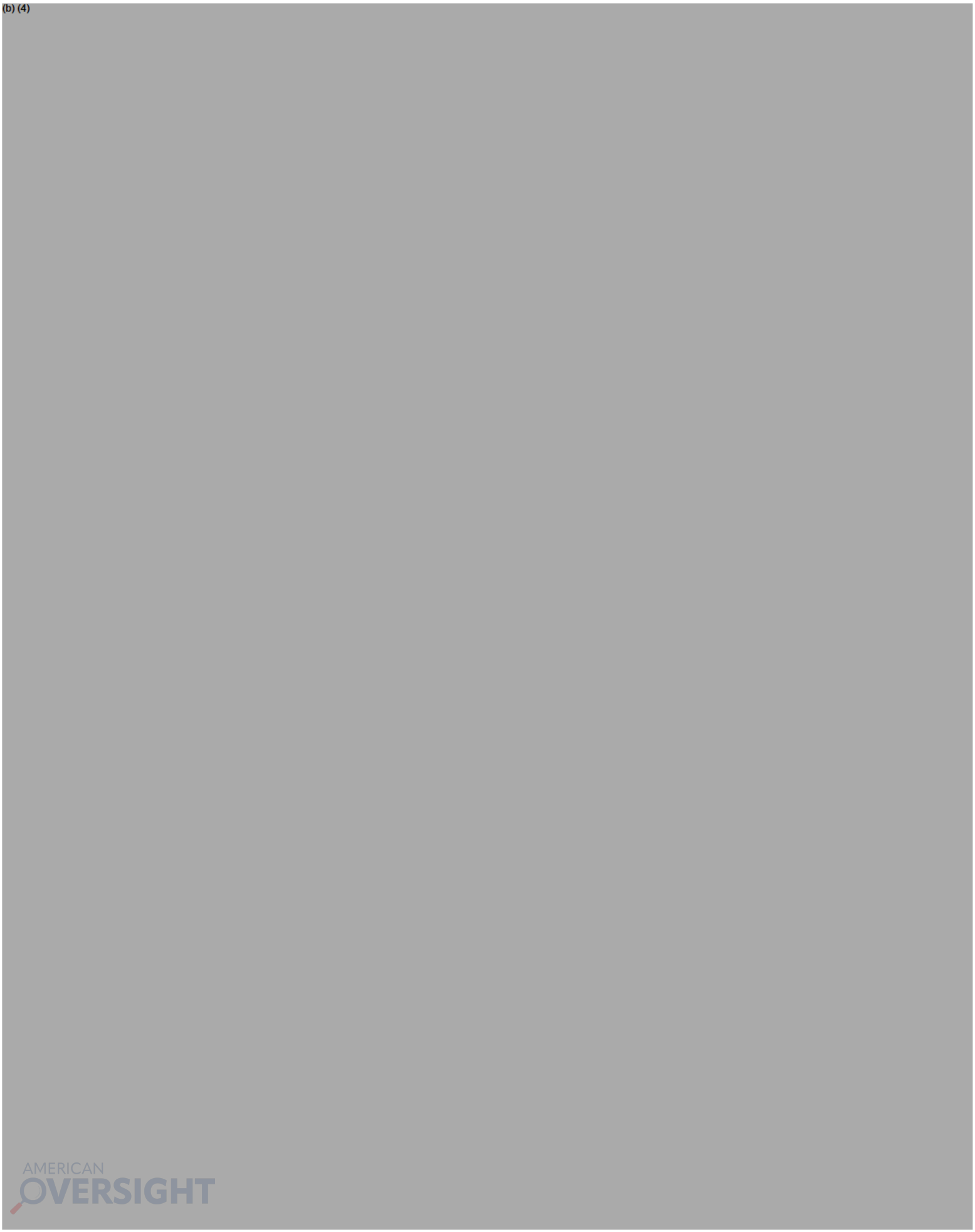
Thank you for the interest. In terms of more information;

(b) (4) [redacted]

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(b) (4)
AMERICAN
OVERSIGHT

(b) (4)



**From:** Shuren, Jeff
**Sent:** Saturday, 8 February 2020 4:13 AM
**To:** (b) (6)
**Subject:** Re: (b) (4)

Hi (b) (6)

It's good to hear from you. Thank you for reaching out to me.

I reviewed your slide deck and saw the video. It would help me to have a little more information. Can you please describe what the tool is intended to be used for (b) (4) who you intend the (b) (4) to be used by (b) (4) the specific inputs it would use, and the specific outputs (b) (4)

Jeff

---

**From:** (b) (6)
**Date:** February 7, 2020 at 10:15:52 PM EST

AMERICAN OVERSIGHT

**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** (b) (4)

(b) (6), (b) (4)



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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/3/2020 7:00:40 AM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]
**Subject:** FW: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

FYI

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 3, 2020 at 6:48:34 AM EST
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Solomon, Steven M <Steven.Solomon@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Subject:** FW: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

FYI for awareness

---

**From:** Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>
**Date:** February 3, 2020 at 5:46:00 AM EST
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Cc:** Anderson, Erika <Erika.Anderson@fda.hhs.gov>
**Subject:** FW: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

FYI.

---

**From:** Salazar, Julio <Julio.Salazar@fda.hhs.gov>
**Date:** February 2, 2020 at 22:14:54 EST
**To:** Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>, Ross, Bruce <Bruce.Ross@fda.hhs.gov>, Yates, Connie <Connie.Yates@fda.hhs.gov>, Oehlsen, Michael <Michael.Oehlsen@fda.hhs.gov>
**Cc:** Gabrel, Celia <Celia.Gabrel@fda.hhs.gov>, Kambere, Marijo <Marijo.Kambere@fda.hhs.gov>, Mathern, Jennifer <Jennifer.Mathern@fda.hhs.gov>
**Subject:** FW: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

(b) (5)

AMERICAN OVERSIGHT

(b) (5) [redacted]

**Julio Salazar**
*Country Director*

**FDA China Office**
**U.S. Food and Drug Administration**
**U.S. Embassy Beijing**
Tel: +86-10-8531-4248
BB: +1-240-731-5270
Julio.Salazar@fda.hhs.gov

SalazarJ10@state.gov






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---

**From:** Millman, Alexander J. (CDC/DDID/NCIRD/ID) <irm6@cdc.gov>
**Sent:** Monday, February 03, 2020 10:42 AM
**To:** Salazar, Julio <Julio.Salazar@fda.hhs.gov>
**Cc:** Simonds, Robert J (CDC) <rxs5@cdc.gov>
**Subject:** FW: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

Hi Julio,

This includes my response with the official report from the Ministry of Agriculture as well as the news article about this case.
Alex

---

**From:** (b) (6) [redacted] >
**Sent:** Monday, February 3, 2020 9:25 AM
**To:** Millman, Alexander J. (CDC/DDID/NCIRD/ID) <irm6@cdc.gov>; (b) (6) [redacted]
**Cc:** Beijing Econ Unit Chiefs <BeijingEconUnitChiefs@state.gov>; BEIJING 2020 Coronavirus <BEIJING2020Coronavirus@state.gov>; 'Parrish-Fuentes, Adrienne (OS/OGA' <Adrienne.Parrish-fuentes@hhs.gov>
**Subject:** RE: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

This has been officially reported on the Ministry of Ag's website. I will let you know if I find anything else.
(b) [redacted]

AMERICAN OVERSIGHT

http://www.moa.gov.cn/gk/yjgl_1/yqfb/202002/t20200201_6336498.htm

The Information Office of the Ministry of Agriculture and Rural Affairs released on February 1 that a poultry H5N1 subtype highly pathogenic bird flu outbreak occurred in Shuangqing District, Shaoyang City, Hunan Province.

On February 1st, the Ministry of Agriculture and Rural Affairs received a report from the China Animal Epidemic Prevention and Control Center. After confirmed by the National Avian Influenza Reference Laboratory, the H5N1 subtype highly pathogenic avian influenza epidemic occurred in broiler chickens raised by a farmer in Shuangqing District, Shaoyang City. The number of broiler chickens kept by the farmers was 7,850, and 4,500 died. After the epidemic occurred, the local government did a good job in handling the epidemic situation in accordance with the requirements of relevant plans and technical specifications for prevention and control. 17,828 poultry have been culled, and all the sick and culled poultry have been harmlessly treated.

SENSITIVE BUT UNCLASSIFIED

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**Sent:** Monday, February 3, 2020 9:14 AM
**To:** (b) (6)
**Cc:** Beijing Econ Unit Chiefs <BeijingEconUnitChiefs@state.gov>; (b) (6)
Parrish-Fuentes, Adrienne (OS/OGA <Adrienne.Parrish-fuentes@hhs.gov>; BEIJING 2020 Coronavirus <BEIJING2020Coronavirus@state.gov>
**Subject:** RE: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

Hi (b) (6),
Thanks for email. We will look into this to see if we can find additional information.
Alex

**From:** (b) (6)
**Sent:** Monday, February 3, 2020 9:09 AM
**To:** (b) (6)
**Cc:** Beijing Econ Unit Chiefs <BeijingEconUnitChiefs@state.gov>; (b) (6)
Parrish-Fuentes, Adrienne (OS/OGA <Adrienne.Parrish-fuentes@hhs.gov>; BEIJING 2020 Coronavirus <BEIJING2020Coronavirus@state.gov>
**Subject:** FW: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

Folks

Anything you can find on this would be very helpful.

(b) (6)

**From:** Schneller, Keith D. EOP/USTR <Keith.D.Schneller@ustr.eop.gov>
**Sent:** Monday, February 3, 2020 1:24 AM
**To:** Bomer Lauritsen, Sharon E. EOP/USTR <Sharon_E_BomerLauritsen@ustr.eop.gov>; Doud, Gregory F. EOP/USTR <Gregory.F.Doud@ustr.eop.gov>; Forsyth, Trey M. EOP/USTR <Trey.M.Forsyth@ustr.eop.gov>
**Cc:** Sheppard, Wade - FAS, Washington, DC <Wade.Sheppard@usda.gov>; Richey, Bobby - FAS, BEIJING, CHINA <Bobby.Richey@fas.usda.gov>; Hafemeister, Jason - OSEC, Washington, DC <Jason.Hafemeister1@usda.gov>; Howe, Julia M. EOP/USTR <Julia_M_Howe@ustr.eop.gov>; (b) (6)
**Subject:** SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

AMERICAN OVERSIGHT

https://www.scmp.com/news/china/society/article/3048566/china-reports-outbreak-deadly-bird-flu-among-chickens-hunan

# China reports outbreak of deadly bird flu among chickens in Hunan province, close to coronavirus epicentre of Wuhan

- **Bird flu outbreak in Hunan province, which lies on the southern border of Hubei province, the epicentre of the coronavirus outbreak**
- **Bird flu is much deadlier than either Sars or the coronavirus, but as of yet no human cases have been reported in this outbreak**

Cissy Zhou
Published: 2:29am, 2 Feb, 2020

China has reported an outbreak of the deadly H5N1 bird flu in Hunan province, which lies on the southern border of Hubei province, the epicentre of the rapidly spreading coronavirus.
"The outbreak occurred in a farm in the Shuangqing district of Shaoyang city. The farm has 7,850 chickens, and 4,500 of the chickens have died from the contagion. Local authorities have culled 17,828 poultry after the outbreak," according to a statement by China's Ministry of Agriculture and Rural Affairs on Saturday. No human cases of the Hunan H5N1 virus have been reported.
The Hunan H5N1 outbreak comes even as the Chinese authorities continue to scramble to contain the spread of the novel coronavirus, further stretching the nation's already heavily strained resources needed to combat the health threats.

The deadly coronavirus infection had claimed 300 lives in China as of Sunday. So far, no deaths have been reported outside the country. The virus has sickened more than 14,000 in China and about 140 overseas so far. The H5N1 avian flu virus, often called bird flu, causes severe respiratory disease in birds and is contagious to humans. The virus was first detected in 1996 in geese in China and is especially deadly for poultry. It is possible, but difficult, to transmit bird flu from person to person, according to the World Health Organisation (WHO).

According to the US Centres for Disease Control and Prevention, "Most human infections with avian influenza viruses ... have occurred after prolonged and close contact with infected birds.
"Rare human-to-human spread with this virus has occurred, but it has not been sustained and no community spread of this virus has ever been identified."
However, bird flu is highly deadly to humans who contract it, with a mortality rate of more than 50 per cent in cases over the last 15 years, which is much deadlier to humans than either Sars (a 10 per cent mortality rate) or the novel coronavirus (a 2 per cent mortality rate in the outbreak so far).

From 2003 to 2019, WHO reported a total of 861 confirmed human cases of H5N1 worldwide, of whom 455 have died. In China, 53 human cases of bird flu infections have been reported in the past 16 years, with 31 having died. In recent days, more than a dozen countries have evacuated their citizens from Hubei province's Wuhan – the epicentre of the coronavirus outbreak – or are in the processing of doing so.

Best Regards,

Keith Schneller
Agricultural Affairs
Office of the U.S. Trade Representative
O: 202-395-9575
C: (b) (6)
E: keith.d.schneller@ustr.eop.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/3/2020 7:00:40 AM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]
**Subject:** FW: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

FYI

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 3, 2020 at 6:48:34 AM EST
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Solomon, Steven M <Steven.Solomon@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Subject:** FW: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

FYI for awareness

---

**From:** Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>
**Date:** February 3, 2020 at 5:46:00 AM EST
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Cc:** Anderson, Erika <Erika.Anderson@fda.hhs.gov>
**Subject:** FW: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

FYI.

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**From:** Salazar, Julio <Julio.Salazar@fda.hhs.gov>
**Date:** February 2, 2020 at 22:14:54 EST
**To:** Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>, Ross, Bruce <Bruce.Ross@fda.hhs.gov>, Yates, Connie <Connie.Yates@fda.hhs.gov>, Oehlsen, Michael <Michael.Oehlsen@fda.hhs.gov>
**Cc:** Gabrel, Celia <Celia.Gabrel@fda.hhs.gov>, Kambere, Marijo <Marijo.Kambere@fda.hhs.gov>, Mathern, Jennifer <Jennifer.Mathern@fda.hhs.gov>
**Subject:** FW: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

(b) (5)

AMERICAN OVERSIGHT

(b) (5) [redacted]

**Julio Salazar**
*Country Director*

**FDA China Office**
**U.S. Food and Drug Administration**
**U.S. Embassy Beijing**
Tel: +86-10-8531-4248
BB: +1-240-731-5270
Julio.Salazar@fda.hhs.gov

SalazarJ10@state.gov






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**To:** Salazar, Julio <Julio.Salazar@fda.hhs.gov>
**Cc:** Simonds, Robert J (CDC) <rxs5@cdc.gov>
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Hi Julio,

This includes my response with the official report from the Ministry of Agriculture as well as the news article about this case.
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**Cc:** Beijing Econ Unit Chiefs <BeijingEconUnitChiefs@state.gov>; BEIJING 2020 Coronavirus <BEIJING2020Coronavirus@state.gov>; 'Parrish-Fuentes, Adrienne (OS/OGA' <Adrienne.Parrish-fuentes@hhs.gov>
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This has been officially reported on the Ministry of Ag's website. I will let you know if I find anything else.
(b)

AMERICAN OVERSIGHT

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**To:** (b) (6)
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Folks

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**From:** Schneller, Keith D. EOP/USTR <Keith.D.Schneller@ustr.eop.gov>
**Sent:** Monday, February 3, 2020 1:24 AM
**To:** Bomer Lauritsen, Sharon E. EOP/USTR <Sharon_E_BomerLauritsen@ustr.eop.gov>; Doud, Gregory F. EOP/USTR <Gregory.F.Doud@ustr.eop.gov>; Forsyth, Trey M. EOP/USTR <Trey.M.Forsyth@ustr.eop.gov>
**Cc:** Sheppard, Wade - FAS, Washington, DC <Wade.Sheppard@usda.gov>; Richey, Bobby - FAS, BEIJING, CHINA <Bobby.Richey@fas.usda.gov>; Hafemeister, Jason - OSEC, Washington, DC <Jason.Hafemeister1@usda.gov>; Howe, Julia M. EOP/USTR <Julia_M_Howe@ustr.eop.gov>; (b) (6)
**Subject:** SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province

AMERICAN OVERSIGHT

https://www.scmp.com/news/china/society/article/3048566/china-reports-outbreak-deadly-bird-flu-among-chickens-hunan

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Cissy Zhou
Published: 2:29am, 2 Feb, 2020

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"Rare human-to-human spread with this virus has occurred, but it has not been sustained and no community spread of this virus has ever been identified."
However, bird flu is highly deadly to humans who contract it, with a mortality rate of more than 50 per cent in cases over the last 15 years, which is much deadlier to humans than either Sars (a 10 per cent mortality rate) or the novel coronavirus (a 2 per cent mortality rate in the outbreak so far).

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Best Regards,

Keith Schneller
Agricultural Affairs
Office of the U.S. Trade Representative
O: 202-395-9575
C: (b) (6)
E: keith.d.schneller@ustr.eop.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/12/2020 8:49:26 AM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** RE: FDA visit

I haven't heard anything either. Fine to reach out to Anna/Keagan.

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 12, 2020 at 8:45:43 AM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: FDA visit

I have not heard anything from Anna or OCC on CDC and (b) (5)
I think everyone pivoted to focus on coronavirus.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 8:42 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Fwd: FDA visit

Jeff, Ellen,
Have either of you heard any updates from the commissioners office regarding agency conversations with HHS or CDC on (b) (5) ? I ask because a CDC official who has been on our calls this past year reached out to Tim (below) to schedule a visit to WO next week to discuss a handful of topics including (b) (5) . I don't want to overstep if conversations are taking place at the agency level. Do you have enough insight to advise on how to handle this or would you like me to reach out to Anna/Keagan? I did ask Lauren Paulos and she said there is an IOS meeting this week.
Elizabeth

---

**From:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Date:** February 11, 2020 at 9:36:48 AM EST
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: FDA visit

I heard from Brian that (b) (5)

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Friday, February 7, 2020 4:23 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Subject:** RE: FDA visit

AMERICAN OVERSIGHT

Hi there! I haven't heard anything about this but would be curious to know more, as well. Lauren may have more intel when she returns. Very interesting!

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 7, 2020 4:01 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Subject:** FW: FDA visit

Just checking to see if either of you know what might be going on w HHS and CDC? I ask because CDC wants to visit and talk about(b) (5) on Feb 21st. see below.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 7, 2020 3:32 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Cc:** Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Subject:** FW: FDA visit

Hi Elizabeth,

It would be great to pull you in to at least get your guidance on this. The CDC is looking to enhance the relationship with the FDA. As you know, Alberto had developed a close relationship with the CDC that was quite broad. And it seems like there were no significant other senior FDA leaders who had that same relationship. See suggested topics and people to include below.

Pulling a meeting together that is this deep and broad in 2 weeks is likely challenging. (b) (5)

I am fine managing this, if you want.

Thanks!

AMERICAN OVERSIGHT

Best,

*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Sent:** Friday, February 7, 2020 3:26 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Salerno, Reynolds M (CDC) <yyw2@cdc.gov>; Monroe, Stephan S (CDC) <stm2@cdc.gov>; Sen, Oishee (CDC) <qam3@cdc.gov>; Ramsey, Melanie R (CDC) <xma0@cdc.gov>; King, Veronnica (CDC) <ftm3@cdc.gov>; Howard, Stacy M (CDC) <sam5@cdc.gov>; Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>
**Subject:** RE: FDA visit

Tim. We just listed the names and topics in an ad hoc fashion. I'd hope you could put some logic behind it and organize a few meetings tying together a topic with relevant people in a way that made sense and used time efficiently, including the right leadership I did not know to name. I think all five at once would be too much. Ms. Ramsey is our poc. Have a great weekend! Michael

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 7, 2020 3:01 PM
**To:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Cc:** Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) <stm2@cdc.gov>; Sen, Oishee (CDC/DDPHSS/CSELS/OD) <qam3@cdc.gov>; Ramsey, Melanie R. (CDC/DDPHSS/CSELS/OD) <xma0@cdc.gov>; King, Veronnica (CDC/DDPHSS/CSELS/OD) <ftm3@cdc.gov>; Howard, Stacy M. (CDC/DDPHSS/CSELS/DLS) <sam5@cdc.gov>; Campbell, Jennifer (FDA/CDRH) <Jennifer.Campbell@fda.hhs.gov>
**Subject:** RE: FDA visit

Hi Michael,

Thanks for reaching out. Yes! A second visit is very welcome. Friday Feb 21 works for me though we will want to check with others.

Just confirming that you are looking to meeting with all 5 individuals below and me all at once? If so, will reach out and start checking scehedules.

Thanks!

AMERICAN OVERSIGHT

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

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**From:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Sent:** Wednesday, February 5, 2020 5:41 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Salerno, Reynolds M (CDC) <yyw2@cdc.gov>; Monroe, Stephan S (CDC) <stm2@cdc.gov>; Sen, Oishee (CDC) <qam3@cdc.gov>; Ramsey, Melanie R (CDC) <xma0@cdc.gov>; King, Veronnica (CDC) <ftm3@cdc.gov>; Howard, Stacy M (CDC) <sam5@cdc.gov>
**Subject:** FDA visit

Tim, I'd like to follow up with a **second visit**, taking an incremental step in re-introducing leadership on both sides as we discussed in October. Dr. Monroe, CDC's director for the Office of Laboratory Safety and Science, and Dr. Salerno, who you know, our center's director of the Division of Laboratory Systems are available and interested. If you agree, there are three next steps: the date, the agenda, and who we might meet. See suggestions below. But please steer for our CDC-FDA relationship. Ms. Ramsey is our point of contact. Best, Michael

**Proposed Date, all day Friday February 21**

**Draft agenda**

(b) (5)



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**From:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Sent:** Friday, November 1, 2019 4:43 PM
**To:** Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>; Ramsey, Melanie R. (CDC/DDPHSS/CSELS/OD) <xma0@cdc.gov>
**Subject:** CSELS/

Tim,

Great meeting you. I loved our encounter. We did not have enough time to dig into some very interesting issues.

Some suggested actions; I welcome your comments.

(b) (5)

Have a great weekend,

Best, Michael

**Michael F. Iademarco, M.D., M.P.H.**
Rear Admiral and Assistant Surgeon General, U.S. Public Health Service
Director, Center for Surveillance, Epidemiology, and Laboratory Services, CDC, HHS
Phone: +1 (404) 498-6010 (office) and (404) 988-7456 (mobile)
Special Assistant, Ms. Melanie Ramsey, mramsey@cdc.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/3/2020 9:38:33 AM
**To:** Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=(b) (6) ; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
**CC:** Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]
**Subject:** RE: Coronavirus testing equipment and materials

Thank you all. I may tweak the last sentence of the first paragraph to make it a little less legalistic but same message.

Jeff

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Date:** February 3, 2020 at 9:22:25 AM EST
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>
**Subject:** RE: Coronavirus testing equipment and materials

(b) (5)

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**From:** Amin, Stacy
**Sent:** Monday, February 3, 2020 9:21 AM
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
**Subject:** RE: Coronavirus testing equipment and materials

Marcy in OCC had some comments below. Let us know if any are a concern.

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

Happy to discuss further.

---

(b) (5)

Best regards,

Jeff

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 8:48 AM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen (b) (6) @fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: Coronavirus testing equipment and materials

Fine with reply. Thanks, Jeff

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 8:45 AM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen (b) (6) @fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Subject:** RE: Coronavirus testing equipment and materials

All good from my perspective to thx

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 8:41 AM
**To:** Hahn, Stephen (b) (6) @fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** RE: Coronavirus testing equipment and materials

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No concerns from me.

**From:** Hahn, Stephen (b) (6) @fda.hhs.gov>
**Sent:** Monday, February 3, 2020 8:28 AM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** Re: Coronavirus testing equipment and materials

I'm good with the response, Jeff, pending others' input.
Steve

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 3, 2020 at 6:40:22 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hahn, Stephen (b) (6) @fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** Re: Coronavirus testing equipment and materials

Plus Stacy, Denise, and Michael

Jeff, I'm ok with this draft reply.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 3, 2020 at 2:15:24 AM EST
**To:** Hahn, Stephen (b) (6) @fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** FW: Coronavirus testing equipment and materials

Given the sensitivities, I wanted to check with you first before responding to the below email from Dr. Perea-Henze, Deputy Mayor of Health & Human Services of NYC. Here's my draft reply:

(b) (5)

Best regards,

Jeff

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**From:** Perea-Henze, Raul <RPereaHenze@cityhall.nyc.gov>
**Sent:** Sunday, February 2, 2020 5:00 PM
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** B <BCCD@cityhall.nyc.gov>; Fuleihan, Dean <DFuleihan@cityhall.nyc.gov>; Wolfe, Emma <EWolfe@cityhall.nyc.gov>; Barbot, Oxiris (DOHMH) <obarbot@health.nyc.gov>
**Subject:** Coronavirus testing equipment and materials

Dear Drs. Hahn and Stenzel,

The commitment of the Food and Drug Administration to the safety and well-being of all Americans is critical to the work that we do every day at the New York City Department of Health and Mental Hygiene, and is especially important in the context of a public health emergency.

The reliability and accuracy of clinical tests is a basic need in health care and public health. In the current 2019-novel coronavirus (nCoV) public health emergency, public health action that will impact the lives of many will be taken based on the result of a single laboratory diagnostic test, and it is therefore critical that the test be as close to 100% accurate, 100% of the time as possible.

We commend the collaboration between the FDA, the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS) to streamline the development, validation, and authorization of clinical tests that meet regulatory requirements in the rapidly evolving setting of an infectious disease public health emergency. The efficiency of this process is being put to the test in this emergency.

We ask that the evaluation and subsequent Emergency Use Authorization of the CDC-developed diagnostic assay for the detection of 2019-nCoV infection be moved forward as quickly as possible. It is critical that local jurisdictions, including New York City, have access to this test locally to support the rapid and accurate evaluation of patients under investigation (PUI) for 2019-nCoV infection. In New York City, the test result for every PUI will have implications for the health of all New Yorkers. It is imperative that testing be available locally to decrease the time to get a result into the hands of clinicians caring for the patient and the public health officials that need to enact public health interventions to stop the spread of this virus in NYC, and across the country.

As always, thank you for your commitment to the health and safety of New Yorkers and all Americans.

Sincerely,

Raul Perea-Henze, MD, MPH
Deputy Mayor for Health & Human Services
City of New York
(b) (6) @cityhall.nyc.gov

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 1/30/2020 10:19:21 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Thank you. I've emailed you the meeting information.

Also, if you can answer the questions in my first email that would be great or we can talk now if you have a minute. I can call you on your cell.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** January 30, 2020 at 10:15:53 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Yes, I am available at 2 PM tomorrow. Uwe

**Uwe Scherf, M.Sc., Ph.D.**

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 10:15 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Uwe,

Also, are you available tomorrow at 2PM to discuss the CDC EUA with Ellen, myself, and folks from the Commissioner's Office? (b) (5)

Jeff

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** January 30, 2020 at 10:04:53 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Uwe,

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

Sorry for all the questions. Also, happy to talk in the AM before 8:30 AM.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** January 30, 2020 at 7:25:05 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

I am online, can be reached at (b) (6) for any questions. Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 7:18 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Regulatory discretion - Need to confirm process and next steps

I can talk now — (b) (6)

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** January 30, 2020 at 7:14:43 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Regulatory discretion - Need to confirm process and next steps

Hi Jeff,

CDC is asking (bottom of email chain) the following:

(b) (5)

I had a call with OCC that I would like to discuss with you, either in the morning or by phone tonight.

Thanks,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov

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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 7:03 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

See the message below. Per our last exchange, (b) (5) . Please let me know how you plan to proceed. Thanks, Liz

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** January 30, 2020 at 7:00:06 PM EST
**To:** Patel, Anita (CDC) <bop1@cdc.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

I will consider this email a request, and we will respond accordingly. Thanks.

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Date:** January 30, 2020 at 6:58:24 PM EST
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Meant wendi not wendy ☺

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD)
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

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Hi Liz,

When we spoke last week, we considered (b) (5) [redacted]

[redacted]

We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
(b) (6) [redacted]

+ Wendy who is now overseeing lab activities for the response.

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 1/31/2020 5:16:02 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**CC**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: Regulatory discretion - Need to confirm process and next steps

Thank you all!

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:10 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** FW: Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Jeff,

Just to keep you in the loop, the following email just went out to CDC based on Ellen's request. Uwe

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:01 PM
**To:** Patel, Anita (CDC) <bop1@cdc.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Dear Anita,

FDA and CDC have been working interactively together on CDC's request for an Emergency Use Authorization (EUA) for its 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens. At this time, there is no *in vitro* diagnostic test approved, cleared or authorized for such use.

On January 30th, CDC notified FDA that it would like to distribute the test to certain laboratories so that they can use the test prior to issuance of an EUA. This would help to address the significant public health concerns raised by the infectious disease at this early stage, and may help to prevent the spread of the infectious disease by addressing the high testing demands currently being faced by CDC.

We understand that CDC would like to distribute the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit, and any components, to laboratories designated by CDC as qualified and, in the United States, such laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. We also understand that CDC will ask each of the state laboratories to send positive samples and (b) (5) negative samples to CDC for further validation testing.

Based on our understanding of the facts and the public health concerns at issue here – specifically, that there is currently no other test available to respond to this emergency and that CDC is actively pursuing EUA authorization – at this time, FDA does not intend to object to the distribution and use of this test as described above. We ask that you

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please send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford (Kim.Sapsford@fda.hhs.gov) and the Director of the Division of Microbiology Devices, Uwe Scherf (Uwe.Scherf@fda.hhs.gov).

Kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Hi Liz,
When we spoke last week, we considered (b) (5) [redacted]

[redacted]

We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
(b) (6) [redacted]

+ Wendy who is now overseeing lab activities for the response.

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 1/31/2020 8:29:40 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Re: Regulatory discretion - Need to confirm process and next steps

Great. This is a good example of how the system can work well.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** January 31, 2020 at 8:21:18 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Regulatory discretion - Need to confirm process and next steps

Jeff, Elizabeth and Ellen,

CDC's 1st request for testing sites came in, Chicago and Richmond. DMD acknowledged the receipt.

Uwe

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 7:03 PM
**To:** Patel, Anita (CDC) <bop1@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Weldon, William C (CDC) <wiw4@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Anita,

DMD acknowledge the receipt of this information.

Thanks, Uwe

---

AMERICAN OVERSIGHT

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Date:** January 31, 2020 at 5:57:26 PM EST

**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Weldon, William C (CDC) <wiw4@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe and Kim,
Please see below for the locations for the first two lab locations.
Best,
Anita

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:49 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Here is the info:

Illinois Dept of Public Health-Chicago Laboratory
Attn: Matt Charles
2121 West Taylor (b) (6)
Chicago, IL 60612
Phone: (b) (6)
matt.charles@illinois.gov

California Department of Public Health
Attn: Debra Wadford
850 Marina Bay Parkway
Richmond, CA 94804
Debra.wadford@cdph.ca.gov
Phone: (b) (6)

**Wendi Kuhnert-Tallman**
**phone - 404-639-3103**

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:40 PM
**To:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe,
We greatly appreciate FDA's rapid review of CDC's request. CDC will send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford once locations are confirmed.

We will notify our lab team of the note below and let you know if there are any additional questions.
Thanks again -
Best,
Anita

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:01 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Dear Anita,

FDA and CDC have been working interactively together on CDC's request for an Emergency Use Authorization (EUA) for its 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens. At this time, there is no *in vitro* diagnostic test approved, cleared or authorized for such use.

On January 30th, CDC notified FDA that it would like to distribute the test to certain laboratories so that they can use the test prior to issuance of an EUA. This would help to address the significant public health concerns raised by the infectious disease at this early stage, and may help to prevent the spread of the infectious disease by addressing the high testing demands currently being faced by CDC.

We understand that CDC would like to distribute the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit, and any components, to laboratories designated by CDC as qualified and, in the United States, such laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. We also understand that CDC will ask each of the state laboratories to send positive samples and (b) (5) negative samples to CDC for further validation testing.

Based on our understanding of the facts and the public health concerns at issue here – specifically, that there is currently no other test available to respond to this emergency and that CDC is actively pursuing EUA authorization – at this time, FDA does not intend to object to the distribution and use of this test as described above. We ask that you please send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford (Kim.Sapsford@fda.hhs.gov) and the Director of the Division of Microbiology Devices, Uwe Scherf (Uwe.Scherf@fda.hhs.gov).

Kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AMERICAN OVERSIGHT

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Hi Liz,
When we spoke last week, we considered (b) (5) [redacted]

[redacted]

We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
(b) (6) [redacted]

+ Wendi who is now overseeing lab activities for the response.

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 1/31/2020 6:07:52 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** Re: Regulatory discretion - Need to confirm process and next steps

Excellent. Thank you.

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** January 31, 2020 at 5:55:25 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** FW: Regulatory discretion - Need to confirm process and next steps

Sharing CDC's response

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:40 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe,
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We will notify our lab team of the note below and let you know if there are any additional questions.
Thanks again -
Best,
Anita

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:01 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps
**Importance:** High

AMERICAN OVERSIGHT

Dear Anita,

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Kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Hi Liz,
When we spoke last week, we considered (b) (5)

AMERICAN OVERSIGHT

(b) (5)

We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
(b) (6)

+ Wendi who is now overseeing lab activities for the response.

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 1/30/2020 10:27:00 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Uwe,

Yes, that helps. (b) (5) [redacted]

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** January 30, 2020 at 10:19:53 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Jeff,

Yes, we are waiting for (b) (5) [redacted]

(b) (5) [redacted]

I hope that help,

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 10:05 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Uwe,

(b) (5) [redacted]

AMERICAN OVERSIGHT

Sorry for all the questions. Also, happy to talk in the AM before 8:30 AM.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** January 30, 2020 at 7:25:05 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

I am online, can be reached at (b) (6) for any questions. Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 7:18 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Regulatory discretion - Need to confirm process and next steps

I can talk now — (b) (6)

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** January 30, 2020 at 7:14:43 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Regulatory discretion - Need to confirm process and next steps

Hi Jeff,

CDC is asking (bottom of email chain) the following:

(b) (5)

I had a call with OCC that I would like to discuss with you, either in the morning or by phone tonight.

Thanks,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov

AMERICAN OVERSIGHT

U.S. FOOD & DRUG ADMINISTRATION

*Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:*
***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 7:03 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

See the message below. Per our last exchange, (b) (5) [redacted]. Please let me know how you plan to proceed. Thanks, Liz

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** January 30, 2020 at 7:00:06 PM EST
**To:** Patel, Anita (CDC) <bop1@cdc.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

I will consider this email a request, and we will respond accordingly. Thanks.

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Date:** January 30, 2020 at 6:58:24 PM EST
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Meant wendi not wendy ☺

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD)
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

AMERICAN OVERSIGHT

Hi Liz,

When we spoke last week, we considered (b) (5) [redacted]

[redacted]

We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
(b) (6) [redacted]

+ Wendy who is now overseeing lab activities for the response.

AMERICAN OVERSIGHT

CONFIDENTIAL SETTLEMENT COMMUNICATION PROTECTED BY FED. RULE OF EVIDENCE 408

Version 2
March 10, 2025

*November 20, 2023 Vaughn Index*
*American Oversight v. HHS et. Al., Case No. 1: 20-cv-01063 (D.D.C)*

| Doc. Start | Doc. End | Date of Redacted Doc | Author(s) of Redacted Doc | Document Title | Exemption(s)* | Explanation |
|---|---|---|---|---|---|---|
| 002873 | 002884 | 2/4/2020 | Uwe Scherf | RE: Urgent – CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission | (b)(5) | FDA-CVD-SHERFU-00017497<br><br>Bates: 2878–2880<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) Emergency Use Authorization (EUA) submission, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002885 | 002896 | 2/5/2020 | Uwe Scherf | RE: Urgent – CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission | (b)(5) | FDA-CVD-SCHERFU-00017502<br><br>Bates: 2891–2892<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) Emergency Use Authorization (EUA) submission, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002897 | 002909 | 2/5/2020 | Uwe Scherf | RE: Urgent – CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use | (b)(5) | FDA-CVD-SHERFU-00017507<br><br>Bates: 2903–2905<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) Emergency Use Authorization |

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| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | Authorization submission | | (EUA) submission, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002910 | 002914 | 2/26/2020 | Jeff Shuren | Re: N95 EUA for COVID19 | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035329<br><br>Bates: 2910, 2913–2914<br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee.<br><br>Bates: 2910–2911<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations about the extent of testing and evidence of safety and effectiveness necessary to grant Emergency Use Authorization (EUA) to N95 respirators in healthcare settings for COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2912<br>Personal Privacy Information: The redacted information contains a Webex meeting ID number and password. |
| 002915 | 002918 | 2/16/2020 | Jeff Shuren | RE: Request for enforcement discretion | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035361<br><br>Bates: 2916–2918<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding a request from the Centers for Disease Control and Prevention (CDC) for guidance on the testing of passengers aboard a cruise ship that was docked in Japan and who would be returning to the United States, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| | | | | | | |
|---|---|---|---|---|---|---|
| 002919 | 002926 | 2/21/2020 | Jeff Shuren | RE: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SHURENJ-00035369<br><br>Bates: 2919<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding quality control issues related to the diagnostic test for SARS-CoV-2 developed by the Centers for Disease Control and Prevention (CDC), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2920–2026<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria and results, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002927 | 002931 | 2/16/2020 | Jeff Shuren | Re: Request for enforcement discretion | (b)(5) | FDA-CVD-SHURENJ-00035387<br><br>Bates: 2927–2931<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding a request from the Centers for Disease Control and Prevention (CDC) for guidance on the testing of passengers aboard a cruise ship that was docked in Japan and who would be returning to the United States, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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Version 2
March 10, 2025

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| 002932 | 002936 | 2/23/2020 | Jeff Shuren | RE: N95 decon and reuse -- preparatory to 3M call | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035414<br><br>Bates: 2932–2934<br><br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee.<br><br>Bates: 2932, 2934-2936<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the use and reuse of N95 respirators for COVID-19 in healthcare settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2935–2936<br><br>Personal Privacy Information: The redacted information contains the private phone number of a Department of Health and Human Services' (HHS) employee, a teleconference meeting invitation and dial-in number. The redacted information also contains the private email addresses of the then FDA commissioner and a third-party. |
| 002937 | 002941 | 2/23/2020 | Jeff Shuren | RE: N95 decon and reuse – preparatory to 3M call | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035435<br><br>Bates: 2937–2939<br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee.<br><br>Bates: 2937–2940<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the use and reuse of N95 respirators for COVID-19 use in healthcare settings, the release of which would cause foreseeable harm as it would reveal internal discussions |

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| | | | | | | and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2940–2941<br>Personal Privacy Information: The redacted information contains the private email addresses of a third party and the then FDA commissioner. The redacted information also contains a Department of Health and Human Services (HHS) employee's private phone numbers, a teleconference meeting invitation and dial-in number. |
| 002942 | 002943 | 2/14/2020 | Jeff Shuren | RE: two quick read items to flag-- | (b)(4), (b)(5), (b)(6) | FDACDRH-SHURENJ-00035455<br><br>Bates: 2942, 2943<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding planned updates related to a third party's operating status and potential supply chain disruptions, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2943<br>Confidential Commercial Information: The redacted information discusses a third party's EtO containment system and operating status. The release of this information would inform competitors about this facility's operations and would lead to predictable harm.<br><br>Bates: 2943<br>Personal Privacy Information: The redacted information contains the private phone numbers of a Department of Health and Human Services (HHS) employee. |
| 002944 | 002945 | 2/13/2020 | Jeff Shuren | RE: N95 Respirators – internal confidential | (b)(4), (b)(5), (b)(6) | FDACDRH-SHURENJ-00035472<br><br>Bates: 2944–2945<br>Deliberative Process Privilege: The redacted information in this email exchange includes pre-decisional, internal deliberations regarding testing |

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| | | | | | | verification and quantity of N95 respirators, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2944–2945<br>Personal Privacy Information: The redacted information contains the private email addresses of a Department of Health and Human Services (HHS) employee and the email address of the then FDA commissioner.<br><br>Bates: 2945<br>Confidential Commercial Information: The redacted information relates to the Centers for Disease Control and Prevention's (CDC) testing and manufacturing requirements for the N95 respirators for specific firms. The release of this information would inform competitors about this entity's operations and would lead to predictable harm. |
| 002946 | 002948 | 2/15/2020 | Jeff Shuren | RE: Request for enforcement discretion | (b)(5) | FDA-CVD-SHURENJ-00035478<br><br>Bates: 2947<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) request for guidance on the testing of passengers aboard a cruise ship that was docked in Japan and who would be returning to the United States, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002949 | 002951 | 2/17/2020 | Jeff Shuren | Re: By noon tomorrow | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035491<br><br>Bates: 2949–2950<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding discussion points related to diagnostic capacity, testing development, and utilization, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to |

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| | | | | | | receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2951<br>Personal Privacy Information: The redacted information contains the private phone numbers of a Department of Health and Human Services' (HHS) employee. |
| 002952 | 002955 | 2/15/2020 | Jeff Shuren | RE: Request for enforcement discretion | (b)(5) | FDA-CVD-DHURENJ-00035519<br><br>Bates: 2952–2954<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations related to the Centers for Disease Control and Prevention's (CDC) request for guidance on the testing of passengers aboard a cruise ship that was docked in Japan and who would be returning to the United States and draft language granting CDC's request for guidance, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002956 | 002957 | 2/23/2020 | Jeff Shuren | Fwd: N95 decon and reuse – preparatory to 3M call | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035538<br><br>Bates: 2956–57<br>Personal Privacy Information: The redacted information contains a private email address of the then FDA commissioner.<br><br>Bates: 2956–57<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the use and reuse of N95 respirators for COVID-19 use in healthcare settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2957 |

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| | | | | | | Personal Privacy Information: The redacted information contains the private phone numbers of a Department of Health and Human Services (HHS) employee, the private email address of a third-party, and a teleconference meeting invitation and dial-in number. |
| 002958 | 002959 | 2/14/2020 | Jeff Shuren | Fwd: two quick read items to flag-- | (b)(4), (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035597<br><br>Bates: 2958<br>Confidential Commercial Information: The redacted information discusses a third party's EtO containment system and operating status. The release of this information would inform competitors about this facility's operations and would lead to predictable harm.<br><br>Bates: 2958–59<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding flagged items related to COVID-19 and potential supply chain disruptions, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2959<br>Personal Privacy Information: The redacted information contains the private phone numbers of a Department of Health and Human Services (HHS) employee. |
| 002960 | 002966 | 2/23/2020 | Jeff Shuren | RE: Cut-off change – Number of public health labs that verified CDC panel for use | (b)(5) | FDA-CVD-SHURENJ-00035632<br><br>Bates: 2960–2964, 2966<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) testing and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 002967 | 002969 | 2/17/2020 | Jeff Shuren | Re: CDC 2019-nCoV Test Update | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035640<br><br>Bates: 2967<br>Personal Privacy Information: The redacted information contains private email address information of the then FDA commissioner.<br><br>Bates: 2967–2968<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding internal strategies for updates on FDA activities related to the 2019 n-CoV response, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2968–2969<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) testing and the diagnostic processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2969<br>Personal Privacy Information: The redacted information contains the private phone numbers of a Department of Health and Human Services' (HHS) employee and a private email address of the then FDA commissioner. |
| 002970 | 002973 | 2/15/2020 | Jeff Shuren | Re: Request for enforcement discretion | (b)(5) | FDA-CVD-SHURENJ-00035656<br><br>Bates: 2970–2972<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC)'s request for guidance on the testing of passengers aboard a cruise ship that was docked in Japan and who |

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| | | | | | | would be returning to the United States, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002974 | 002976 | 2/17/2020 | Jeff Shuren | RE: CDC 2019-nCo Test Update | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035810<br><br>Bates: 2974–2976<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding internal strategies for updates on FDA activities related to 2019 nCoV response as well as updates related to the Centers for Disease Control and Prevention's 2019 nCoV testing and diagnostic process, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2974–2975<br>Personal Privacy Information: The redacted information contains email address information for the then FDA commissioner and the private phone number of a Department of Health and Human Services (HHS) employee. |
| 002977 | 002979 | 2/15/2020 | Jeff Shuren | RE: Request for enforcement discretion | (b)(5) | FDA-CVD-SHURENJ-00035827<br><br>Bates: 2978<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC)'s request for guidance on the testing of passengers aboard a cruise ship that was docked in Japan and who would be returning to the United States and draft language that FDA's Center for Devices and Radiological Health (CDRH) sent to FDA's Office of the Chief Counsel (OCC) for review, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002980 | 002985 | 2/8/2020 | Jeff Shuren | Re(b)(4) | (b)(4), (b)(6) | FDA-CVD-SHURENJ-00035990 |

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| | | | | | | Bates: 2980–2985<br>Confidential Commercial Information: The withheld information contains confidential commercial information regarding the proprietary data of a specific company's device development plan. The release of this information would inform competitors about this entity's operations and would lead to predictable harm.<br><br>Bates: 2981, 2984-2895<br>Personal Privacy Information: The redacted information contains the email address of private third-party. |
| 002986 | 002993 | 2/3/2020 | Jeff Shuren | FW: SCMP: China reports outbreak of H5N1 in Hunan Province which borders with Hubei Province | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036019<br><br>Bates: 2986–2987, 2990–2991<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations related to reports regarding an outbreak of H5Nl in the Hunan Province of China, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 2987–2989, 2991–2993<br>Personal Privacy Information: The redacted information contains the email addresses of State Department employees and United States Trade Representative employees. The redacted information also contains the private phone number of a United States Trade Representative employee and the name of a United States Trade Representative employee. |
| 002994 | 002998 | 2/12/2020 | Jeff Shuren | RE: FDA visit | (b)(5) | FDA-CVD-SHURENJ-00036108<br><br>Bates: 2994–2995, 2997-2998<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding draft agenda items for a Centers for Disease Control and Prevention (CDC) visit to FDA, the release of which would cause foreseeable harm as it would reveal |

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| | | | | | | internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002999 | 003002 | 2/3/2020 | Jeff Shuren | RE: Coronavirus testing equipment and materials | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036129<br><br>Bates: 2999–3000<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel (OCC) regarding coronavirus testing equipment and materials.<br><br>Bates: 2999–3002<br>Personal Privacy Information: The redacted information contains email address information for then FDA Commissioner and the email address of a New York City Hall employee.<br><br>Bates: 2999–3001<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding a draft response letter to Dr. Perea-Henze, the Deputy Major of Health & Human Services of NYC related to coronavirus testing equipment and materials, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003003 | 003006 | 1/30/2020 | Jeff Shuren | RE: Regulatory discretion – Need to confirm process and next steps | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036269<br><br>Bates: 3003–3006<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding distribution of the Centers for Disease Control and Prevention's (CDC) test for SAR-CoV-2 and next steps, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| | | | | | | Bates: 3004, 3006<br>Personal Privacy Information: The redacted information contains the private phone numbers of FDA employees. |
| 003007 | 003008 | 1/31/2020 | Jeff Shuren | RE: Regulatory discretion – Need to confirm process and next steps | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036328<br><br>Bates: 3008<br>Personal Privacy Information: The redacted information contains the private phone number of a Centers for Disease Control and Prevention (CDC) employee.<br><br>Bates: 3007–3008<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) request for confirmation related to the regulatory process for an Emergency Use Authorization (EUA) and next steps, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003009 | 003012 | 1/31/2020 | Jeff Shuren | Re: Regulatory discretion – Need to confirm process and next steps | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036328<br><br>Bates: 3010<br><br>Personal Privacy Information: The redacted information contains the private phone number of California Department of Public Health employee and the private phone number and office location of an Illinois Department of Public Health-Chicago Laboratory employee.<br><br>Bates: 3011–3012<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding quality control issues related to the diagnostic test for SARS-CoV-2 developed by the Centers for Disease Control and Prevention (CDC), the release of which would cause foreseeable harm as it would reveal internal discussions and |

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| | | | | | | strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3012<br>Personal Privacy Information: The redacted information contains the private phone number of a Centers for Disease Control and Prevention (CDC) employee. |
| 003013 | 003015 | 1/31/2023 | Jeff Shuren | Re: Regulatory discretion – Need to confirm process and next steps | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036552<br><br>Bates: 3014–3015<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding quality control issues related to the diagnostic test for SARS-CoV-2 developed by the Centers for Disease Control and Prevention (CDC), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3015<br>Personal Privacy Information: The redacted information contains the private phone number of a Centers for Disease Control and Prevention (CDC) employee. |
| 003016 | 003019 | 1/30/2020 | Jeff Shuren | RE: Regulatory discretion – Need to confirm process and next steps | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036643<br><br>Bates: 3016–3019<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) request for confirmation on next steps in developing the diagnostic test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3017, 3019 |

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| | | | | | | Personal Privacy Information: The redacted information contains the private phone numbers of FDA employees and a Centers for Disease Control and Prevention (CDC) employee. |

* Page prefix is FDACDRH-p4-AO
** Exemption codes refer to the sections of the Freedom of Information statue 5 U.S.C. § 552(b).

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/25/2020 7:12:53 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/54/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/25/20 6 AM update:

**Status of activities on diagnostics:**

- 2/24/20 CDC proposed to change wording the intended use of their EUA from:
  - The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals **who meet CDC criteria for 2019-nCoV testing**

  - To:

(b) (5) [redacted]

**Also, CDC communicate that they will move forward with changing their assay to a N1+N2 only assay.**
**CDC's intention is to have both changes done with one submission.**

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- CDC will provide additional confirmation testing had been conducted by CDC on presumptive positive samples. FDA will rely this additional information for the statistical justification included in the benefit-risk assessment for CDC to exclude using the N3 primer/probeset as part of their assay moving forward.

- A total of 75 IVD Developers have requested and received EUA review template

(b) (5)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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(b)(5) Draft Authorization Letter to CDC

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(b)(5) Draft Authorization Letter to CDC

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(b)(5) Draft Authorization Letter to CDC

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(b)(4) Wadsworth Center SOP

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(b)(4) Wadsworth Center SOP

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NEW YORK STATE OF OPPORTUNITY. Department of Health

**ANDREW M. CUOMO**
Governor

**HOWARD A. ZUCKER, M.D., J.D.**
Commissioner

**SALLY DRESLIN, M.S., R.N.**
Executive Deputy Commissioner

February 28, 2020

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**ATTN:** Division Director: Dr. Uwe Scherf, OHT7-OIR/OPEQ/CDRH/FDA

***RE:*** *Request for Emergency Use Authorization (EUA) Interactive Review of the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel*

Dear Dr. Scherf,

The Wadsworth Center, NYSDOH is submitting an Emergency Use Authorization (EUA) interactive review for a SARS-CoV-2 diagnostic assay, so that we can obtain feedback from the FDA concerning the studies and/or testing outlined in our EUA submission package.

The SARS-CoV-2 diagnostic assay in the submission is based on using the CDC protocol, including oligo sequences, instruments and cycling conditions. Changes from the CDC protocol include the use of commercially purchased primers and probes and intended use is limited to the Wadsworth Center and potentially the New York City public health laboratory, if they perform the appropriate validation as required by the FDA.

In addition to this letter, also attached in this initial submission email, is the first draft of our completed EUA Interactive Review template for FDA review.

In case you should have any questions regarding the information provided and/or need additional information or data from us, please contact me immediately either via email at jill.taylor@health.ny.gov or phone at 518-474-3157.

Sincerely,

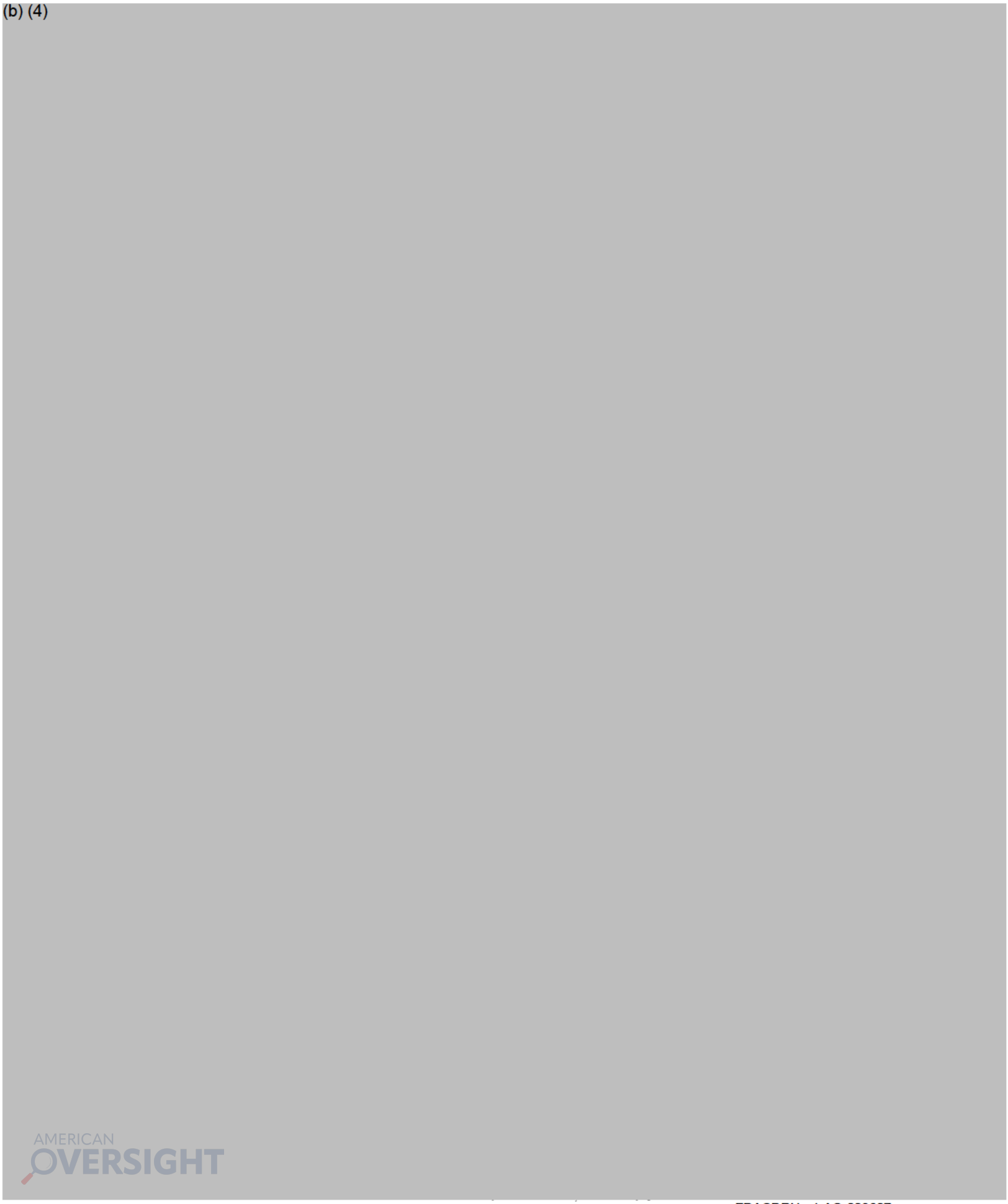
Jill Taylor, Ph.D.
Director, Wadsworth Center

Attachment

AMERICAN OVERSIGHT

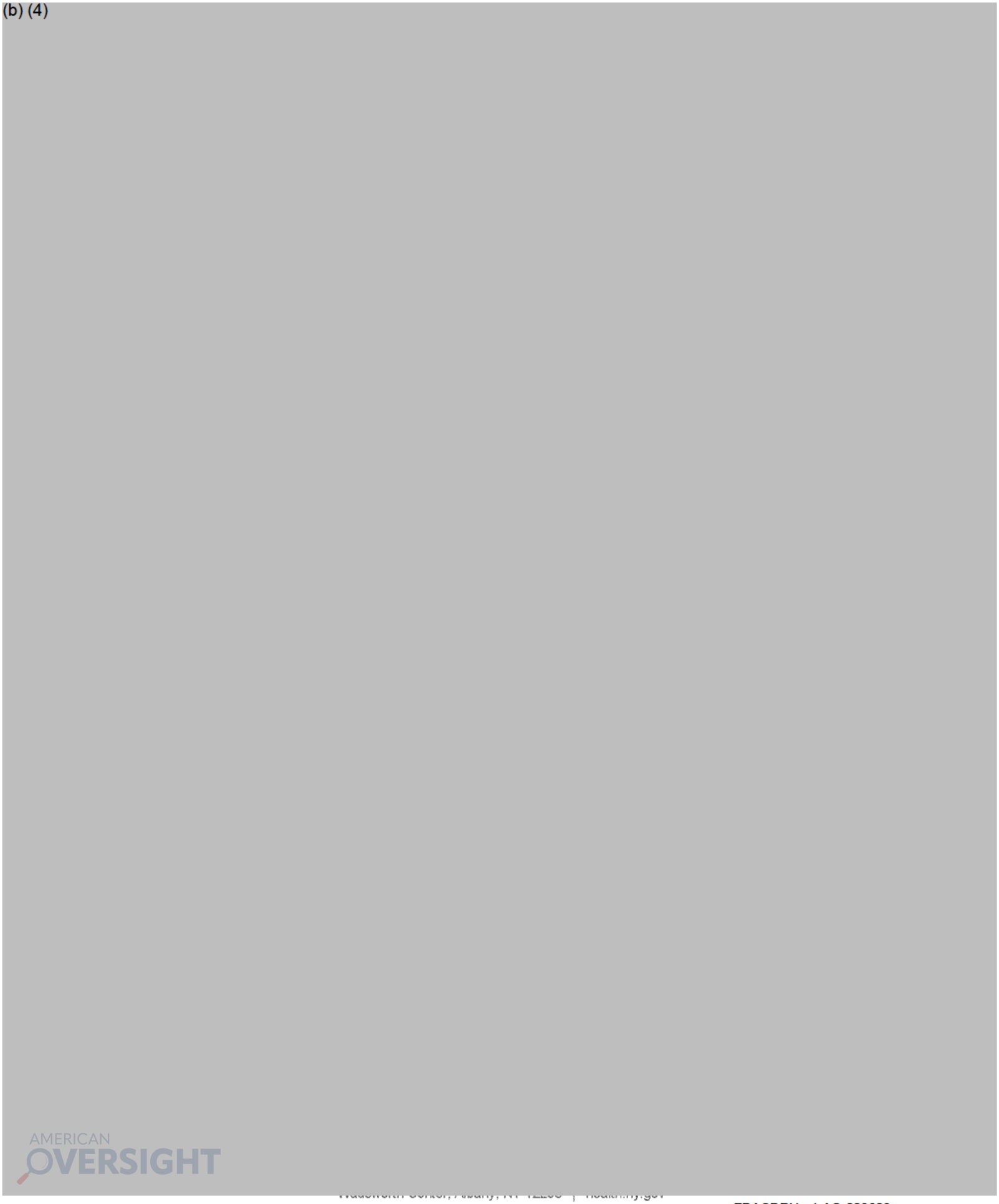
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AMERICAN OVERSIGHT



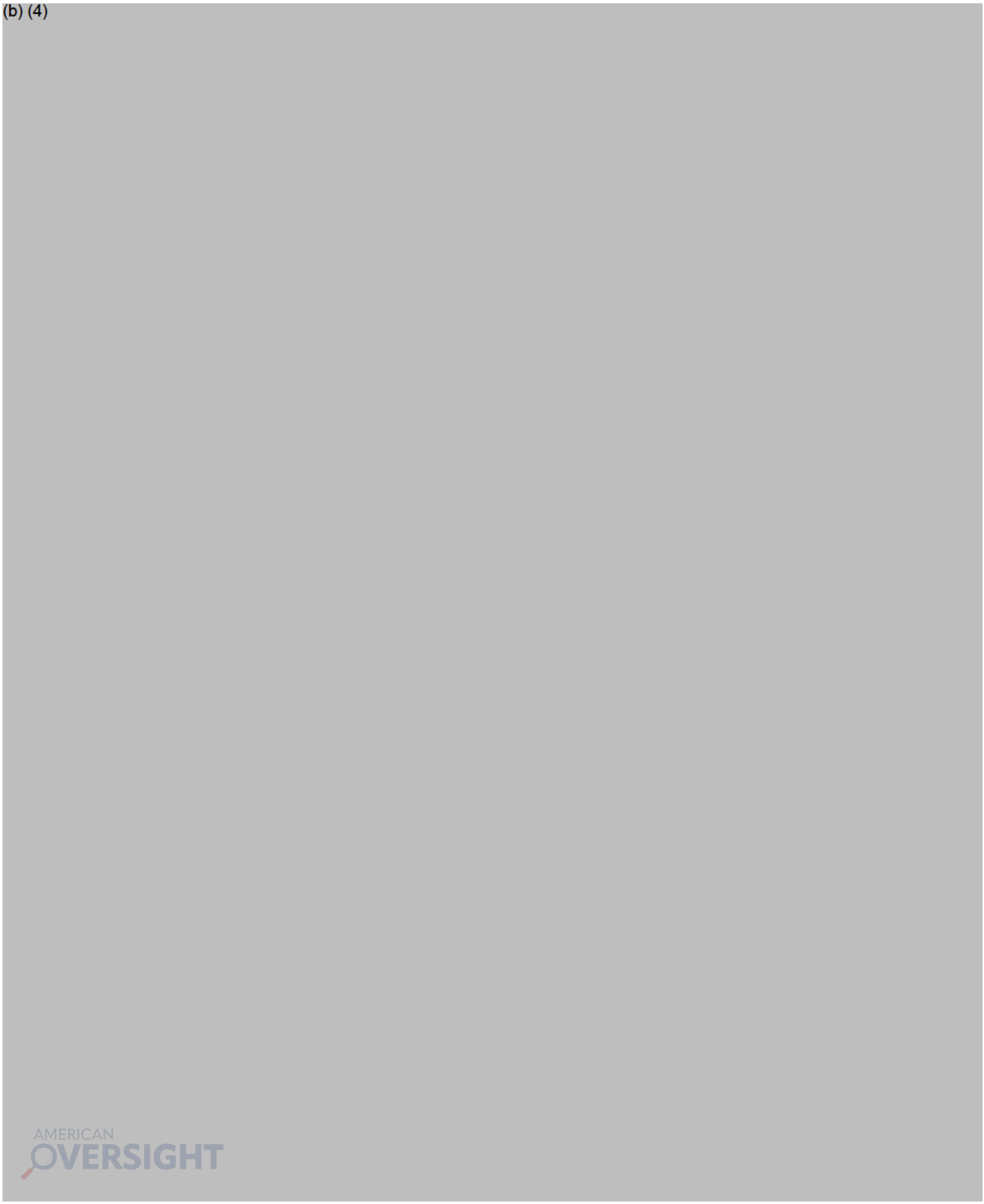

AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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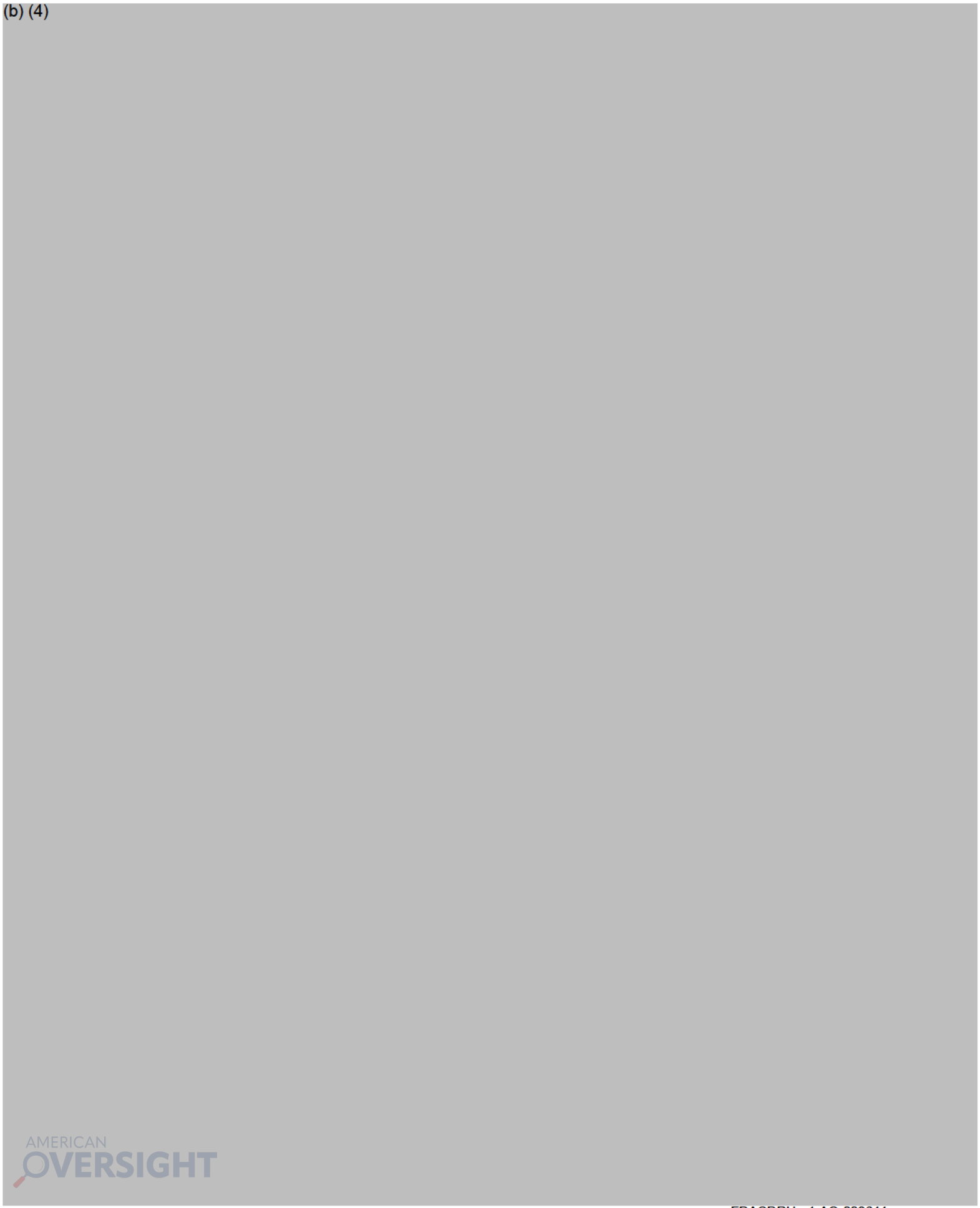


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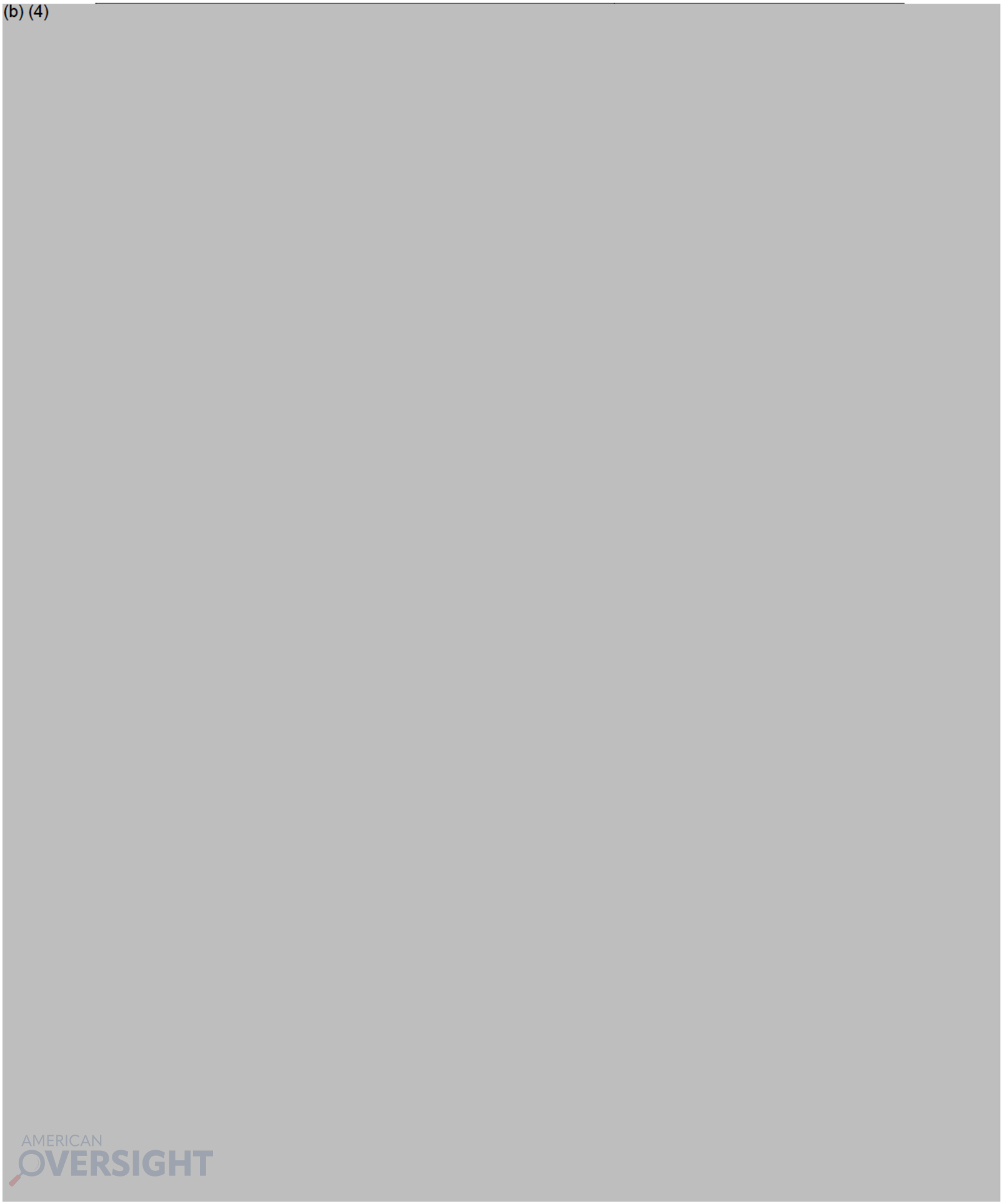
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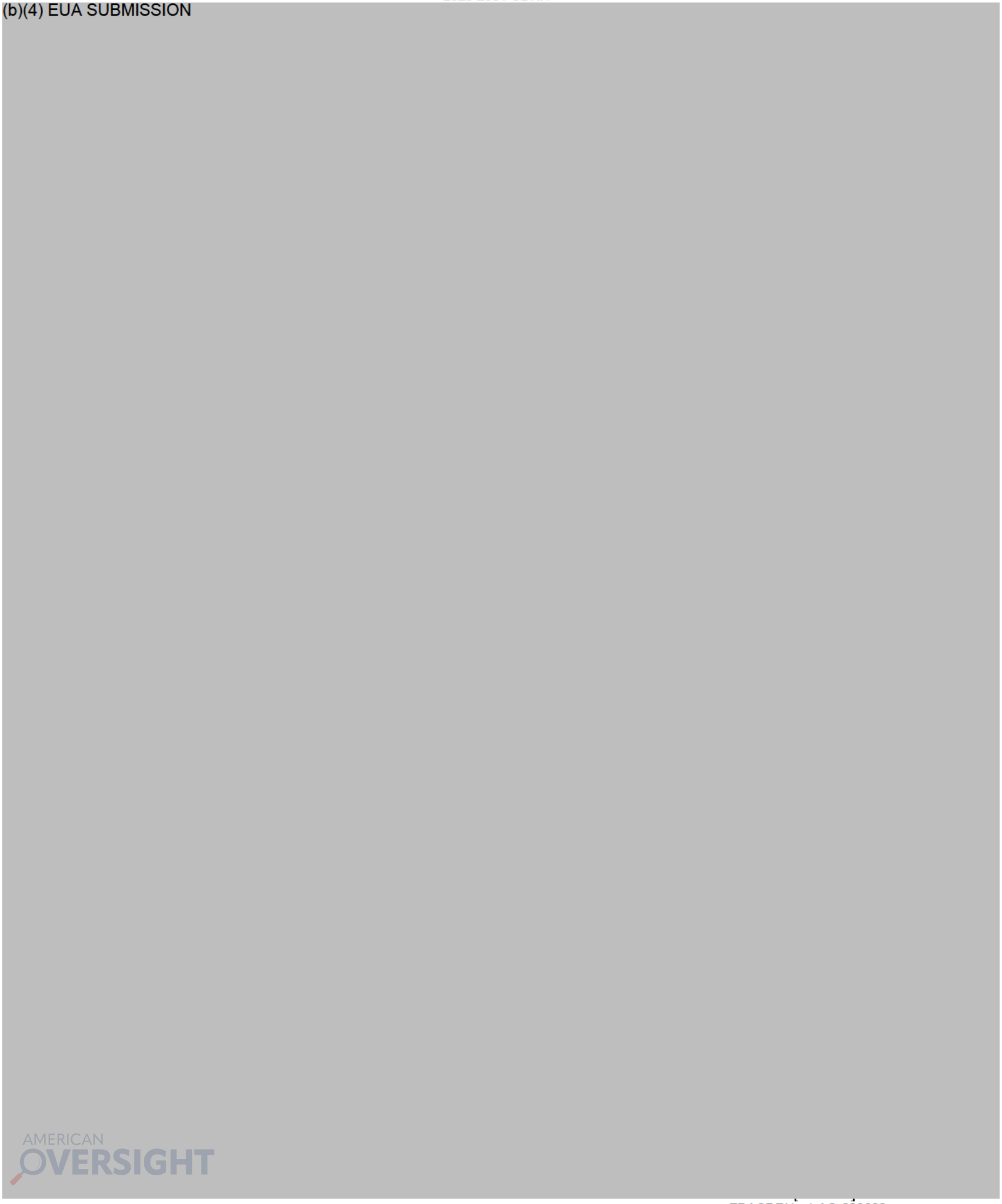


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(b)(4) EUA SUBMISSION



AMERICAN OVERSIGHT

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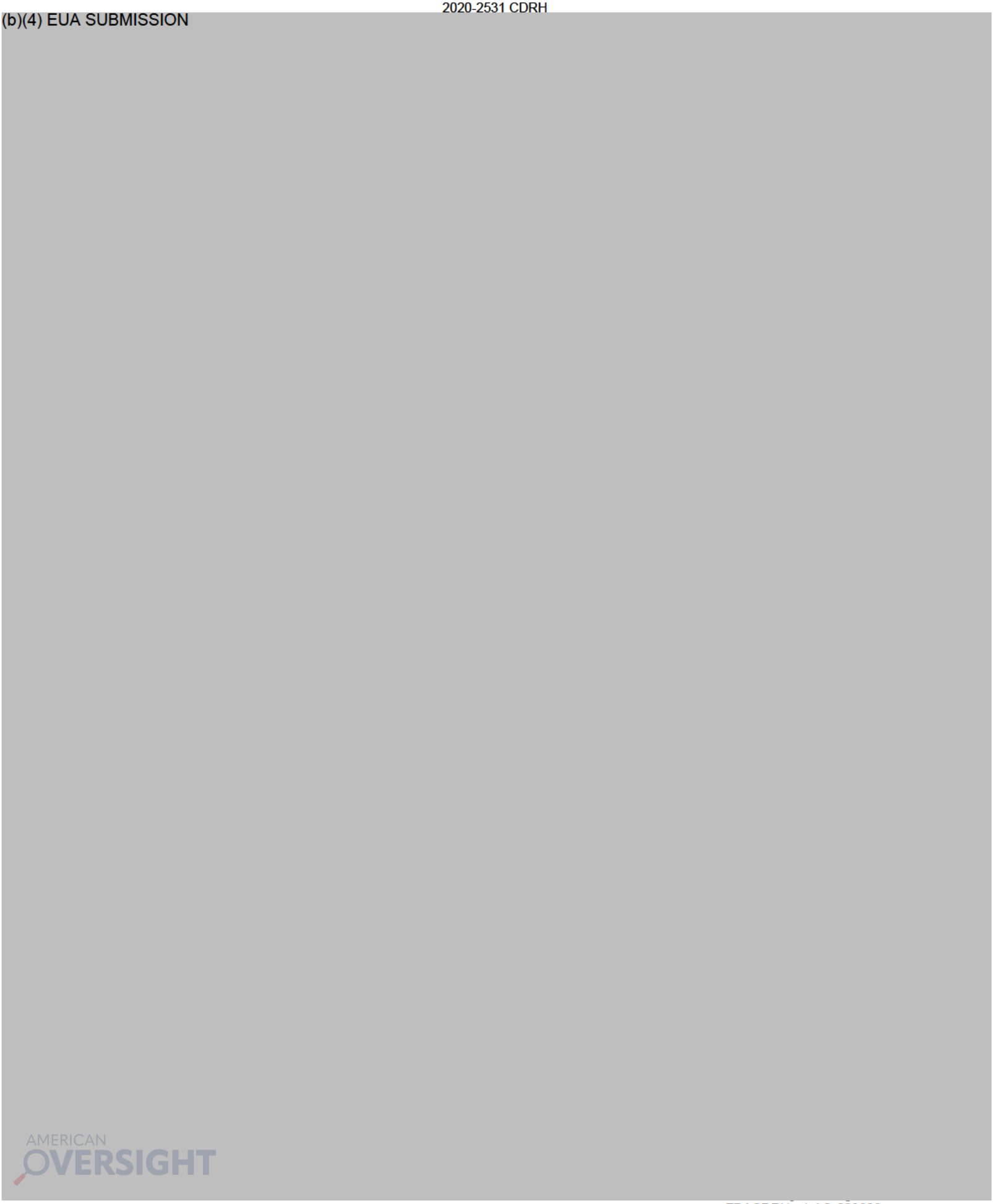
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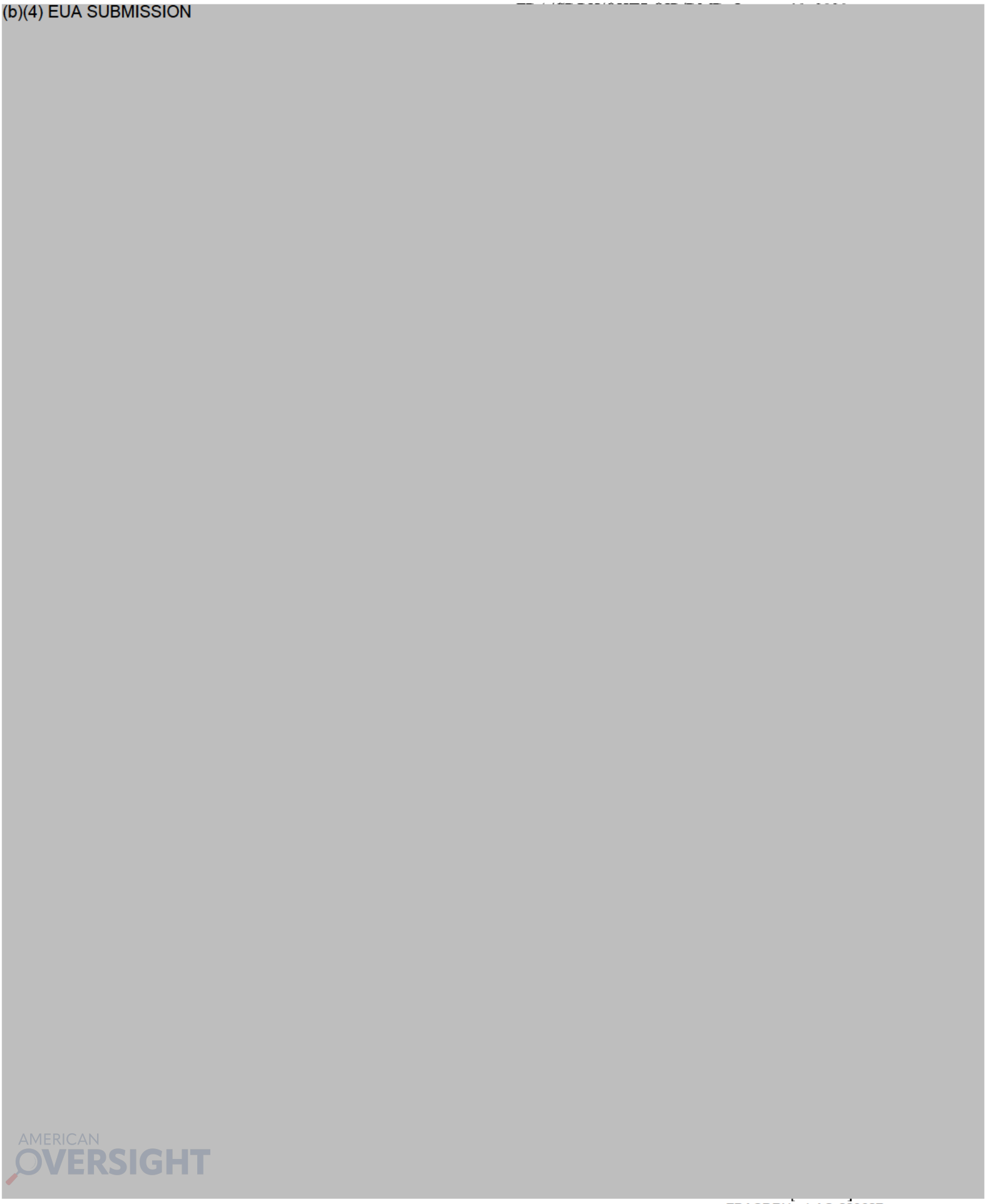
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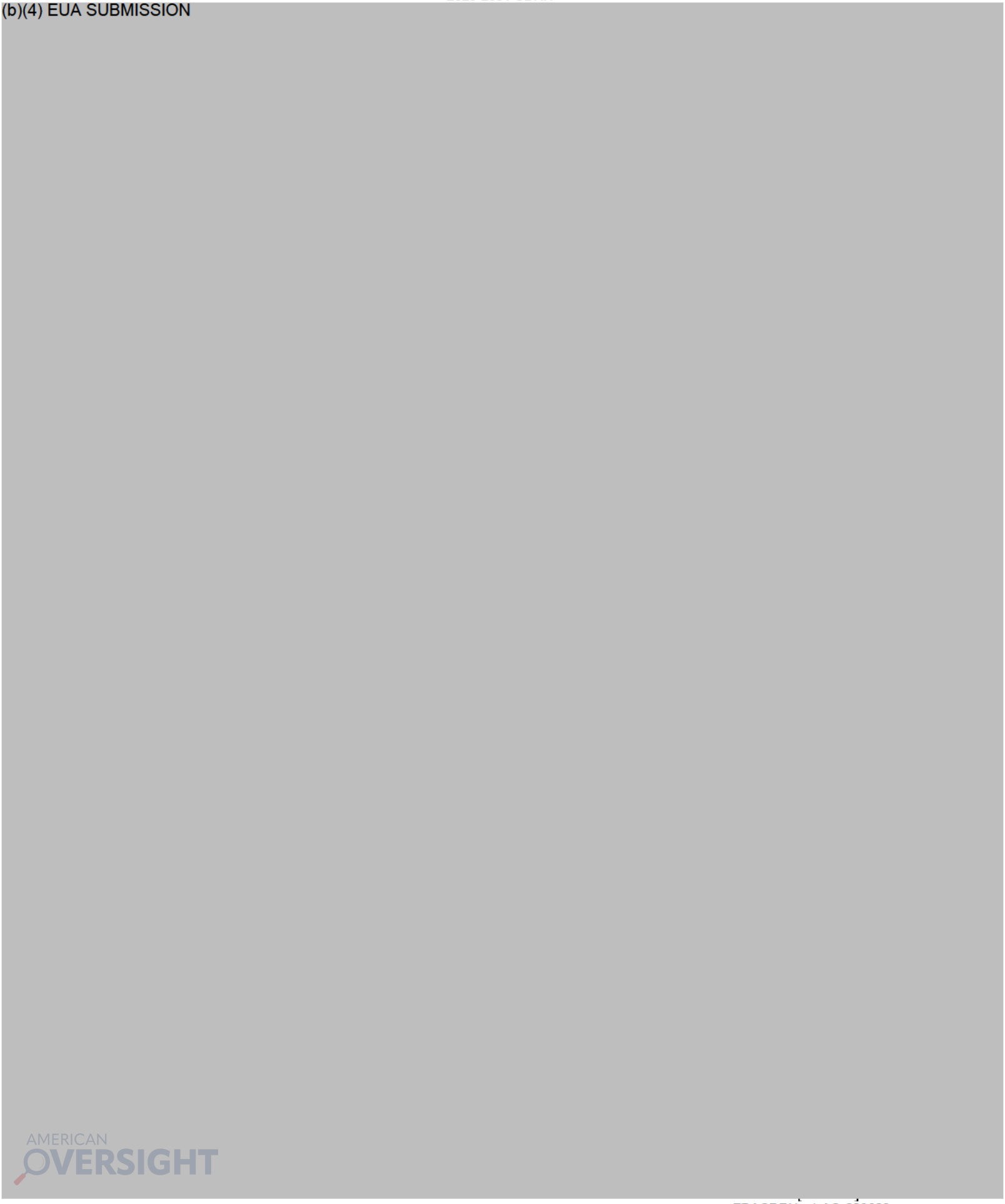
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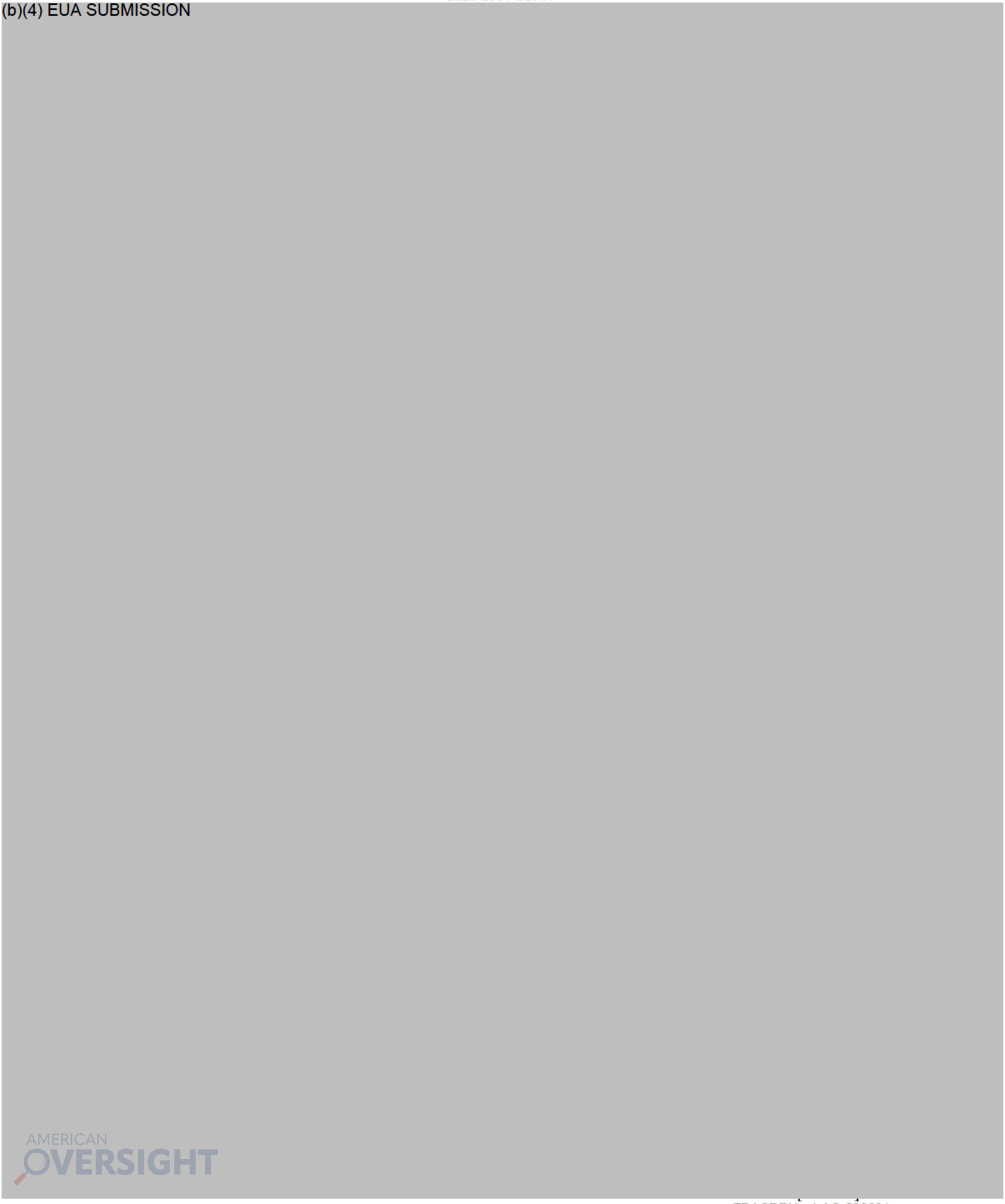
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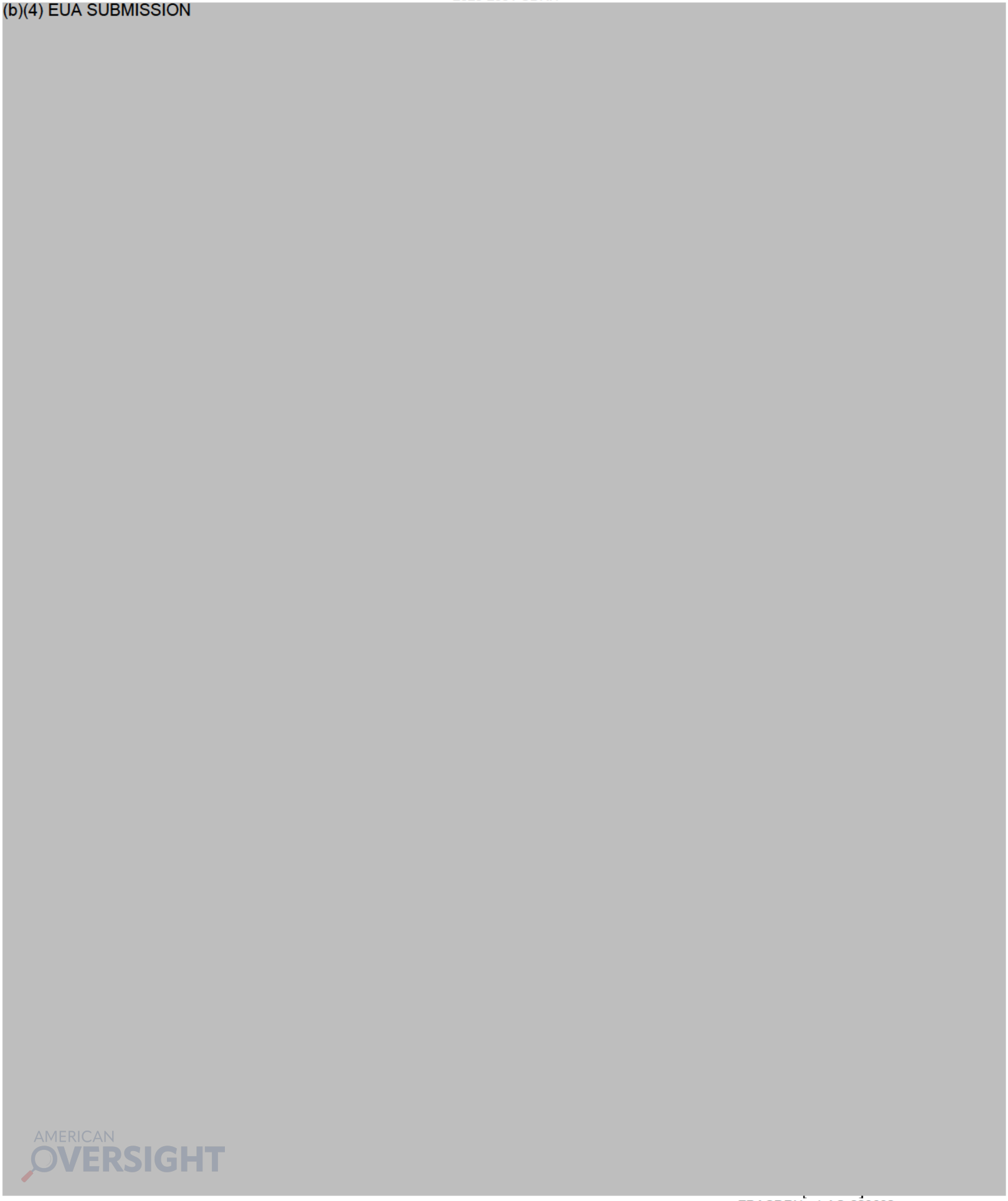
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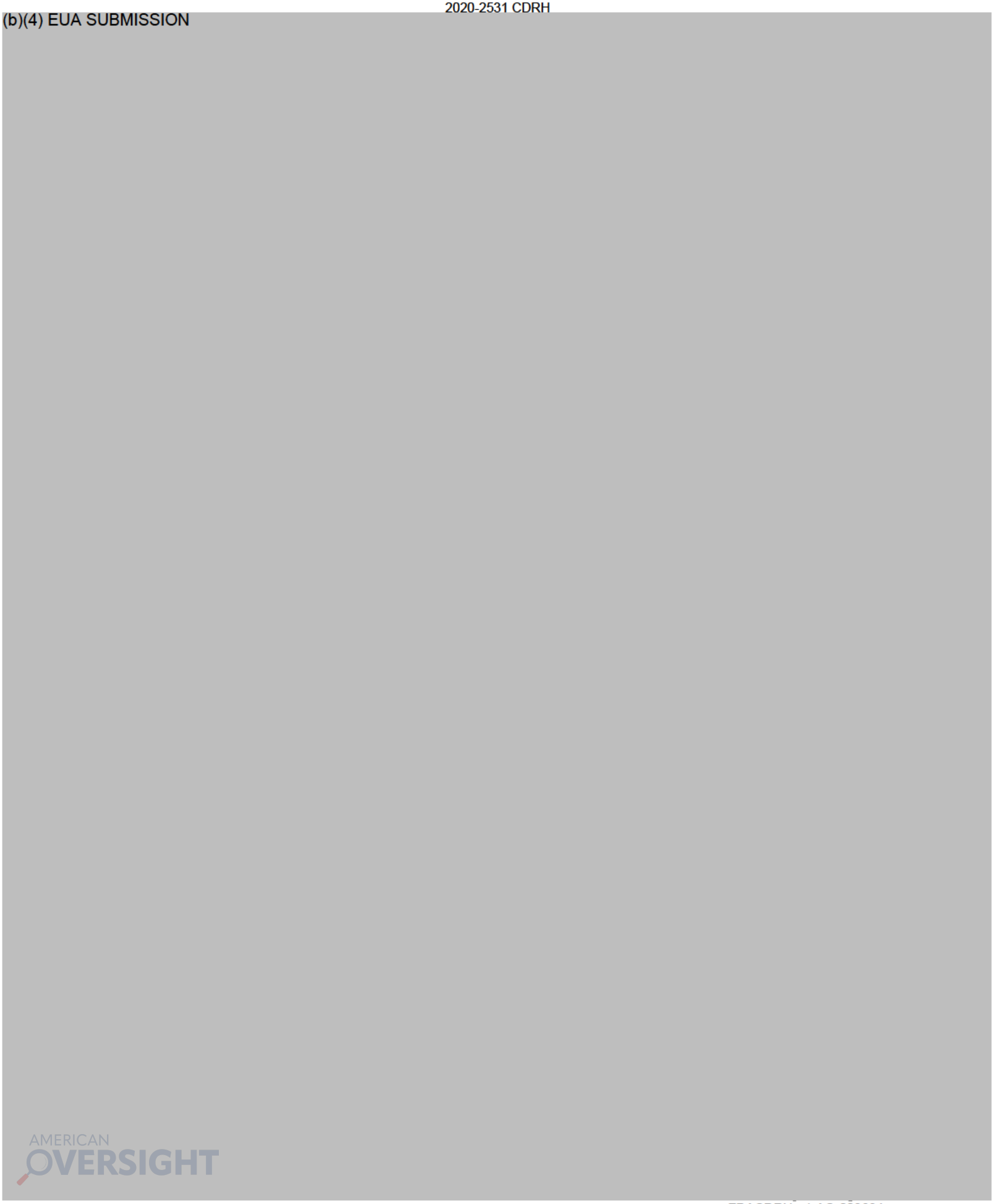


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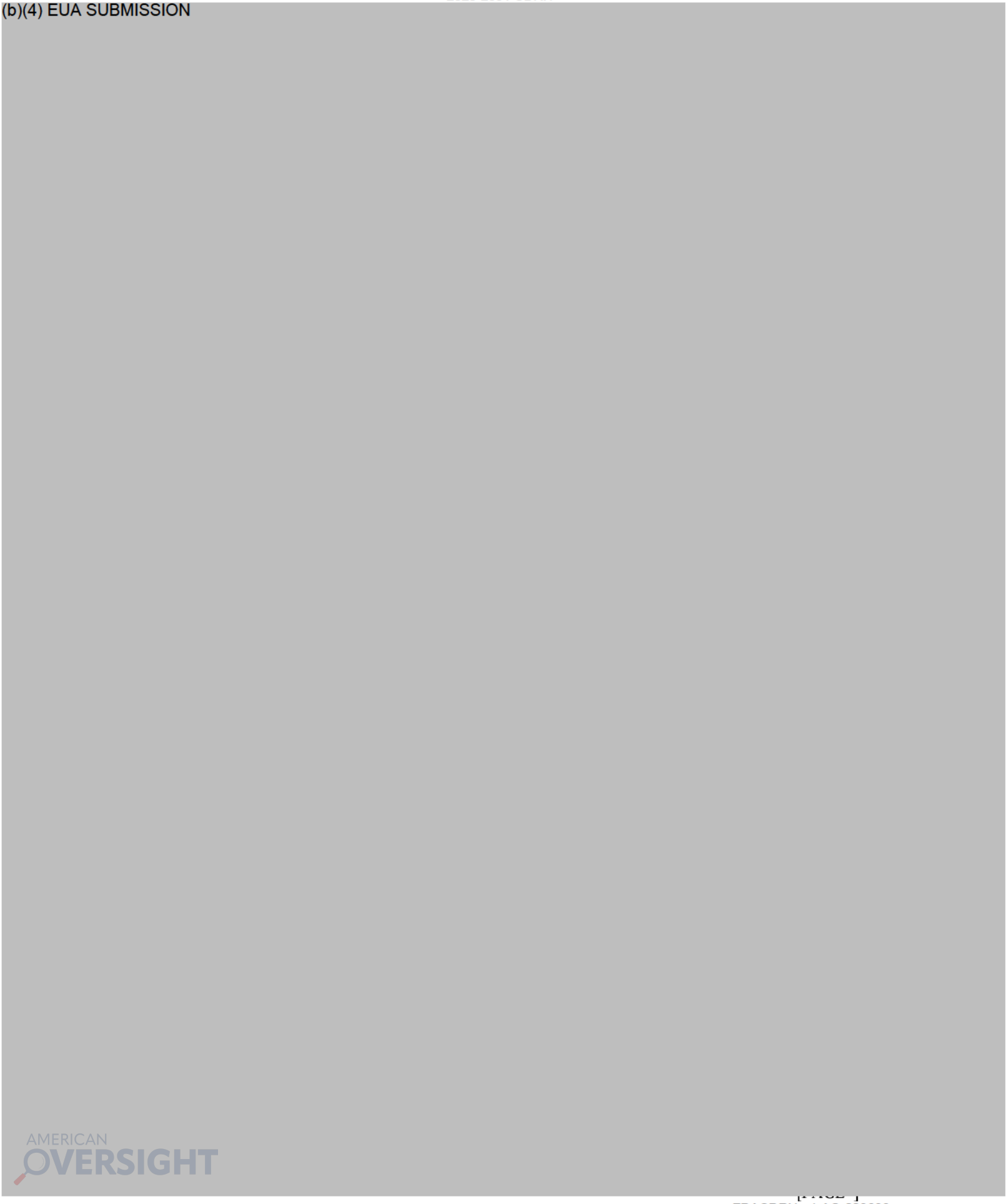


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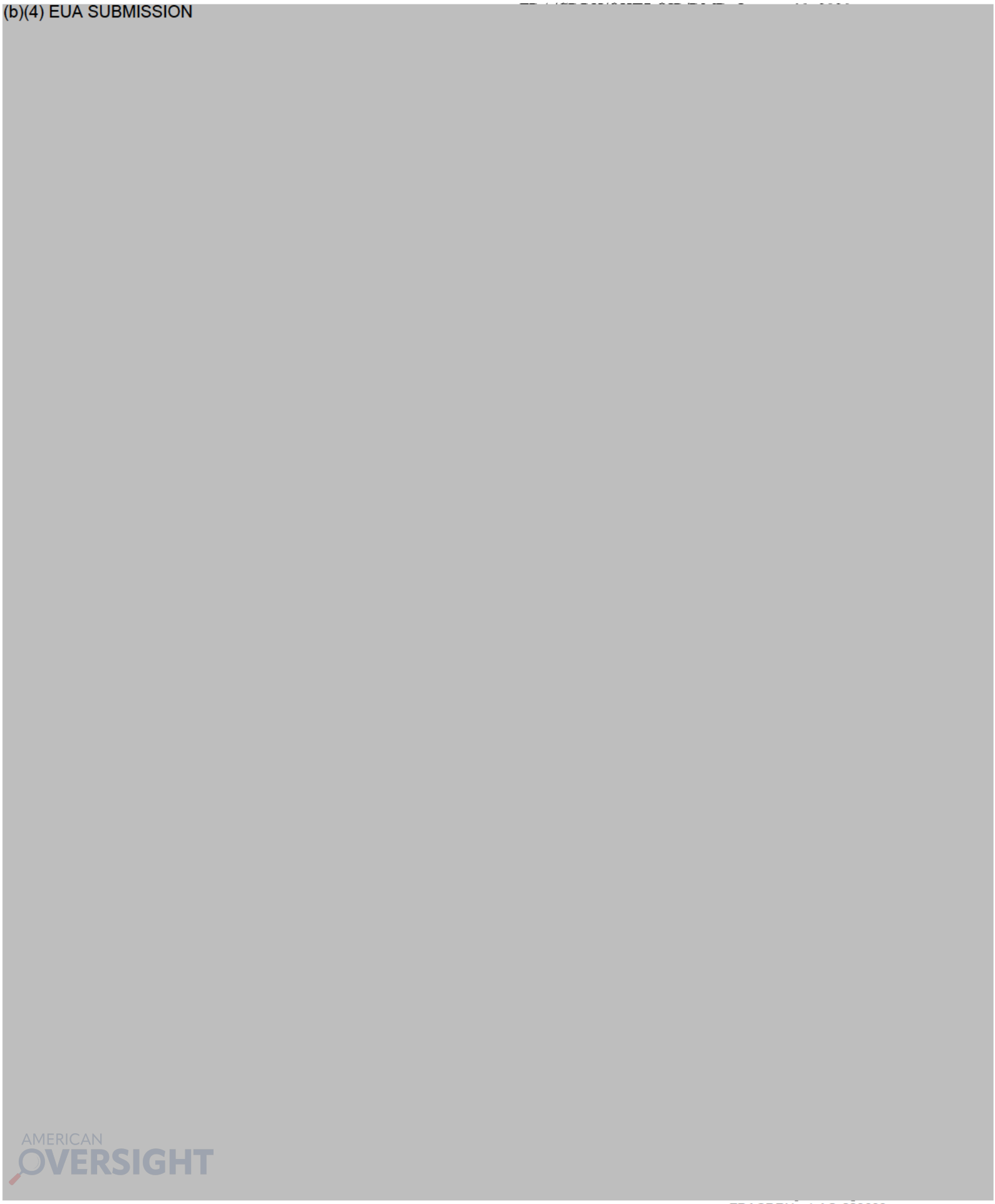
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AMERICAN OVERSIGHT

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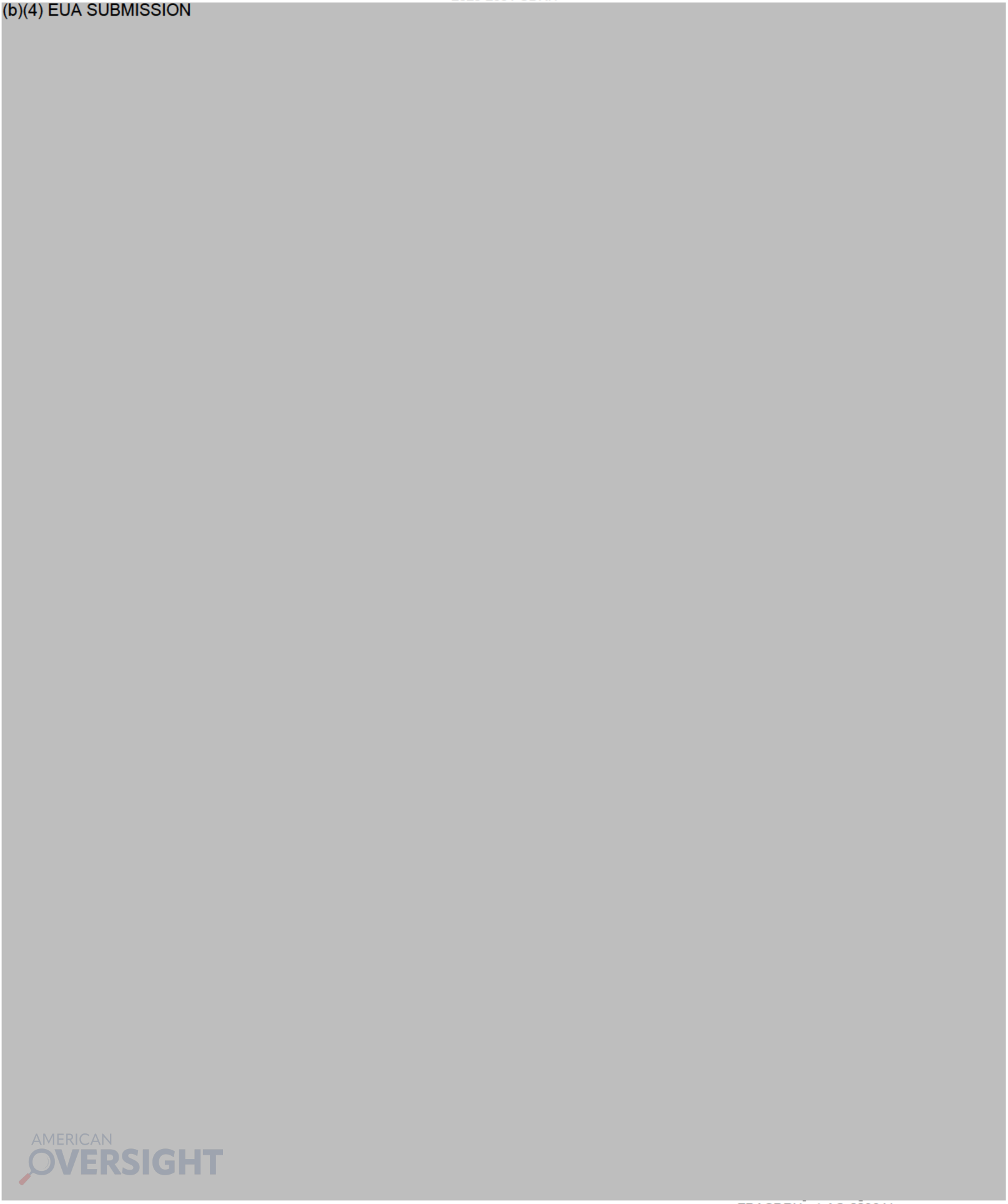


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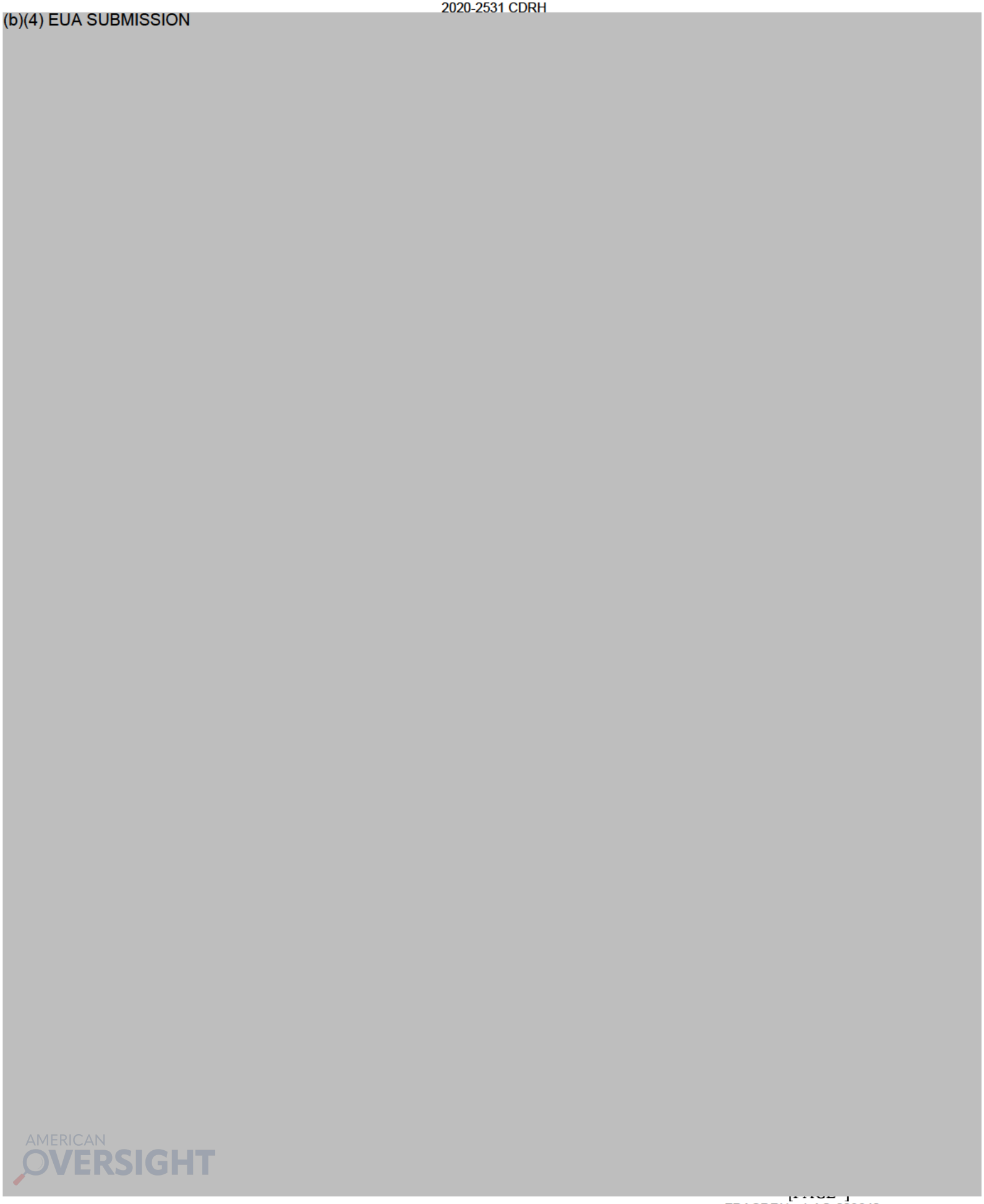
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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

(b)(4) EUA SUBMISSION

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/28/2020 3:27:44 PM
**To:** Proctor, Tremyl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35056b97ee224343b77af6a0973d5d61-Tremyl.Proc]
**Subject:** FW: the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel
**Attachments:** (b) (4)oligos 01.29.20.pdf; SOP LVD-117.1 LVD QC Criteria for Lot-to-Lot Verification Testing.pdf; Synthetic RNA concentration data.pdf; FDA3514_Wadsworth SARS-CoV Cover sheet 2 02.28.20.pdf; Request for EUA Interactive Review of New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel_rev.pdf; NYS DOH Info for Healthcare Providers on NYS SARS-CoV-2 Real-Time RT-PCR Diag Panel.docx; NYS DOH Info for Patients on NYS SARS-CoV-2 Real-Time RT-PCR Diag Panel.docx; SOP LVD-131 SARS-CoV-2 real-time RT-PCR.doc; Wadsworth submission EUA Review for NAT_SARS-CoV-2 _ 2.28.2020.doc

Tremyl,

Can you please print out the following documents for us. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Friday, February 28, 2020 3:21 PM
**To:** oir-policy <CDRH-OIR-POPS@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Subject:** the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

In the attached files, please find the following documents for the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

1. Cover letter from the Wadsworth Center Director, Dr. Jill Taylor
2. Completed form 3514
3. Wadsworth Center EUA Interactive Review Submission for Molecular-Based test for SARS-CoV-2
4. Associated appendices to the submission:

a. Oligo spec sheets from manufacturer
b. Transcript spec sheet from manufacturer
c. NYSDOH SOP for lot to lot verification testing
d. NYSDOH SOP for the New York State SARS-CoV-2 real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel
e. NYSDOH Info for Patients on New York State SARS-CoV-2 real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

AMERICAN OVERSIGHT

f. NYSDOH Info for Healthcare Providers on New York State SARS-CoV-2 real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george




AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 3/1/2020 10:26:00 AM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: confirmatory testing

Li,

You are absolutely correct. After this initial "confirmation" period, all positives are still presumptive, and should be confirmed by state and public health authorities and/or CDC.

Uwe
-----Original Message-----
From: Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
Sent: Sunday, March 1, 2020 10:05 AM
To: Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: FW: confirmatory testing

Hi all,

Are all test positives still presumptive and needed to be confirmed by CDC or local public health labs? If yes, my understanding regarding the new guidance regarding LDTs is that first 5 positive and 5 negative specimens need to be confirmed by another EUA test. It could be any EUA tests, not necessary the CDC EUA test performed at the CDC or public health labs. After this initial "confirmation" period, all positives are still presumptive, and should be confirmed by state and public health authorities and/or CDC.

Please confirm my understanding.

Thanks,
Li

-----Original Message-----
From: Alex Greninger <agrening@uw.edu>
Sent: Saturday, February 29, 2020 11:54 PM
To: Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
Subject: confirmatory testing

Hi Li,

One more piece of clarification. The FDA guidance now asks for the first five negative and positive specimens to be submitted for confirmatory testing. I can't find the specific language now, but I was under the impression that you wanted all positive results confirmed by state and public health authorities and/or CDC.

(b) (4)
(b) (4) Are we supposed to forward all positives onto public health for confirmatory testing?

Best wishes,
Alex

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 8:02:33 AM
**To**: Briggs, Joseph (Joseph.Briggs@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Joseph.Briggsbaf]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: Reference Wadsworth

We very likely will get word  got word that The New York State Wadsworth Center can reference the data in the CDC's 2019 nCoV EUA application.  I hope this will help with the package insert.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

February 29, 2020

U.S. Food & Drug Administration
Center for Devices and radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver spring, MD 20993-0002

ATTN:
Uwe Scherf, M.Sc., Ph.D
Director, Division of Microbiology Devices, OIR

**Request for Emergency Use Authorization of the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel**

Dear Dr. Scherf,

The Wadsworth Center, New York State Department of Health is submitting the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel for consideration under Emergency Use Authorization (EUA).

The New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel is a real-time RT-PCR test, intended for the presumptive qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory tract specimens from individuals who meet CDC COVID-19 clinical and/or epidemiological criteria. Testing is limited to the Wadsworth Center, New York State Department of Public Health, and the New York City Department of Health and Mental Hygiene, Public Health Laboratories.

On the basis of the information submitted in this document, Wadsworth Center believes that the potential benefits from the use of the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel are expected to outweigh the risks, concludes that the test meets all the key criteria for an emergency use authorization, and therefore requests for an EUA.

In case you should have any questions regarding the information provided and/or need additional information/data from us please contact me immediately either via email at Jill.Taylor@health.ny.gov or phone at (518) 474 3157.

Sincerely,

Jill Taylor, PhD
Director, Wadsworth Center

AMERICAN OVERSIGHT

(b)(5) DRAFT EUA AUTHORIZATION LETTER TO NEW YORK DEPARTMENT OF HEALTH

AMERICAN OVERSIGHT

(b)(5) DRAFT EUA AUTHORIZATION LETTER TO NEW YORK DEPARTMENT OF HEALTH

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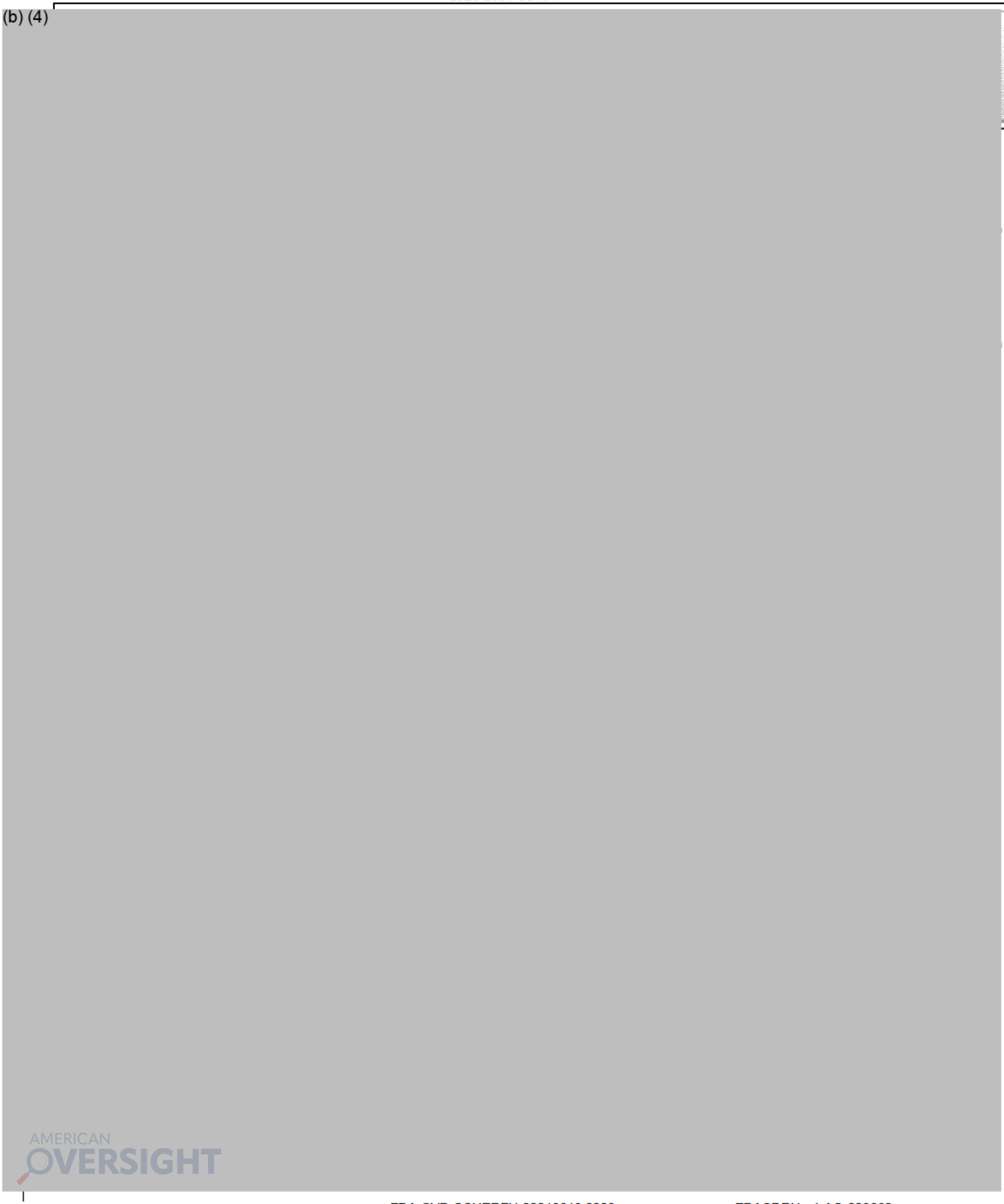
(b)(5) DRAFT EUA AUTHORIZATION LETTER TO NEW YORK DEPARTMENT OF HEALTH

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(b)(5) DRAFT EUA AUTHORIZATION LETTER TO NEW YORK DEPARTMENT OF HEALTH

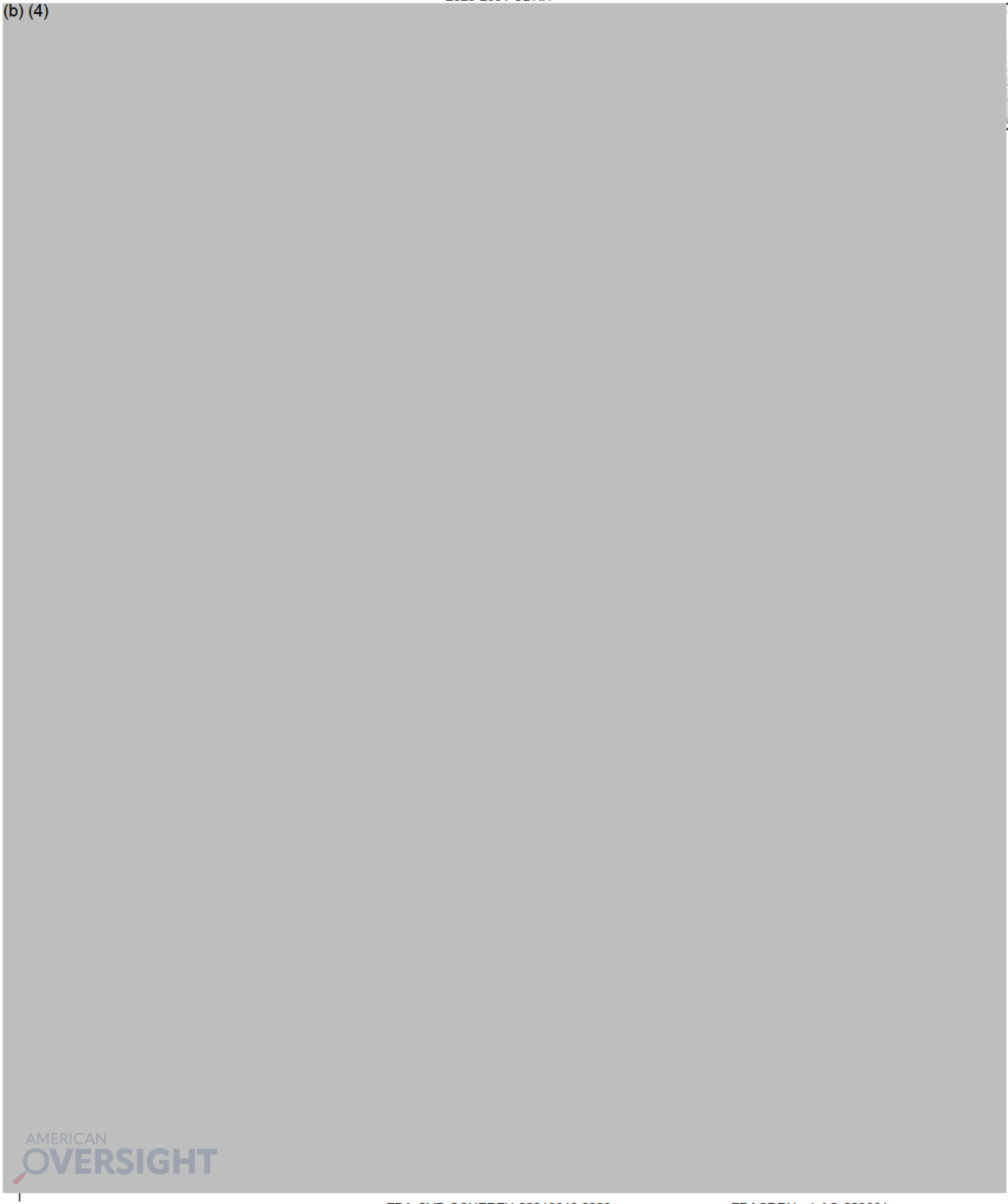
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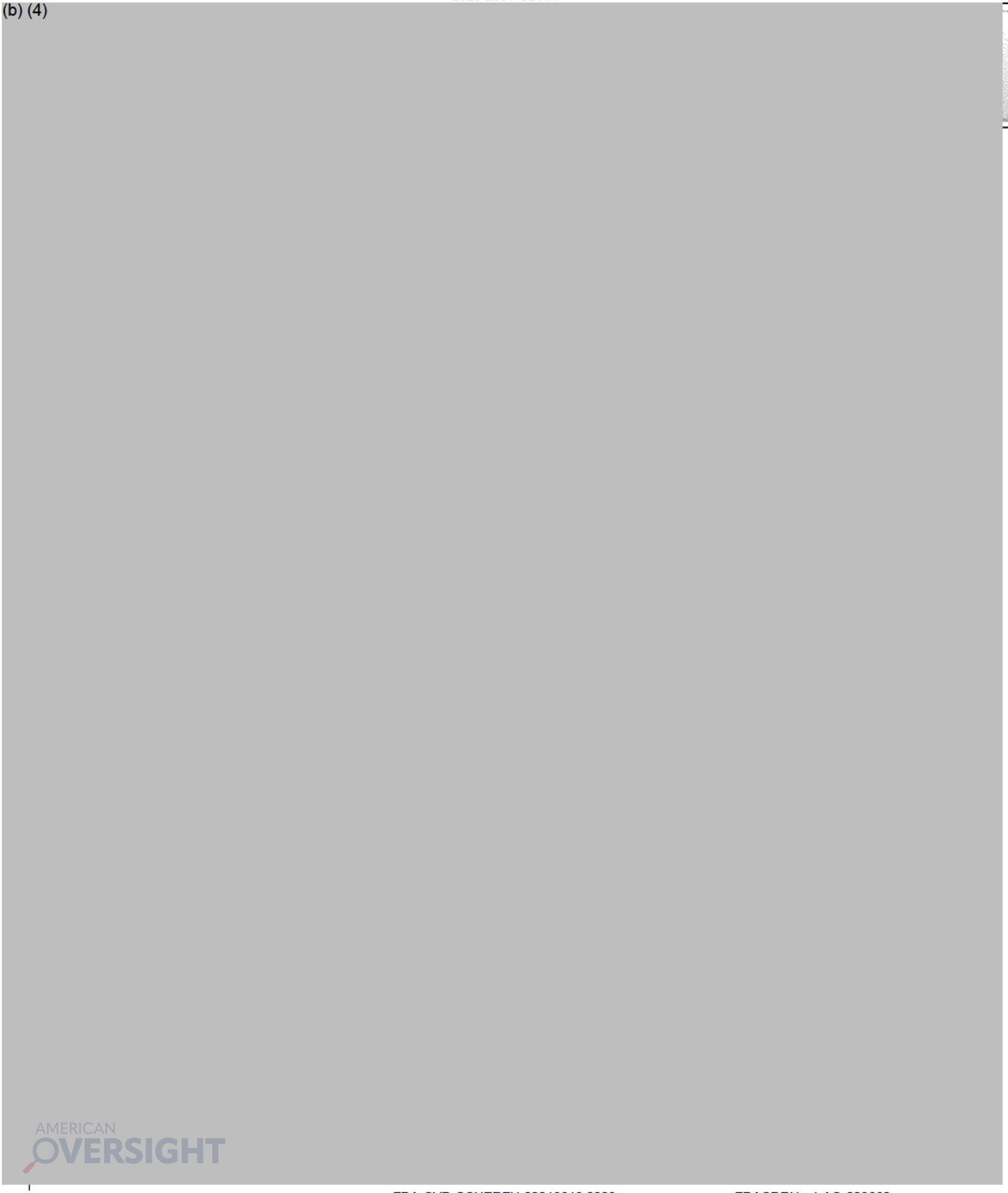
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AMERICAN OVERSIGHT

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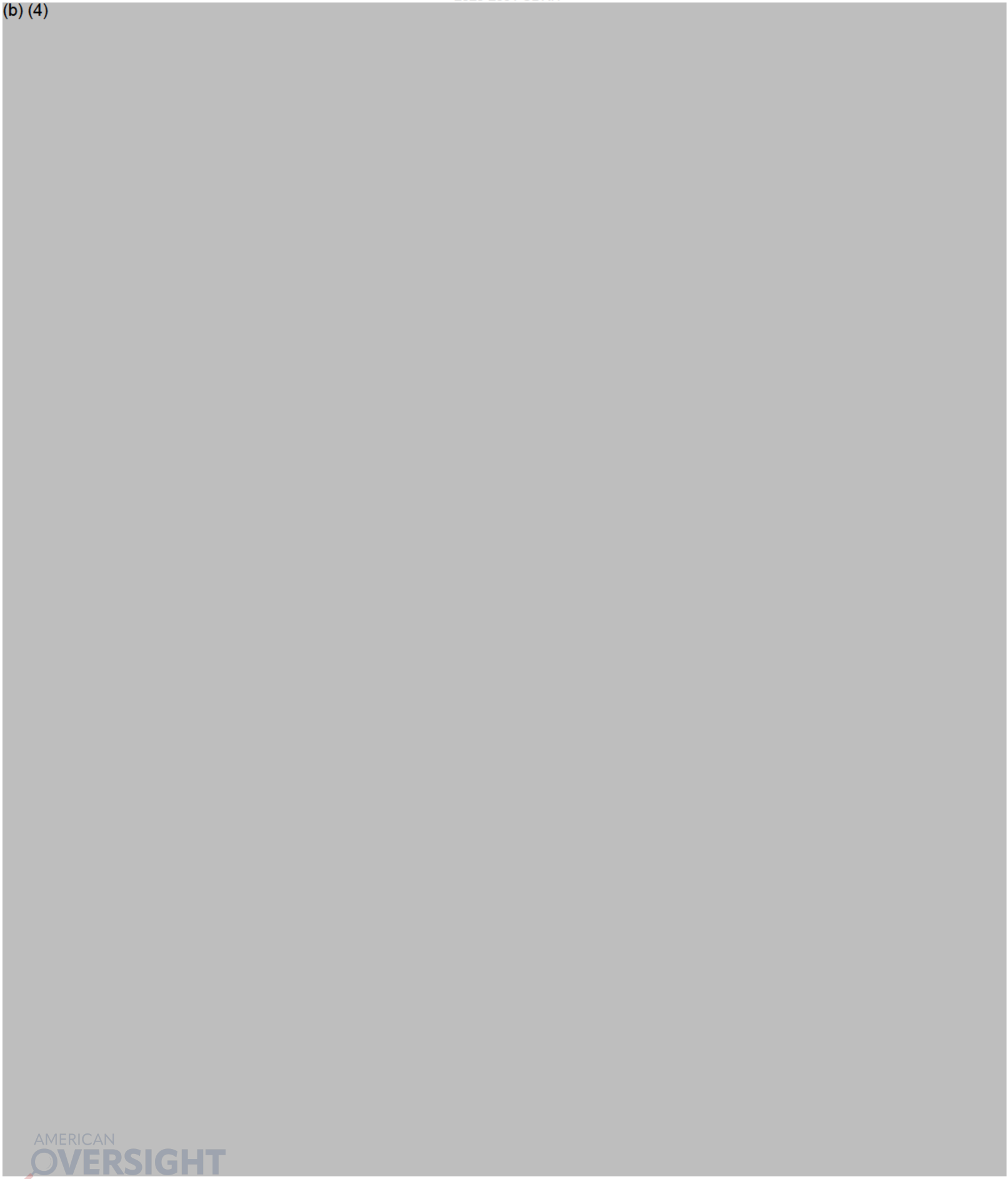
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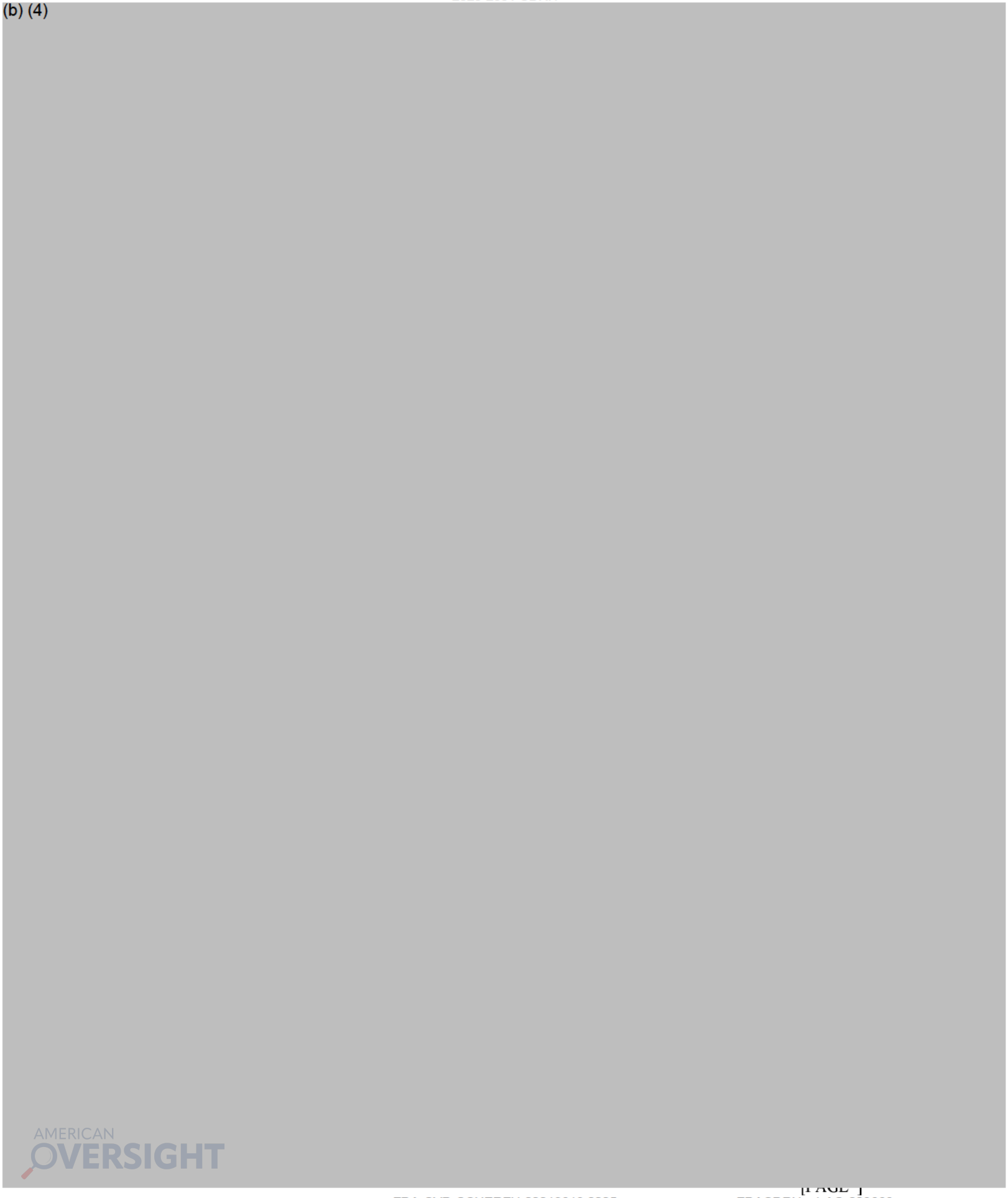
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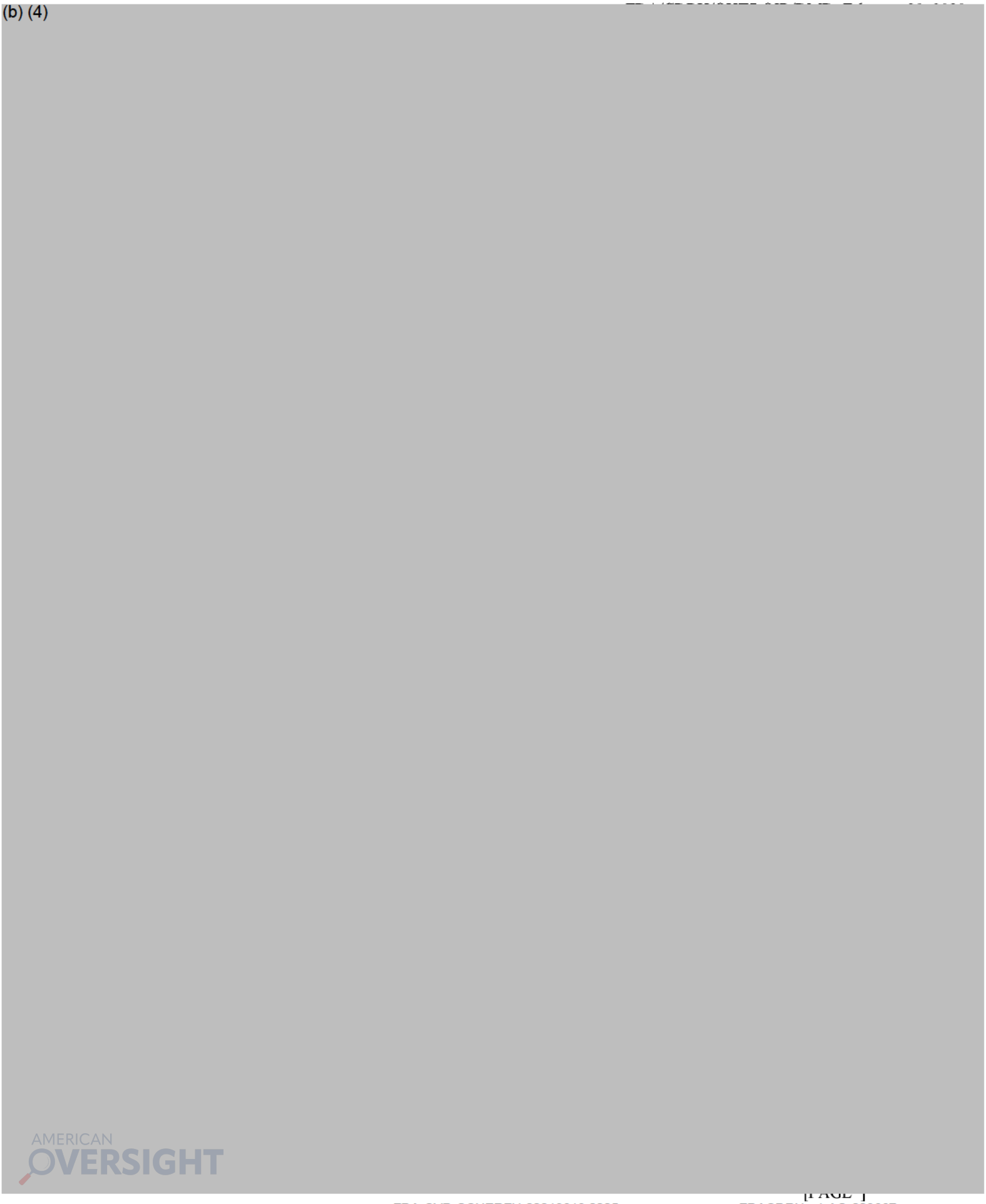
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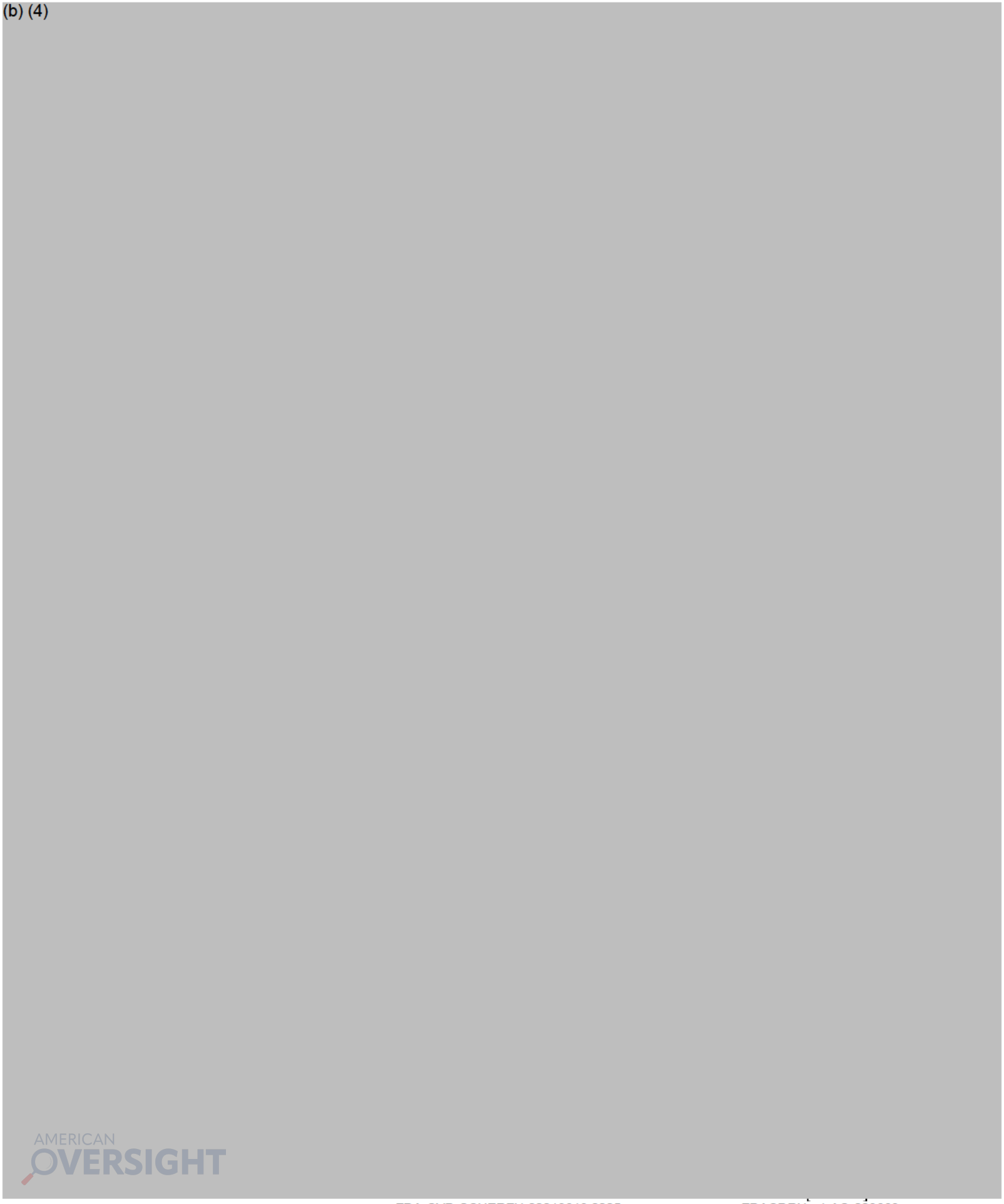
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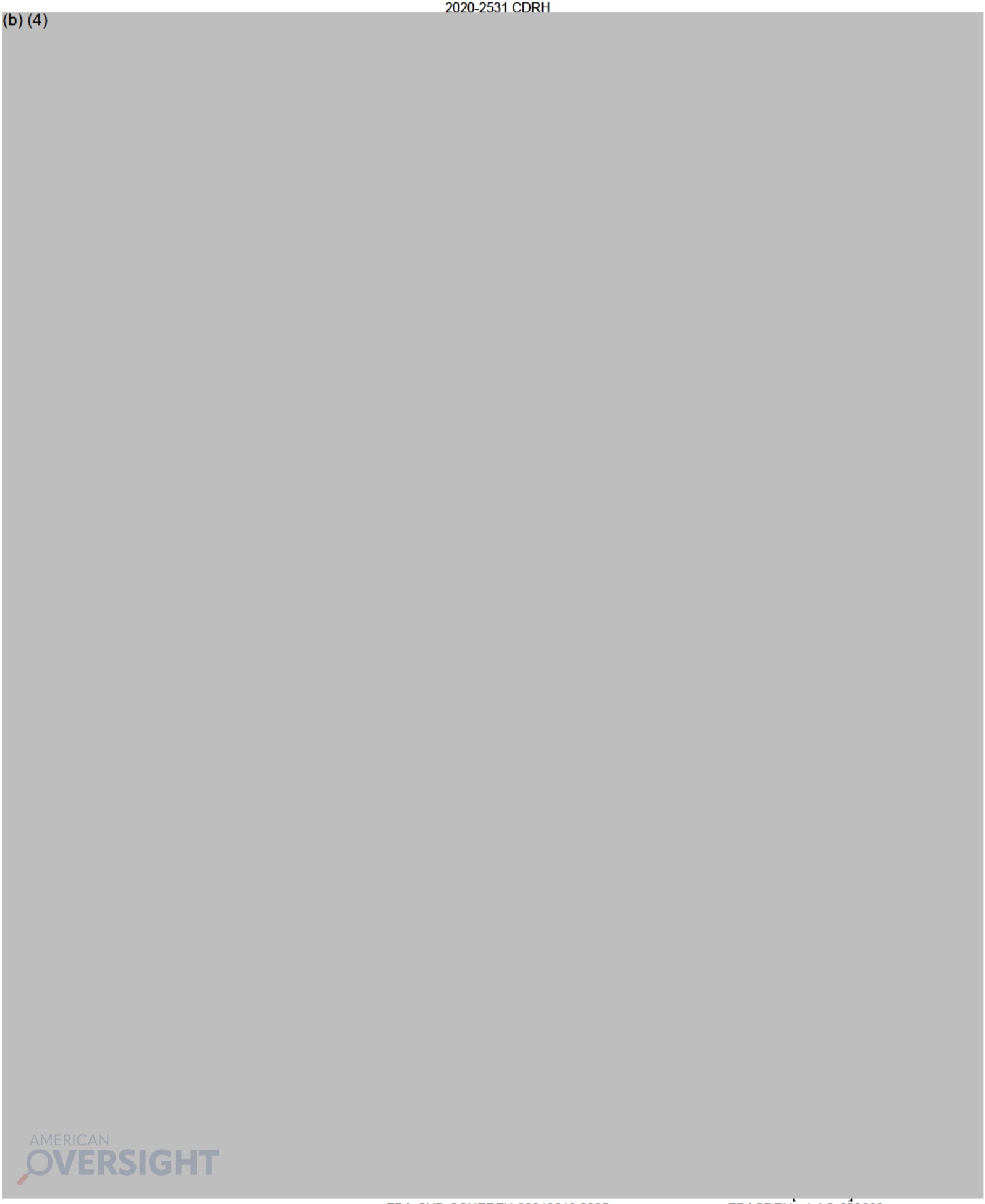
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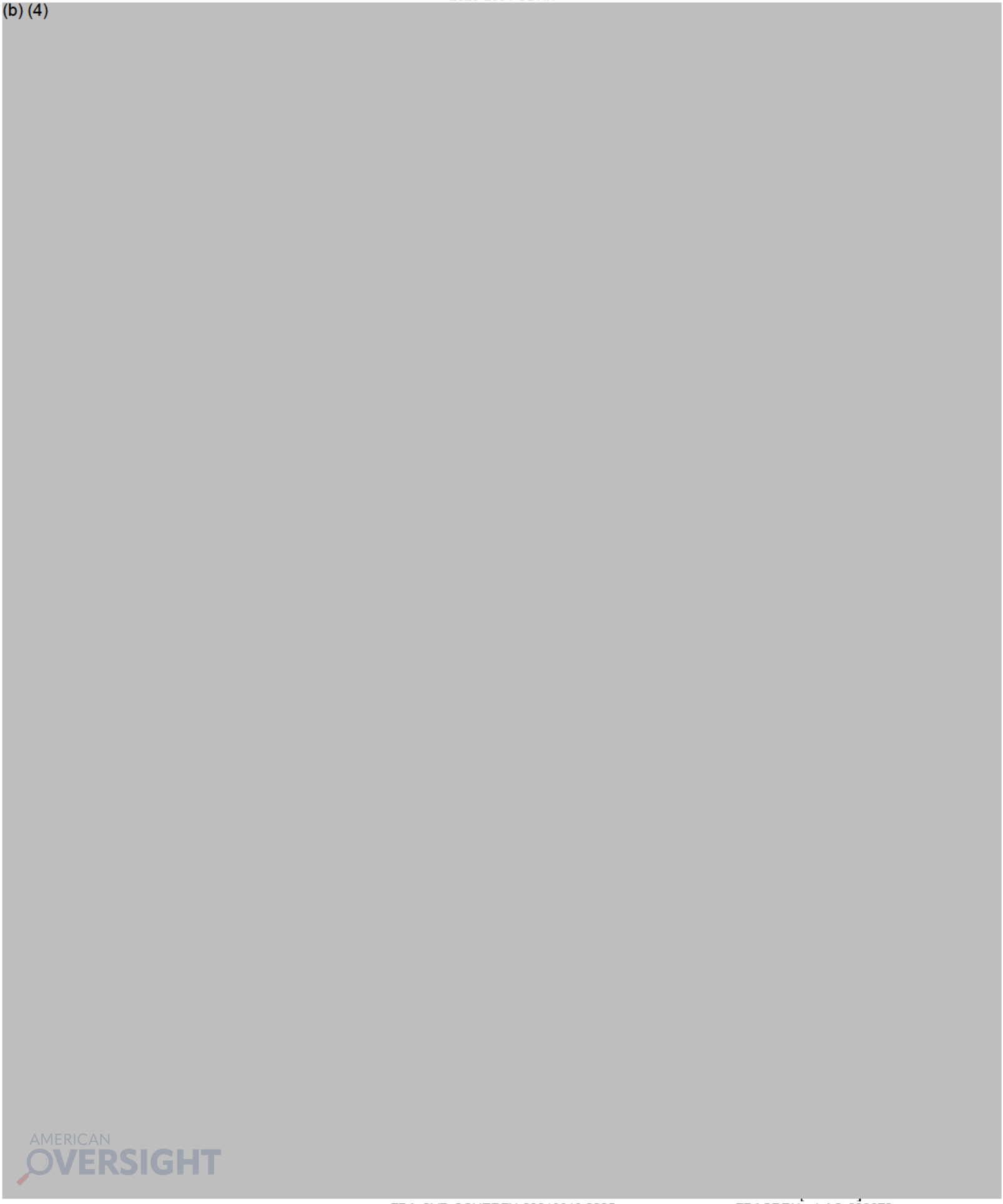
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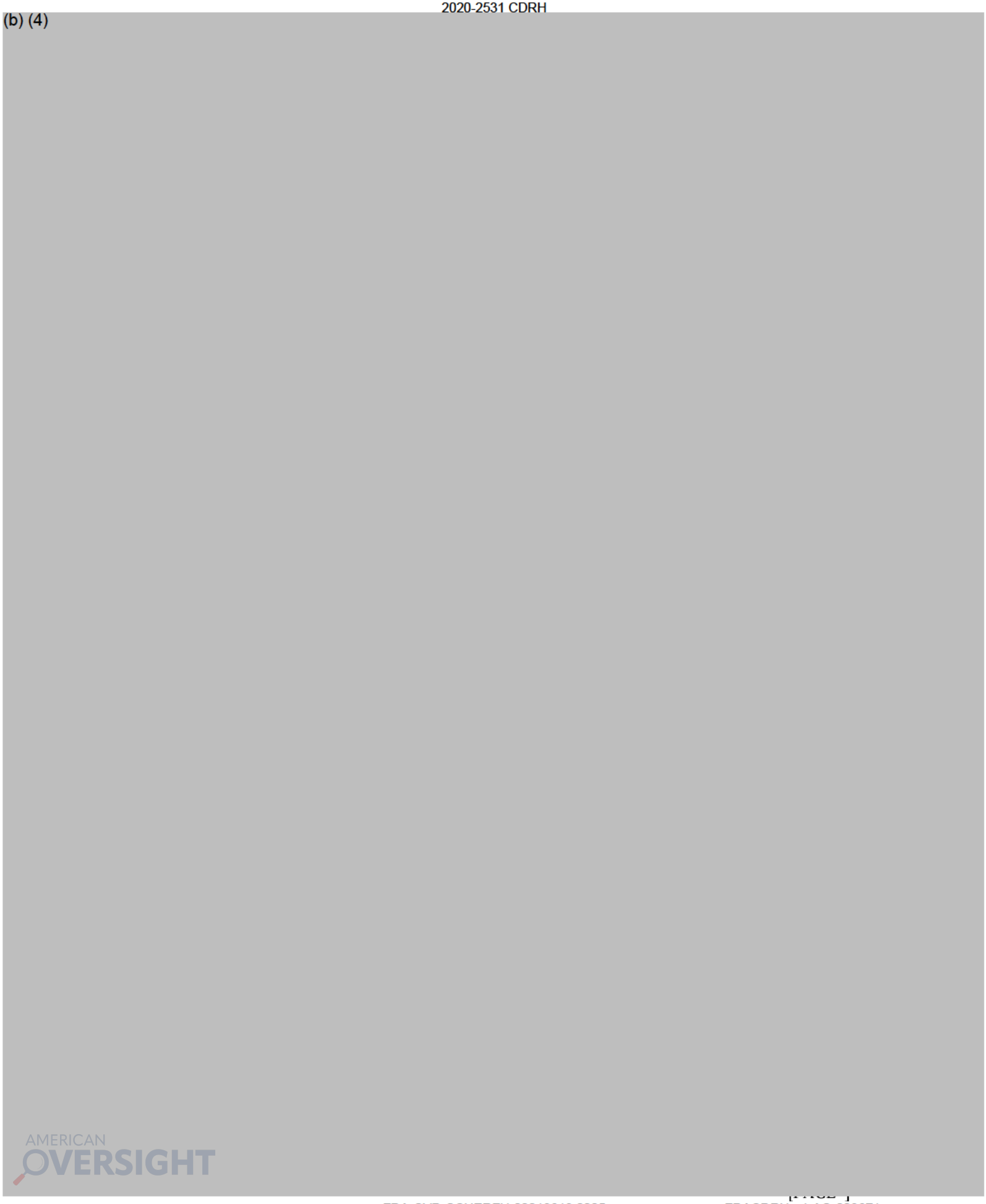
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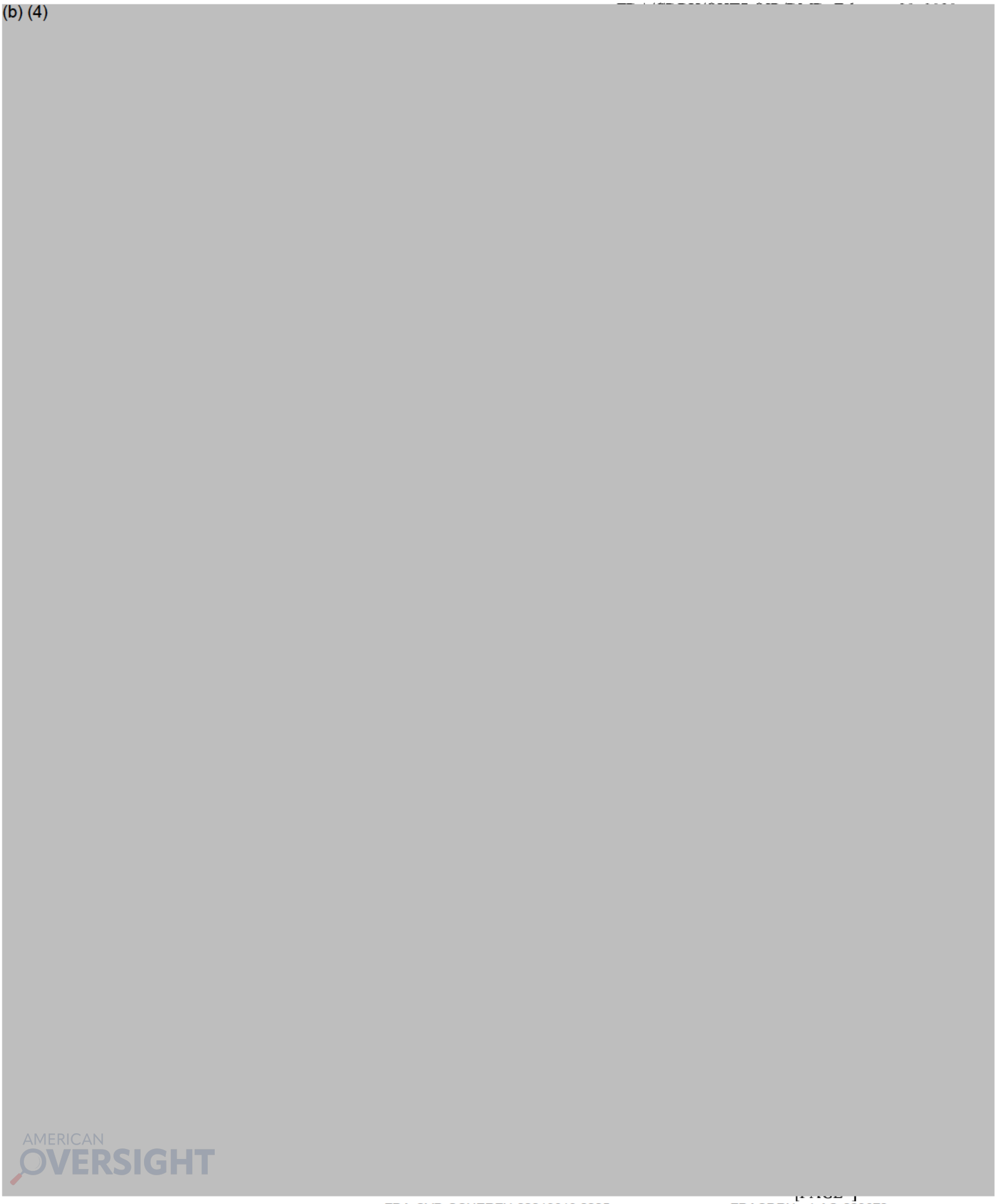
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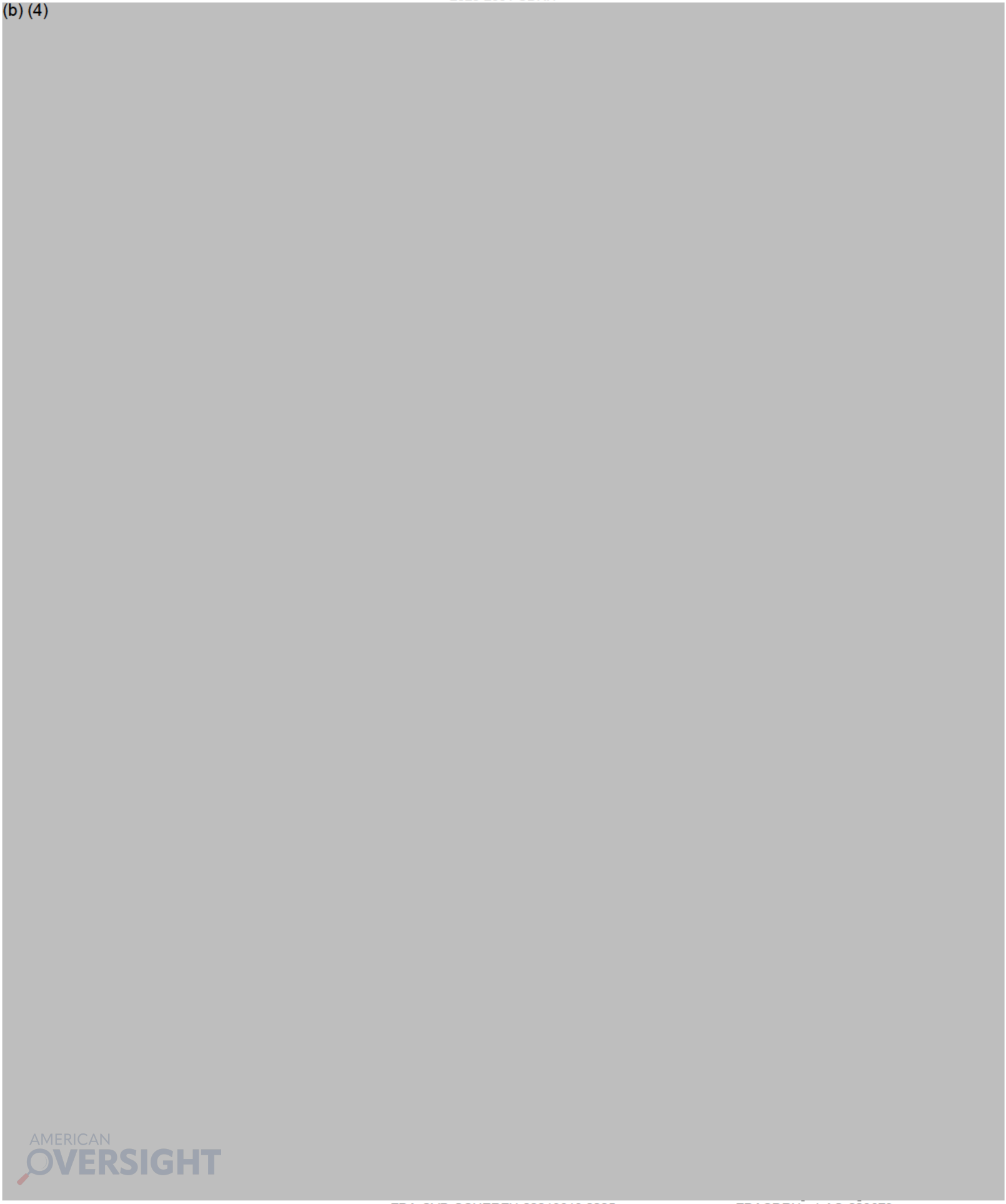
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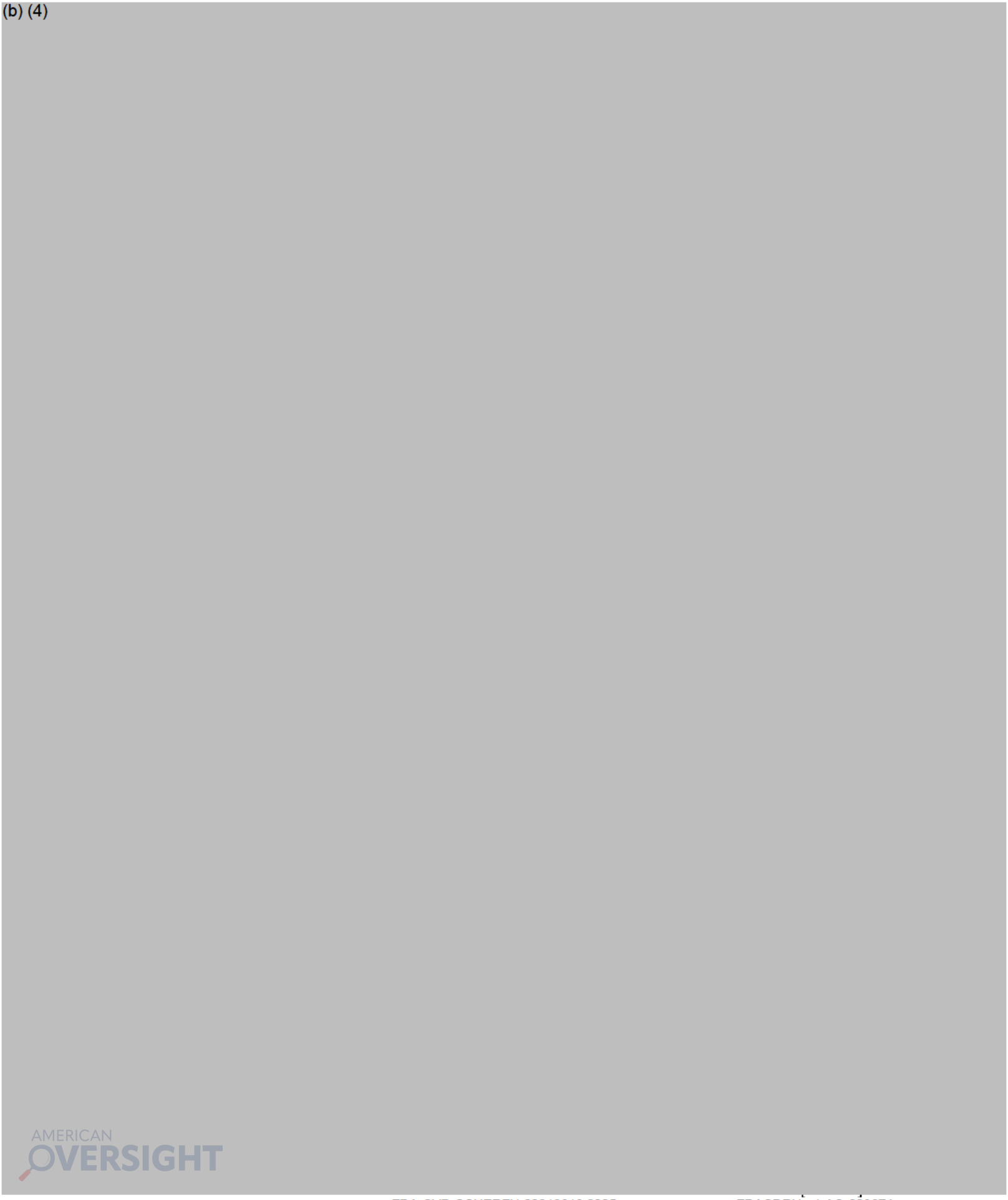
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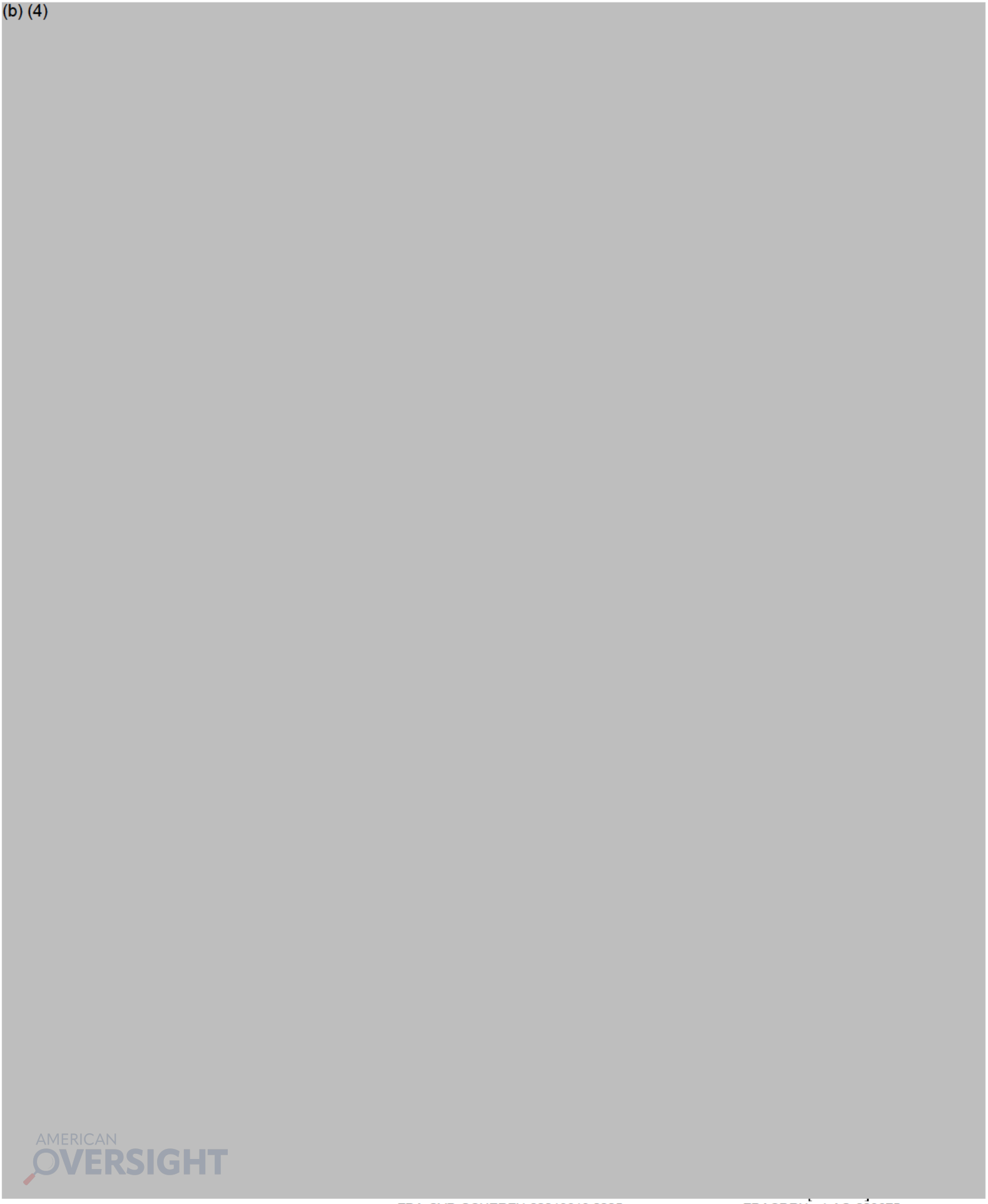
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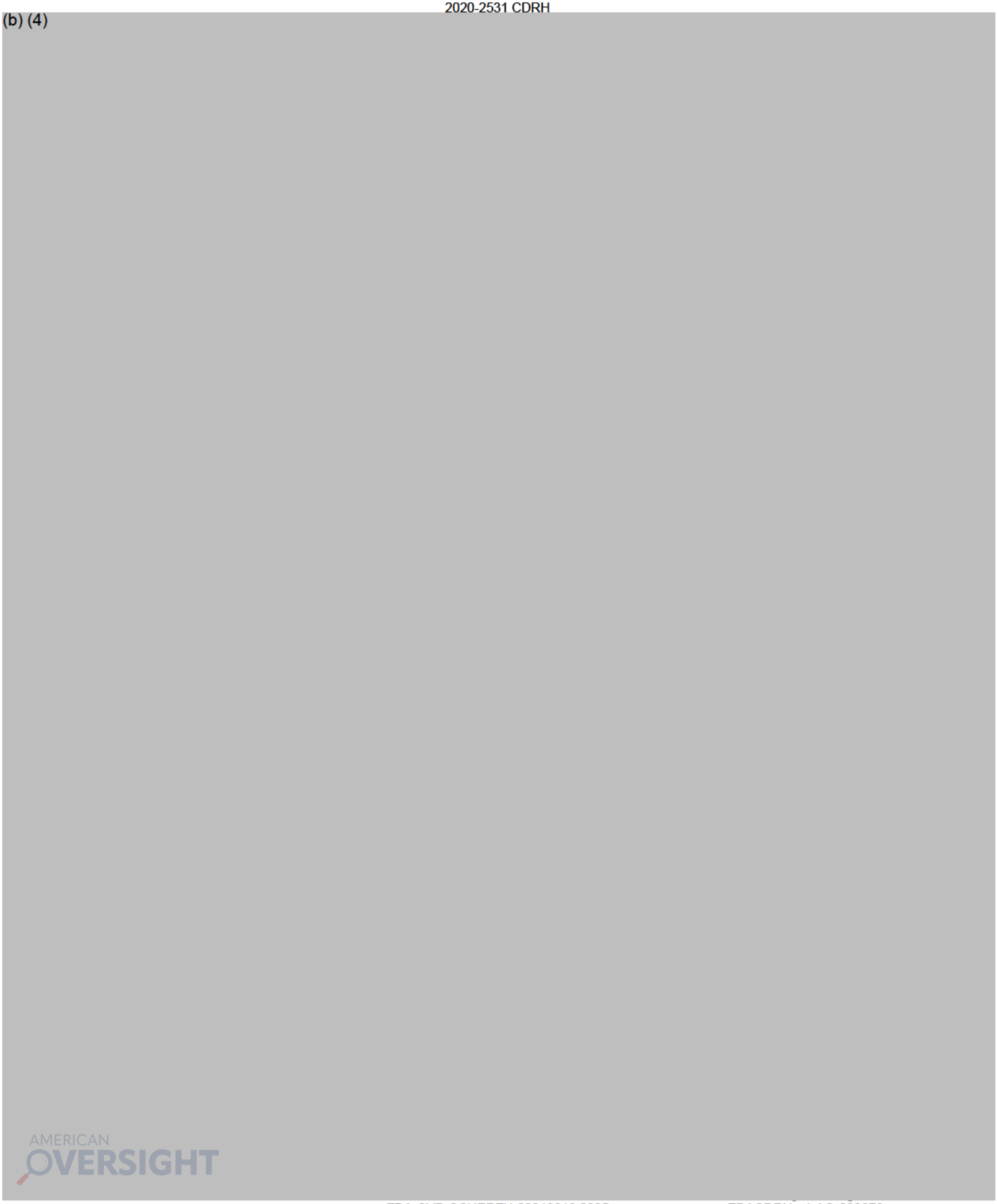
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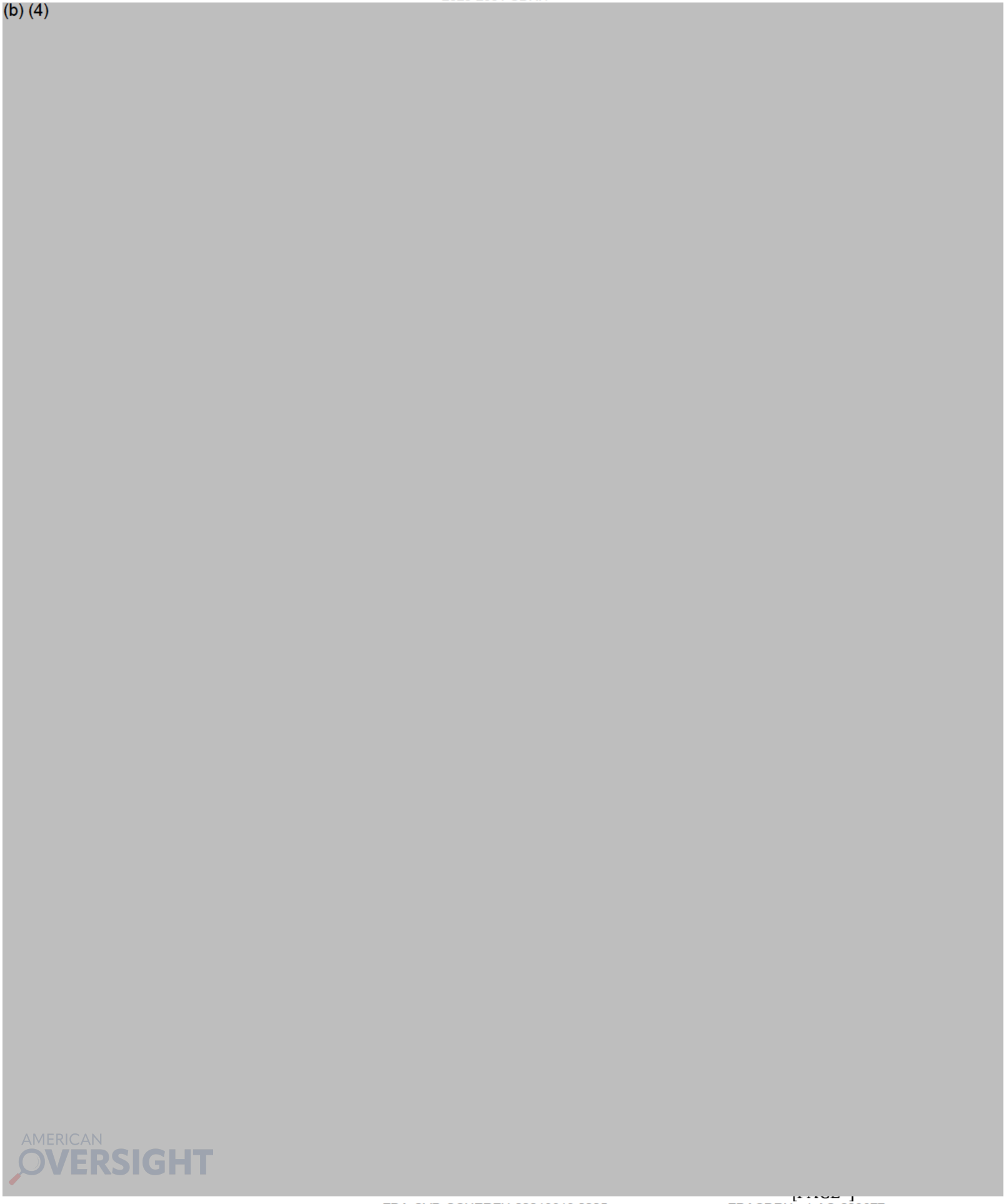
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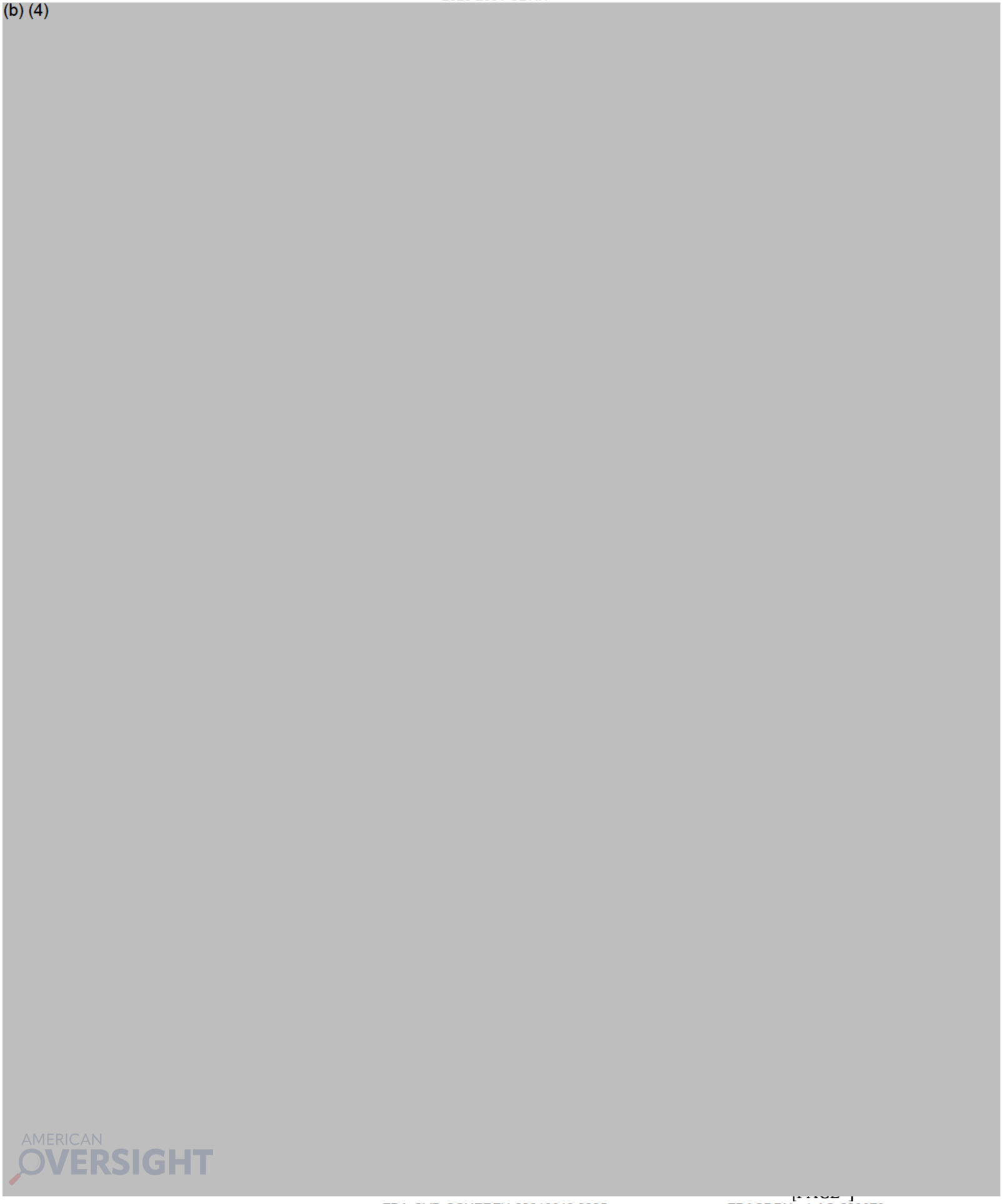
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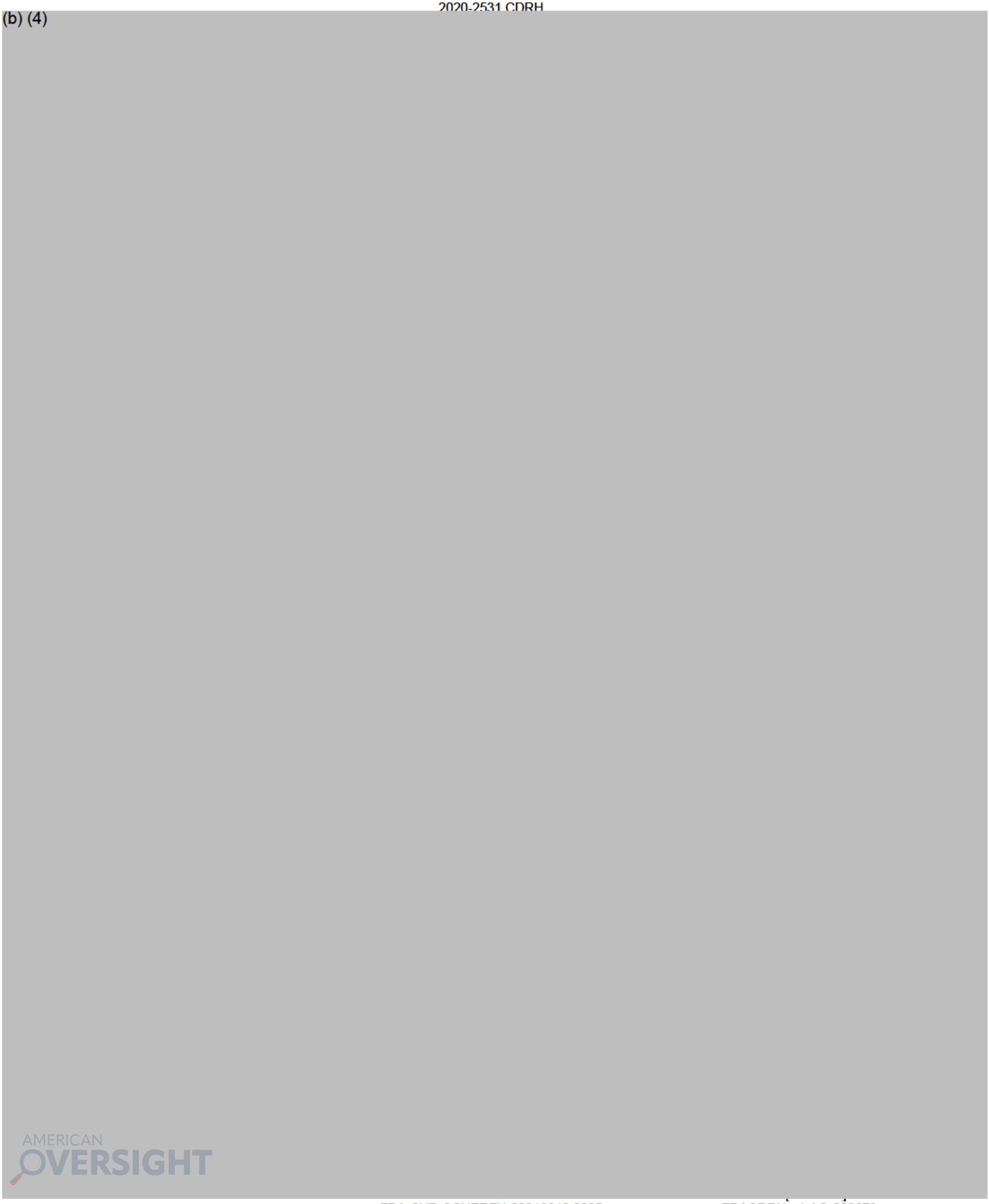
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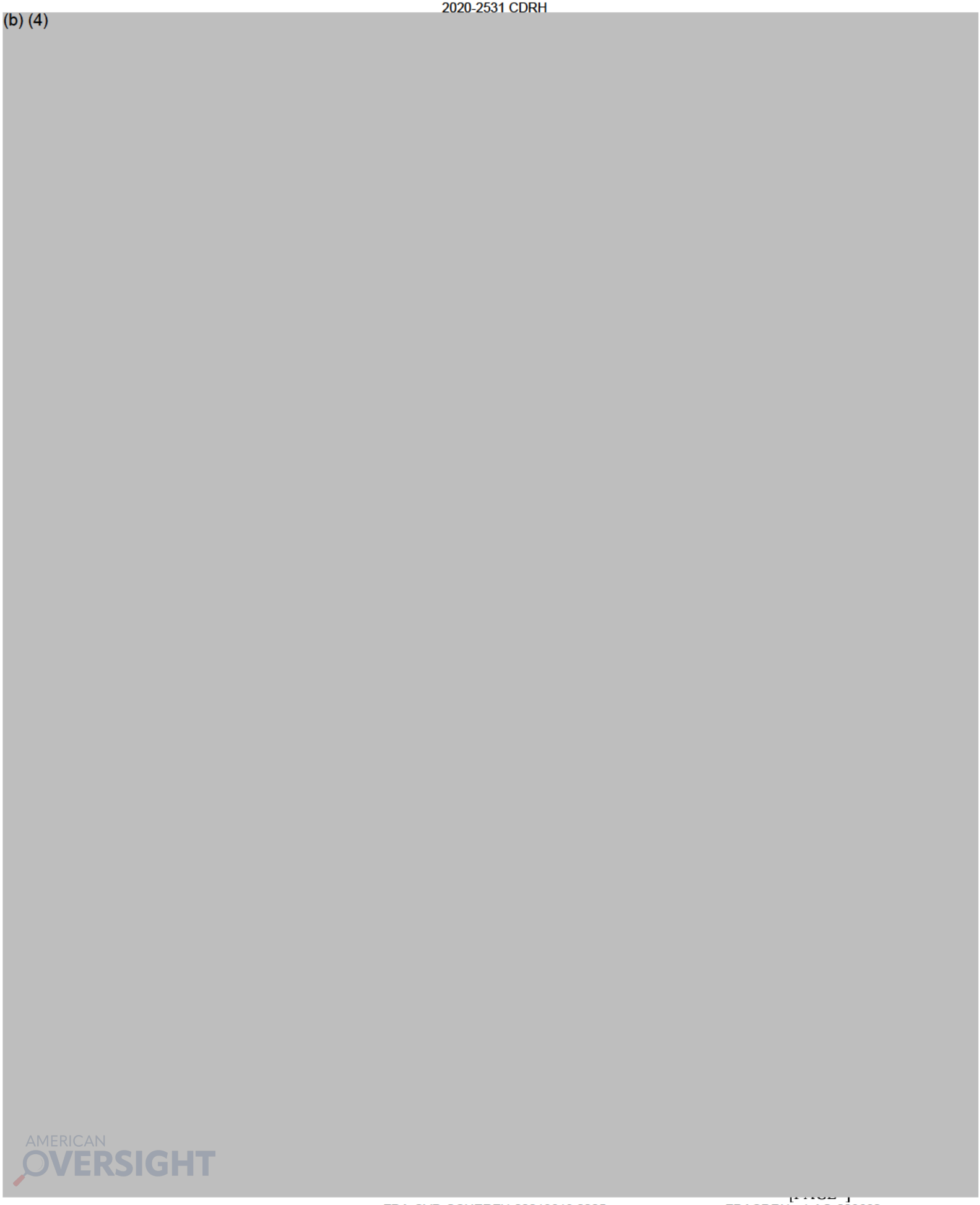
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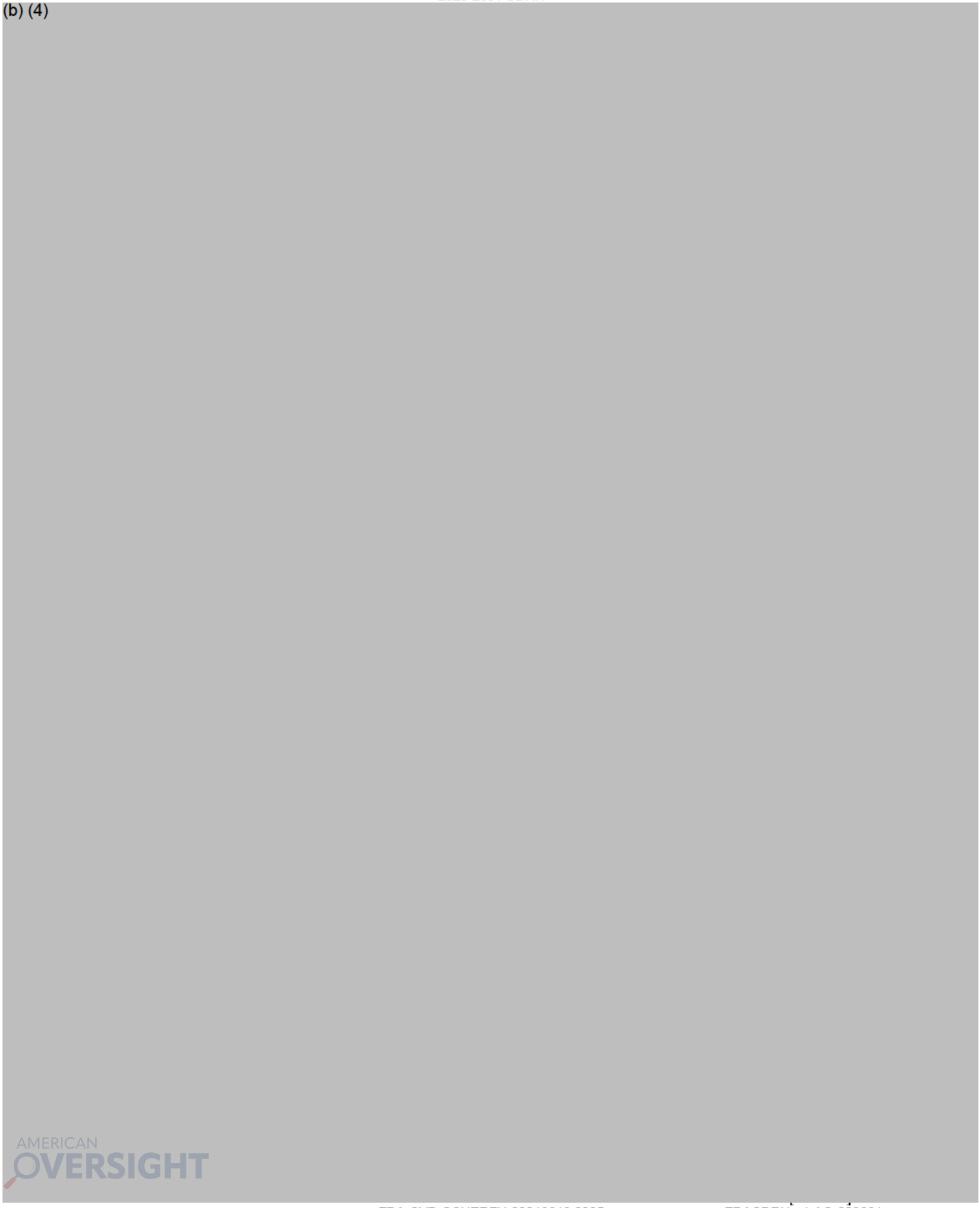
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(b) (4)



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(b) (4)



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 9:18:42 PM
**To**: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]; Briggs, Joseph (Joseph.Briggs@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Joseph.Briggsbaf]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject**: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel
**Attachments**: 1-Final.SARS.CoV.2.FDA letter.pdf; 2_NYS DOH EUA Letter of Authorization 02292020 FINAL.doc; 3_NYS DOH EUA Diagnostic Panel HCP FS 02292020 FINAL.docx; 4_NYS DOH EUA Diagnostic Panel Patient FS 02292020 FINAL.docx; 5-EUA200003_Review Memo NewYork SARS-nCoV Real_Time RT-PCR Panel_29FEB2020_Final.doc

Dear Jennifer, Liz, Dennis, Marcy and Michael,

Please find attached the formal EUA request package for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel with the following documents for OCET and OCC's review and clearance:

1) Wadsworth Center, New York State Department of Health Cover Letter - pdf
2) Draft EUA Letter of Authorization – with some notes for OCET/OCC – MS word
3) CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel HCP Fact Sheet – MS word
4) CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Patient Fact Sheet – MS word

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5) DMD EUA Lead Memo for CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel – MS word

CDRH considers these documents as cleared.

Thank you so much for your collaboration and help getting this second EUA for 2019-nCoV authorized so expeditiously!

Best regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 3/1/2020 4:38:35 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject**: RE: PEUA200009

Agree. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 2:51 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: PEUA200009

Sounds good to me Tamara – I will do that.

Thank you
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Sunday, March 01, 2020 2:48 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: PEUA200009

(b) (5)

Uwe, do you have any objections?

Thanks,

Tamara

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, March 01, 2020 2:10 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: PEUA200009

Dear Uwe and Tamara,

(b) (5)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

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**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, March 01, 2020 1:47 PM

**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: PEUA200009

Hi all,

Based on a quick review of the accelerated PRE-EUA template, (b) (4), (b) (5)
(b) (4), (b) (5)

(b) (5)

Kim,
Can you please start working on the fact sheets and LOA? (b) (5)
(b) (5) Please advise.

I need to attend to some family business, and will back on-line after 7:00 pm.

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, March 01, 2020 1:10 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: PEUA200009

See below. There is apparently an accelerated pre-EUA template from FDA? Where can I find it?
(b) (4), (b) (5) I will review the accelerated template tonight.
Li

---

**From:** Alex Greninger <agrening@uw.edu>
**Sent:** Sunday, March 01, 2020 12:58 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: PEUA200009

Hi Li,

Here's the most updated document I have; it is on the accelerated pre-EUA template (sorry). (b) (4)
(b) (4)

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(b) (4)

Best wishes,
alex

Alex Greninger MD, PhD, MS, MPhil
Assistant Professor, Department of Laboratory Medicine
Associate Director, Virology Division
University of Washington
Lab: 850 Republican St, S130
Seattle, WA 98109
Clinical Lab: 1616 Eastlake Ave East, Suite 320
Seattle, WA 98102
Phone: (b) (6)
Fax: 206-616-4340
agrening@uw.edu

On Mar 1, 2020, at 9:07 AM, Li, Li (CDRH) <Li.Li2@fda.hhs.gov> wrote:

Hi Alex,

Just to clarify, we are currently working on a pre-EUA (PEUA200009). After we work out all the issues, you will then submit an official EUA request package. Based on the new FDA guidance on LDTs yesterday, you can offer the UW LDT for patient testing as soon as you complete the validation of the LDT. You should then submit an official EUA request within 15 days of offering the LDT for patient testing.

I will review your updated template (hopefully with validation data) as soon as possible and provide you with feedback as we continue to work on pre-EUA200009. But based on the new FDA guidance on LDTs yesterday, this continued preEUA process should not delay patient testing using the UW test once you determine that all validations are completed.

Thanks,
Li

**From:** Alex Greninger <agrening@uw.edu>
**Sent:** Sunday, March 01, 2020 11:54 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** Re:

(b) (4)

cheers,
alex

On Mar 1, 2020, at 8:53 AM, Li, Li (CDRH) <Li.Li2@fda.hhs.gov> wrote:

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(b) (4)

Li

---

**From:** Alex Greninger <agrening@uw.edu>
**Sent:** Sunday, March 01, 2020 11:40 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:**

would you prefer next pre-EUA for feedback on the new template or the old template?

alex

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# EMERGENCY USE AUTHORIZATION (EUA)

## EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (2019-nCoV)

## GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow ***[Text]*** should be completed by the IVD developer (sponsor) as applicable to their specific test. Text in **bold** outlines the Food and Drug Administration (FDA) suggestions and clarifications for the sponsors' consideration when completing the required information in a specific section.

- This is a EUA interactive review template for Pre-EUA/EUA submissions concerning molecular-based single target tests for detection of 2019 Novel Coronavirus (2019-nCoV), Wuhan, China. If you are developing a multiplex molecular-based assay for the detection and differentiation of nucleic acids from a panel of microorganisms, please review Appendix A for FDA recommendations.

- This is a EUA interactive review template for Pre-EUA/EUA submissions and not a guidance document. The template is subject to change as we learn more about the 2019-nCoV disease and its risk-benefit profile. Recipients will receive notice and updated templates as they become available.

- This EUA interactive review template is an FDA internal document and any proprietary information provided within the template and during the interactive review process will remain confidential as it does in a regular FDA premarket submission.

- Feedback provided by FDA during the interactive review of your pre-EUA/EUA is subject to change as we learn more about the 2019-nCoV disease and the risk-benefit profile evolves to address unmet public health needs.

- Prior to a potential authorization FDA will require developers of molecular-based tests to assess traceability of their test to an FDA-recommended reference material panel if available at the time. Specific details about the traceability study and the FDA-recommended reference material panel will be provided by the Lead Reviewer assigned to the Pre-EUA submission once the analytical and clinical evaluation data has been reviewed and found to be acceptable.

- Please be reminded that tests for the detection of 2019-nCoV or 2019-nCoV infection must not be distributed and/or used for clinical diagnoses without premarket clearance, approval, or EUA by the FDA. Clinical samples for 2019-nCoV testing should be sent to the appropriate public health laboratories until the IVD device subject of this Pre-EUA submission has received authorization from the FDA.

- Clinical specimens may be required to support the EUA request. Furthermore, please note that applicable regulations for human subject protection do apply under the

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EUA. Please refer to the Clinical Evaluation section of this document for more details.

- If authorized, the EUA means that this 2019-nCoV IVD is temporarily authorized for use until the public health emergency is terminated or the EUA is revoked by the FDA.

    - FDA recommends that you consider registration and listing your EUA product once you have been issued an EUA. If this is problematic, please notify the Agency during your Pre-EUA.
    - The EUA is not a pathway to permanent marketing of your device. Therefore, we strongly recommend that you consider, in addition to an EUA, a traditional premarket submission for your IVD so that your device can still be legally marketed after termination of the emergency declaration. We recommend that you identify as soon as possible in the Pre-EUA review process any consideration of moving your product forward towards De Novo/510(k) clearance. If so some of our feedback to you may take such a long-term goal into consideration in order to prevent additional testing where it may not be needed. Therefore, please consider submitting a Pre-Submission to inquire what studies would be required for a premarket approval/ clearance of your 2019-nCoV IVD. Details on how to submit a Pre-Submission to the Agency are outlined in the FDA guidance document: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

## A. EXECUTIVE SUMMARY (as of X/XX/20XX)

## B. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the ***[test name]*** to ***[indicate labs, if applicable]*** for the *in vitro* qualitative detection of RNA from the 2019-nCoV in ***[add all claimed specimen types, e.g., nasopharyngeal/oropharyngeal swabs, sputa, BAL, stool, and serum, etc.]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated with 2019-nCoV infection) and CDC novel coronavirus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated) to aid in the diagnosis of 2019-nCoV infection.

## C. MEASURAND

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Specific nucleic acid sequences from the genome of the 2019-nCoV **[*please specify the targeted gene(s) of the pathogen*]**.

## D. APPLICANT

***[Official name, address and contact information of applicant]***

## E. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name - ***[test name]***
Established Name - ***[test name]***

## F. REGULATORY INFORMATION

***Approval/Clearance Status:***
The ***[test name]*** test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

***Product Code:***
[XXX – FDA will complete]

## G. PROPOSED INTENDED USE

***1) Intended Use:***
**The proposed IU will be finalized based on the data and recommendations from Public Health authorities at the time of authorization – example text is provided below for a qualitative molecular test that detects organism RNA but may be adapted according to the specific emergency situation addressed by the device.**

[***Test name***] is a [***specify test technology such as, real-time RT-PCR test***] intended for the qualitative detection of nucleic acid from the 2019-nCoV in [***describe all the specimen types***] from individuals meeting CDC 2019-nCoV clinical criteria (e.g., clinical signs and symptoms associated with 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated). Testing is limited to [***laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories***].

Results are for the identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in **[*name specimen type*]** during the acute phase of infection. Positive results

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are indicative of active infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The ***[test name]*** is intended for use by **[*include intended user, e.g., trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures*]**. The ***[test name]*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

***2) Special Conditions for Use Statements:***

For prescription use only
For in vitro diagnostic use only

***3) Special Instrument Requirements:***

The ***[test name]*** test is to be used with the [***list all RT-PCR Instruments, software requirements, automated extraction instruments***].

## H. DEVICE DESCRIPTION AND TEST PRINCIPLE

**Example text has been added under each of the sub-headings below for a fluorescence based rRT-PCR test for detection of organism RNA. If a different test principle is used by the test for the detection of a specific analyte please modify the description accordingly to capture the salient points in each of the sub-headings below. Please note that for new investigative technologies FDA may request additional detailed information so we can adequately assess the risks and benefits associated with the device.**

***1) Product Overview/Test Principle:***

**Describe the technology of the test and how this technology works to identify the measurand, the instruments employed/required to perform the test from sample collection to result (include all claimed extraction and PCR detection instruments), and the specimen types for which you claim to have specific performance characteristics as described below. If applicable, list all primer and probe sets and briefly describe what they detect. Please include the nucleic acid sequences for all primers and probes used in the test. Please indicate if the test uses biotin-Streptavidin/avidin chemistry in any of the steps for coupling reagents. Please note that an alignment with available reference genomes for different strains of the target pathogen is requested as part of the inclusivity evaluation (Section N).**

The ***[test name]*** is a real-time reverse transcription polymerase chain reaction (rRT - PCR) test. The 2019-nCoV primer and probe set(s) is designed to detect RNA from

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the 2019-nCoV in ***[list all the specimens]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated).

2) ***Description of Test Steps:***

**List and describe in detail all the steps of the test sequentially from specimen collection to detection.**

Nucleic acids are isolated and purified from ***[specimens]*** using ***[please describe the method(s) of extraction (please specify the specimen input volume for extraction and/or test, the nucleic acid elution volume and whether isolation/purification is manual and/or automated)].*** The purified nucleic acid is reverse transcribed using ***[enzyme mix/kits – please specify the input volume of purified nucleic acid added to the rRT-PCR reaction mix]*** into cDNA which is then subsequently amplified in ***[please describe the instrument(s) and enzyme mix]***. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by ***[please describe the detection instrument(s)]***.

3) ***Control Material(s) to be Used with [test name]:***

**List all control materials (provided with the test kit and/or required but not provided with the test kit and describe what they are, how they are expected to work, where in the testing process they are used, and the frequency of use. If a control is commercially available, provide supplier's name and catalog number or other identifier; if your device relies on external controls that are manufactured by a third party please note that these controls should also be validated within your analytical and clinical studies described below in Section (N).**

Controls that will be provided with the test kit include:

a) A "no template" (negative) control is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***

b) A positive template control is needed to ***[describe need]*** and is used ***[describe use – please specify the concentration of the positive control relative to the LoD of your test (note that ideally the positive control concentration should be such that it is close to the LoD of your test) and also specify frequency of use]***

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c) An extraction control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use].*** **Please note that if the no template control and positive control, are taken through the entire sample processing procedure, including the extraction, then a separate extraction control is not required**.

d) An internal control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use]***.

Controls that are required but not provided with the test kit include ***[describe control – provide recommended sources of the control materials – either a separate control kit for purchase that you the applicant develops or a control material that can be purchased from a third party].*** This/these control(s) is/are needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***.

**Please note that any control recommended to be used with your device (provided with the kit or not) needs to be validated in the context of your analytical and clinical study (i.e., you will need to run these controls as part of your studies). In instances where control material is not readily available through 3rd party vendors (which is often the case at the beginning of an outbreak) FDA may request that you include suitable control material with your device. Please note that external control materials are considered particularly important in the context of EUA devices because often GMP requirements for the manufacture of the EUA device are waived in emergency situations and reagent stability studies are limited. Hence the external controls offer some assurance of EUA test performance in the hands of the end user.**

## I. INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. **Please describe if a Ct cutoff is used as part of your testing algorithm and/or if the end user is required to review fluorescent curves for weakly positive samples before final interpretation. Although not typical for molecular-based tests, if the test result involves the use of an algorithm/calculation, for example a ratio value, when determining the final patient test result, please include a detailed description and any additional calibration materials that may be required.**

1) ***[Test name] Controls – Positive, Negative and Internal***

**Describe in detail the expected results generated, including acceptance criteria, for all the controls described in detail in Section H above. Describe the measured values (if applicable) for valid and invalid controls and outline the recommended actions the laboratory should take in the event of an invalid control result.**

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2) ***Examination and Interpretation of Patient Specimen Results:***

**Describe when clinical specimen test results should be assessed and outline the criteria for test validity**. **Example text**: Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

**Clearly indicate how to interpret numeric test values (if applicable) as positive or negative for presence of the 2019-nCoV. Indicate if the end user is required to review fluorescent curves for weakly positive samples before final interpretation and how to identify indeterminate/inconclusive results (if they exist) results and how the user should resolve them, e.g. if repeat testing may be required.**

**When applicable, provide a table clearly describing the possible combinations of test result values for each primer/probe set, and how they should be combined into a final interpretation of the result for your test. If the test produces result that will be used as part of a CDC recommended testing algorithm, please indicate what follow-up testing/process should be conducted, if applicable.**

## J. PRODUCT MANUFACTURING

**Please note that if you are developing a test for use at a single site (i.e., a laboratory developed test LDT), some of the information requested in this section may not be applicable. Please contact FDA for additional guidance for an emergency use LDT.**

The ***[test name]*** has been validated using only the components referenced in this submission and shall not be changed without prior concurrence from the FDA.

*1)* ***Overview of Manufacturing and Distribution:***

The product will be manufactured at [***manufacturer's name and FDA registration number (if applicable) or laboratory name if an LDT***] by [***manufacturer name, or laboratory name if an LDT***] personnel consistent with practices for the production of **[*types of devices*]** based on [***type of quality system****]. Material manufactured by [***manufacturer's name, or laboratory name if an LDT***] may be bottled and kitted by [***packager name***] manufacturing facility.

***Under the Emergency Use Authorization (EUA) most of the 21 CFR 820 Quality System Regulation (QSR) requirements can be waived for the duration of the EUA. FDA expects that developers follow comparable practices as much as possible and may consider previous compliance history when determining whether or not to waive certain QSR requirements for a specific product. Please note adverse events, as per 21 CFR Part 803, have to be reported for authorized devices (see Section R).**

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The current manufacturing capabilities include the ability to manufacture approximately **[*please insert the approximate number of units/products that can currently be manufactured per week at the manufacturing facility*]** products per week, however in the event of a surge in demand this could be increased to **[*please insert the approximate maximum number of units/products that could potentially be manufactured per week at the manufacturing facility if there was a surge in demand*]** product per week within a **[*please specify in weeks/months the expected timeframe required to increase product production if required*]** timeframe.

The product will be distributed by **[*please describe the distribution plan for the product and list all current distributors*]**.

2) ***Components Included with the Test***

Components manufactured by [***manufacturer's name and FDA registration number (if applicable)***] and supplied with the test include:
**List all components and reagents provided for your test, including a description of the primers and probes, volumes, concentrations, quantities, buffer components, etc.**

3) ***Components Required But Not Included with the Test***

Components required but not included with the test:
**List all components and reagents not included with the test that must be supplied by the user to perform the test, with specific supplier names and catalog numbers or other identifiers for obtaining these components and reagents. Please include here all specific consumables that were validated for use with your device, that are not interchangeable with other products and that are needed to guarantee device performance as established in the EUA validation studies listed in Section N below.**

4) ***Testing Capabilities***

**Briefly describe current sample throughput capacity, total time required to perform the test (from clinical specimen collection, specimen transport to result), and number of tests that can be performed per instrument run and per day.**

5) ***Reagent Stability:***

**Briefly describe stability test plan for *[test name]* reagents and include any accelerated stability information if available. Please note that reagent stability studies do not need to be completed at the time of EUA issuance, however the study design should be agreed upon during interactive review and the stability studies started immediately following authorization, if not before. When designing your stability study, we have some general recommendations that are outlined in Appendix B, for your consideration.**

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## K. PERFORMANCE EVALUATION

**If you plan to claim multiple target analytes to aid in differential diagnosis or you plan to claim multiple RT-PCR instruments and/or extraction methods, please refer to Appendix A and C, respectively, more information. Please note that any omission of a requested study in this document should be documented and justified.**

### *1) Analytical Sensitivity:*

a) *Limit of Detection (LoD):* **You should determine the LoD of the device utilizing the entire test system from sample preparation to detection for each clinical matrix claimed. Please note that claims for additional anticoagulants, for blood specimens, can be supported by a matrix equivalency study as outlined in Section N, subsection 3 below. The LoD is determined using dilutions of live propagated and titered 2019-nCoV stocks (CFU/mL or PFU/mL) spiked into a relevant clinical matrix. If wild-type virus is not available at the time of your validation studies, please contact FDA to discuss a potential alternative. Please note that if available please also provide Genomic Equivalent Copies (GEC)/mL units for the stock solutions used and include an explanation on how they were determined. Please note that LoD studies should be performed with live organisms, as described above. If you plan to use inactivated organism in your LoD determination you should describe how the material was inactivated and perform a study to determine whether the inactivation process impacted the LoD of the device.**

**First a tentative LoD must be established through limiting dilutions of the prepared material with 3-5 replicate measurements. Please note for all the analytical studies described in Section N that require replicate testing, one replicate equates to one independent extraction and PCR detection. Once a tentative LoD is established, the LoD should be confirmed by preparing at least 20 additional replicates at the LoD concentration and demonstrating that the organism was detected with a minimum 95% positivity (19/20). If this confirmatory study achieves a positivity of 100%, then a lower concentration needs to be tested (with 20 replicates) until <100% positivity is obtained.**

**Please use the following format when submitting LoD information and data:**

LoD studies determine the lowest detectable concentration of 2019-nCoV at which approximately 95% of all (true positive) replicates test positive. The LoD was determined by limiting dilution studies using characterized samples.

**List/describe the following in this section:**

- **Titers and strains of the 2019-nCoV stocks used for the LoD study and describe how the organism stocks were prepared and how the titers were determined.**

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- **The dilution factor and number of serial dilutions of the characterized 2019-nCoV that were tested to determine the LoD for each primer and probe set.**
- **The nucleic acid extraction/purification method.**
- **The real time PCR instrument.**

Serial dilutions of the characterized 2019-nCoV were then tested in **[*number of replicates (i.e., recommend that sample is extracted independently three-five times and each extraction tested once)*]** replicates. The lowest concentration at which all [***number of replicates***] replicates were positive was treated as the tentative LoD for each test. The LoD of each test was then confirmed by testing [***number of replicates (at least 20 recommended)***] with concentrations at the tentative limit of detection. The final LoD of each test was determined to be the lowest concentration resulting in positive detection of [***number of positive replicates (at least 19 out of 20 replicates)***]. [***Include analysis of LoD results, indicating the final LoD for each test***]

**Tentative LoD: [*Please provide a summary of the data for each strain tested]* example table 2019-nCoV stocks is provided below:**

| 2019-nCoV Strain Tested | Stock 2019-nCoV Titer | Serial 10-Fold Dilution Factor | Concentration in Dilution Tested [Include Units] | Replicate 1 $C_t$ | Replicate 2 $C_t$ | Replicate 3 $C_t$ | Replicate 4 $C_t$ | Replicate 5 $C_t$ | Call Rate | Lowest Concentration with Uniform Positivity per Analyte | Limit of Detection (LoD) per Virus Strain |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Example:*** *[analyte]* | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

b) FDA Sensitivity Evaluation: The analytical sensitivity of the test has to be further assessed by evaluating an FDA-recommended reference material using an FDA developed protocol if applicable and/or when available. Details will be provided during the Pre-EUA interactive review.

c) *Reactivity/Inclusivity:* Reactivity of the ***[test name]*** was evaluated for additional isolates of 2019-nCoV.

**Reactivity: *[test name]* example table below**

| 2019-nCoV Strain/Isolate | Source/Sample Type* | Concentration | Ct** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

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| | | | |
|---|---|---|---|
| | | | |

***Please list source of material used for wet testing and sample type tested (i.e., organism – live or inactivated, purified nucleic acid – whole genome etc.).**
**** If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**At a minimum, the strain used in your LoD evaluation should be listed here (multiple isolates of the same 2019-nCoV strain that was used for the LoD studies can also be included if available). If additional isolates are not available at the time of your validation studies, please discuss with FDA. Each isolate should be tested at or near the LoD (no more than 3x LOD) of the test, spiked into clinical matrix utilizing the entire test system, including extraction. If you plan to claim more than one type of clinical matrix, we recommend that you perform this study in the most challenging clinical matrix, testing a minimum of 3 replicates. In addition, the wet testing should be accompanied by extensive inclusivity *in silico* analysis of the test primer and probes with all known strains/isolates (past/present) of 2019-nCoV (including the strain/isolate used for wet testing).**

## 2) *Analytical Specificity:*

a) *Cross-Reactivity:* Cross-reactivity of the ***[test name]*** was evaluated using both *in silico* analysis and by testing whole organisms **[*pathogen*]** (concentration) or purified nucleic acid from other ***[describe organisms]*** (concentration/reaction).

**Cross-Reactivity: *[test name]* example table for wet tested organisms below**

| Virus/Bacteria/Parasite | Strain | Source/ Sample type | Concentration | Ct Values* |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

***If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**Cross-reactivity studies are preformed to demonstrate that the test does not react with related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen. The FDA Tables 1 and 2, below are intended to recommend simulate testing of patients having infections with organisms which cause similar symptoms to those observed at the onset of 2019-nCoV infection. The FDA Tables also include other organisms and strains which have significant genetic similarity and therefore a higher likelihood of cross-reacting with 2019-nCoV specific reagents. Also included in the FDA Tables are recommended unclaimed organisms/strains which are likely to be endemic to the currently affected area should be included in cross-reactivity testing since these organisms/strains will be an important aspect of the differential diagnosis of 2019-nCoV infection.**

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**FDA Table 1 Cross-Reactivity: List of Organisms to be wet-tested and analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens**

| Other high priority pathogens from the same genetic family | High priority organisms likely in the circulating area |
|---|---|
| Human coronavirus 229E | Adenovirus (e.g. C1 Ad. 71) |
| Human coronavirus OC43 | Human Metapneumovirus (hMPV) |
| Human coronavirus HKU1 | Parainfluenza virus 1-4 |
| Human coronavirus NL63 | Influenza A |
| SARS-coronavirus | Influenza B |
| MERS-coronavirus | Enterovirus (e.g. EV68) |
| | Respiratory syncytial virus |
| | Rhinovirus |
| | *Chlamydia pneumonia* |
| | *Haemophilus influenzae* |
| | *Legionella pneumophila* |
| | *Mycobacterium tuberculosis* |
| | *Streptococus pneumonia* |
| | *Streptococcus pyogenes* |
| | *Bordetella pertussis* |
| | *Mycoplasma pneumoniae* |
| | *Pneumocystis jirovecii* (PJP) |
| | Pooled human nasal wash - *to represent diverse microbial flora in the human respiratory tract* |
| | |

**FDA Table 2 Cross-Reactivity: List of Organisms to be analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens:**

| Other high priority pathogens from the same genetic family | High priority organisms, including organisms commonly found in the clinical matrix |
|---|---|
| | Influenza C |
| | Parechovirus |
| | *Candida albicans* |
| | *Corynebacterium diphtheriae* |
| | *Legionella non-pneumophila* |
| | *Bacillus anthracis* (Anthrax) |
| | *Moraxella catarrhalis* |
| | *Neisseria elongate and meningitidis* |
| | *Pseudomonas aeruginosa* |
| | *Staphylococcus epidermis* |
| | *Staphylococcus salivarius* |
| | *Leptospirosis* |

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| | |
|---|---|
| | *Chlamydia psittaci* |
| | *Coxiella burnetii (Q-Fever)* |
| | *Streptococcus aureus* |
| | |

***In silico*** **analysis should be performed on all potentially cross-reactive organisms outlined in the FDA Tables 1 and 2 above. You should provide the result summary of the** ***in silico*** **blast analysis (tabular format) evaluating whether there is any significant amplification of non-target sequences that could either result is cross-reactivity or potentially interfere with the detectability of the actual target analyte. As such we are asking that you provide individual blast results (non-truncated alignments) for each of the primers and probes used in your device with potential cross-reacting organisms. Please provide for our review the percent sequence homology for each organism relative to the target analyte primers/probes in your test. Please use the example table below when presenting the results of** ***in silico*** **analysis in your submission:**

**Results of *In Silico* Analysis**

| Pathogen | Strain | GenBank Acc# | % Homology Test FP (i.e. 0-100%) | % Homology Test RP | % Homology Test Probe |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**The analysis should include multiple representative strains from GenBank for each organism. If** ***in silico*** **analysis reveals other potential cross-reactants (i.e., ≥80% homology between one of your primers or the probe to any of the sequences of listed potential cross reactants), you should carefully review the alignments and determine based on the positions of the homologous stretches and mismatches if additional cross-reactivity and/or interference (please refer to item b below – microbial interference studies) wet testing will be required to rule out cross-reactivity or interference of that organism that may affect the performance of your device. In these circumstances if wet-testing is omitted you should include an explanation as to why** ***in silico*** **generated data is not clinically relevant (irrelevant isolate, location/extent of match within primer/probe, etc.), or why the performance of your test would not be impacted.**

**Organisms in FDA Table 1 should be wet tested in addition to the** ***in silico*** **analysis. Omissions from wet-testing should be discussed with FDA and supported by a well-documented justification that includes a due diligence attempt to obtain the live or inactivated organisms (and/or purified nucleic acid – which is acceptable for cross reactivity evaluation for an EUA).**

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**The wet testing evaluation should reflect test specimens prepared at the highest clinically relevant level of organism (i.e., a minimum of $10^6$ CFU/ml or higher for bacteria and $10^5$ $TCID_{50}$/mL or PFU/ml or higher for viruses) and should be tested with a minimum of three replicates per organism test specimen. Test specimens can be prepared by spiking cultured isolates/inactivated organisms/ purified nucleic acids (whole genome) into negative clinical matrix and determining cross reactivity based on triplicate replicates. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix.**

**If you plan to claim non-blood or non-respiratory clinical specimen types for diagnostic use with your device, e.g., stool specimens, etc., please consult FDA for more information on additional organisms that may be recommended for cross-reactivity testing, common examples are provided below for stool specimens (FDA Table 3):**

**FDA Table 3: Organisms to be analyzed for non-blood clinical specimens:**

| **Stool** |
|---|
| *Escherichia coli* |
| *Lactobacillus* |
| *Bacillus* spp. |
| *Clostridium* Spp. |
| *Enterobacter* |
| *Enterococcus* |
| Fusobacterium |
| Bacteroidetes |
| Bifidobacterium |
| Ruminococcus |
| |

b) *Microbial Interference Studies:* **If *in silico* analysis reveals ≥ 80% homology between the cross-reactivity microorganisms and your test primers/ probe(s), we recommend that you either perform (1) a microbial interference study with 2019-nCoV and the microorganisms that your test primers/ probe(s) have homology to, (2) as an alternative to the microbial interference study, you may provide justification as to why (e.g., amount of primer(s)/ probe(s) included in your master mix) the performance of your test would not be impacted by the presence of a causative agent of a clinically significant co-infection, or (3) explain why the *in silico* results are clinically irrelevant. In the case of the microbial interference study, interference should be evaluated using samples spiked at a low 2019-nCoV concentration, at 3x LoD, and a high interferent level (either microorganisms or nucleic acids purified from them), to represent the worst-case scenario, with a minimum of 3 replicates. If you plan to claim more than**

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**one type of blood clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix. If the LoDs are similar in the blood clinical matrices the study should be performed in the most challenging matrix, i.e., whole blood. In addition, if you are claiming blood and non-blood clinical specimens you may be required to perform this study in more than one clinical matrix. If interference is observed at the level tested, an additional titration study should be performed to determine the highest microorganism interferent level the 2019-nCoV test can tolerate.**

**c)** *Endogenous Interference Substances Studies*: **The extent of testing for endogenous interference substances depends on the matrix that is claimed for the device as well as on the technology of the device, e.g., if a nucleic extraction procedure is performed prior to testing or not. For EUA we do not typically ask for interference studies for tests that use conventional PCR and/or well-established extraction methods prior to testing (e.g., Boom method and column-based extraction methods).**

**For extraction procedures that are new or for nucleic acid-based technologies that are different from conventional PCR (e.g., various isothermal methods), we expect testing of potential interferents. The impact of interfering substances should be evaluated over the expected clinical range of the potentially interfering substance. Potential sources of endogenous interference include, but are not limited to, the ones listed in the tables below. It is important to note that the evaluation of interference and the generation of false negative results should be done using samples containing the analyte at or near the LoD and should not exceed 3x LoD. You should test a minimum of 3 replicates per substance. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed between the different clinical matrices this may warrant this study being performed in more than one clinical matrix. Biotin interference poses a risk to laboratory tests that incorporate the free biotin-streptavidin capture method. Therefore, please review this safety communication https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication and the following DRAFT guidance - Testing for Biotin Interference in In Vitro Diagnostic Devices (Web view) to determine if biotin interference testing may be warranted for your device. We also recommend you consult with FDA prior to initiating biotin interference testing, if applicable.**

**The tables below indicate the potentially interfering substances that may be found in blood and respiratory specimens. For other non-blood specimen types, such as stool, the list of substances could be expanded – please consult with FDA.**

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *positive* results:**

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| Potential Interfering Substance | Concentration | Results (Detected X/3) |
|---|---|---|
| **Respiratory Specimens** | | |
| Mucin: bovine submaxillary gland, type I-S | | |
| Blood (human) | | |
| Nasal sprays or drops | | |
| Nasal corticosteroids | | |
| Nasal gel | | |
| FluMist | | |
| Homeopathic allergy relief medicine | | |
| Throat lozenges, oral anesthetic and analgesic | | |
| Anti-viral drugs | | |
| Antibiotic, nasal ointment | | |
| Antibacterial, systemic | | |
| **Blood Specimens** | | |
| Hemoglobin | 10 mg/mL* | |
| Bilirubin Conjugated | 0.4 mg/mL* | |
| Bilirubin Unconjugated | 0.4 mg/mL* | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | |
| Triglycerides | 15 mg/mL* | |
| Cholesterol | 4 mg/mL* | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | |
| Rheumatoid Factor | 2000 IU/mL* | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *negative* results:**

| Potential Interfering Substance | Concentration* | Viral Strain Level (In multiples of LoD) | Results (Detected X/3) |
|---|---|---|---|
| **Respiratory Specimens** | | | |
| Mucin: bovine submaxillary gland, type I-S | | | |
| Blood (human) | | | |
| Nasal sprays or drops | | | |
| Nasal corticosteroids | | | |
| Nasal gel | | | |
| FluMist | | | |
| Homeopathic allergy relief medicine | | | |
| Throat lozenges, oral anesthetic and analgesic | | | |

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| | | | |
|---|---|---|---|
| Anti-viral drugs | | | |
| Antibiotic, nasal ointment | | | |
| Antibacterial, systemic | | | |
| **Blood Specimens** | | | |
| Hemoglobin | 10 mg/mL* | | |
| Bilirubin Conjugated | 0.4 mg/mL* | | |
| Bilirubin Unconjugated | 0.4 mg/mL* | | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | | |
| Triglycerides | 15 mg/mL* | | |
| Cholesterol | 4 mg/mL* | | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | | |
| Rheumatoid Factor | 2000 IU/mL* | | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

### 3) *Matrix Equivalency (if applicable):*

**A matrix equivalency study may be used to support certain specimen type claims that were not evaluated during the clinical study (e.g., serum versus plasma, use of different anticoagulants, use of difference swab types or viral transport media, etc.). Please note that LoD and clinical specificity studies are required for all claimed matrices. The matrix in which the clinical studies are conducted is the comparator. All other matrices are to be shown to be equivalent to the comparator matrix. We request a minimum of 40 paired samples each obtained from individual persons; negative (10 samples), low positive (1.5-2xLoD, 20 samples), and moderate positive (5-10xLoD, 10 samples) samples should be tested. Positive samples are prepared by spiking paired negative clinical matrix with the same amount of target analyte. Please note that individual (and not pooled) samples should be used in this study.**

### 4) *Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method:*

**A comparative LoD study may be required to support use of a comparator method in your clinical evaluation that has not been validated with a specific specimen type. The comparative LoD study should be conducted testing the same dilution series using both, your test and the comparator you chose in parallel (to dilution endpoints for both tests), 3-5 replicates per dilution level are sufficient for this study.**

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5) ***Specimen Stability and Fresh-frozen Testing:***

**A specimen stability study may be required to support specimen stability claims in the instructions for use outside of those typically outlined in CSLI standards. A fresh/frozen and/or freeze/thaw study may be required to support the use of frozen specimens if they are used as part of the clinical evaluation. Please consult with FDA concerning an appropriate study design prior to initiating any studies.**

6) ***Clinical Evaluation:***

**This section should describe the clinical study used to evaluate the performance of your test. Please note that the exact requirements for the clinical evaluation will be very dependent on, access to 2019-nCoV disease clinical specimens at the time of the studies and the nature of the emergency. Our general clinical study evaluation recommendations for respiratory and serum clinical specimens are outlined below. If you are interested in claiming additional specimen types, for example, stool, please contact FDA for current recommendations. Please note these clinical study recommendations may be subject to change as we continue to learn about the 2019-nCoV disease or as the risk benefit analysis changes.**

**The clinical performance in general should be evaluated for each unique claimed clinical specimen type - with the exception of claims that can be supported by a matrix equivalency study (outlined in Section 3 above). The performance characteristics should ideally be established using a clinical study with a limited number of prospective samples. If a prospective study is not feasible, an acceptable alternative would be to test retrospectively collected 2019-nCoV nucleic acid negative and positive specimens from patients, accompanied by some basic information such as, the specimen collection date, date of onset of symptoms (if present/known), tests used to identify 2019-nCoV nucleic acid positive specimens, etc. Depending on the nature of the disease, if no prospective or retrospective specimens are available at the time of your pre-EUA submission for the 2019-nCoV disease we may accept a fully contrived clinical evaluation. The clinical evaluation should be comprised of a minimum of 100 negative individually collected specimens and 50 individual positive specimens (prospective, retrospective and/or contrived). Use of pooled specimens are not acceptable for the clinical evaluation of your test. Please see FDA Table 5 for more details. Please note that if a fully contrived clinical study is used to support your Pre-EUA submission, additional clinical testing of a limited number of natural clinical positive specimens and potentially negative specimens from the endemic region, if available, may be required at the time when this Pre-EUA transitions to an EUA as a result of an Emergency declaration for 2019-nCoV disease.**

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## FDA Table 5: Clinical study Recommendations:

| Details | Study Including Prospective/ Retrospective Specimens | Fully Contrived Sample Study |
|---|---|---|
| Minimum Number of Positive Specimens | 50<br><br>The number of natural (prospective/retrospective) positive clinical specimens should be at least 25 (collected from symptomatic patients in the 2019-nCoV disease endemic region(s)) and, if necessary, may be supplemented with contrived samples to generate the total of 50 positive specimens. Contrived samples should be prepared as described in the fully contrived sample study column. | 50<br><br>The contrived positive samples should be made in individual negative clinical matrix collected from subjects from a non-endemic population (pooled matrix is not acceptable for the clinical evaluation). Please note that the negative clinical matrix used for spiking should be confirmed negative by your test device prior to spiking. Half of the contrived positive samples can be prepared by spiking the 2019-nCoV at LoD and the remaining contrived positive samples should cover the range of the test up to and not higher than 5 x LoD.<br><br>Negative respiratory specimens: Can be archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection.<br><br>Negative blood specimens: Can be collected from healthy subjects from non-endemic areas. |
| Minimum Number of Negative Specimens | 100<br><br>Note: In general, for EUA the 100 individual negative samples can be collected from; (1) archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection for respiratory specimens, and (2) healthy subjects from non-endemic areas for blood specimens, that are "expected 2019-nCoV disease negative". Note these negative specimens can be used to also prepare any contrived positive specimens used in support of the clinical evaluation of the test.<br><br>Please note this recommendation is dependent on the current outbreak situation and is subject to change as we learn more about the 2019-nCoV disease/outbreak. If the outbreak situation for 2019-nCoV disease is primarily outside of the continental U.S. (OUS) it may be beneficial to consider collecting negative specimens that represent 50% endemic and 50% non-endemic regions. If negative specimens are collected from the endemic region of the 2019-nCoV disease these should be tested with the same comparator chosen for the positive specimens (more details provided below). For non-endemic collected specimens you can compare to the expected "negative" result. | |
| Recommended Comparator Method | Positive: Positive percent agreement should be calculated in comparison to a EUA PCR test (please see the following website for the most recent list of FDA authorized 2019-nCoV | Positive: Compare to expected result.<br><br>Negative: See Minimum Number of Negative Specimens row |

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| | | |
|---|---|---|
| for percent agreement performance calculations | tests: https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm. If no EUA test available at the time of your EUA submission, please consult with FDA about your choice of comparator method – which ideally should be a well validated PCR test with comparable sensitivity to your subject device. Please note that a well validated PCR test should include evaluation of the tests LoD, inclusivity, exclusivity, interference and any clinical testing.<br><br>Negative: See Minimum Number of Negative Specimens row | |
| Comparator Method Note 1 | Please note when using natural clinical specimens, the comparator method must be validated for the specimen type claimed – if not you should perform a Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method study, as explained above (Section 4), to support its use as a comparator method in your clinical study. | N/A |
| Comparator Method Note 2 | Any occurrences of false results should be investigated with an additional validated PCR test and/or targeted sequencing, and the results of the discordant analysis can be footnoted in your final performance table but cannot be used to change the final performance calculations. | |
| Natural Clinical Specimens IRB/Informed Consent Note | For clinical specimens collected to support the EUA request, please note that sample collection needs to adhere to all applicable rules of human subject protection; as such, sample collection needs IRB approval, which includes review of the informed consent forms. Samples need to be collected with informed consent. If leftover de-identified samples are used, FDA exercises enforcement discretion regarding the informed consent requirement if the specimen collection meets the criteria described in the FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable (http://www.fda.gov/cdrh/oivd/guidance/1588.pdf).<br>**Note that IRB approval is still required even if leftover de-identified samples are used in your study.** | |
| Additional Studies Warning | N/A | If fully contrived samples were used in your Pre-EUA submission, additional testing of natural clinical specimens may be requested, if available, to support transition of the Pre-EUA to EUA as a result of an Emergency declaration. |
| Testing Approach Note 1 | Please note all clinical specimens (natural and contrived) should be evaluated in accordance with your proposed diagnostic algorithm, including retesting when appropriate. We understand the limited nature of natural specimens may preclude retesting. In instances were retesting is indicated but not performed, for the purposed of performance evaluation, initial results will be analyzed for performance and equivocal/indeterminate results count against your final performance. | |
| Testing Approach Note 2 | Specimens should be tested in a blinded fashion, e.g., positive and negative samples should be mixed and blinded to the end user, end user should also be blinded to the results of any comparator method testing. | |

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**When you describe your clinical study please indicate/include:**

- **How the specimens were generated/collect/sourced**
- **If the study was fully prospective, mix of prospective, retrospective and/or contrived or fully contrived**
- **The rationale for the concentrations/specimens selected (if using contrived or 3-party sourced specimens)**
- **The total number of specimens tested**
- **The specimen types (clinical matrix)**
- **A summary of the study results**

**In the case of real-time PCR tests, please provide the line data in an Excel file as part of the Pre-EUA submission for each specimen (please indicate for each specimen if it was prospective, retrospective or contrived and the clinical matrix it represents); the data should include the $C_T$ values (for the specimen and the controls) and call/result for your device and, in the case of the natural clinical specimens, the comparator method results should be included as well.**

## L. UNMET NEED ADDRESSED BY THE PRODUCT

**This section will be finalized by FDA based on the state of the emergency at the time of authorization and based on recommendations from Public Health authorities at that time. Example text is provided below but may be adapted according to the specific emergency situation that is addressed by the device and the need at the specific time of the outbreak.**

[Outline background of pathogen, disease and current outbreak]

[Outline details of the disease such as the following:

- likely sources of transmission
- likely symptoms – if any
- Prevalence of symptomatic disease (what fraction of infection results in symptomatic disease)]

Laboratories in the United States are in need of diagnostic tools for use in the 2019-nCoV emergency for rapid diagnosis of acute 2019-nCoV infection.

A public health emergency has been declared by the Secretary of Health and Human Services (HHS) on [Month Day, YEAR] justifying the authorization of emergency use of *in vitro* diagnostic tests for detection of 2019-nCoV and/or diagnosis of 2019-nCoV infection.

The ***[test name]*** can augment clinically important laboratory evidence for individuals with active infection. The 2019-nCoV nucleic acid is generally detectable in [name

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specimen type] during the acute phase of infection (approximately [7] days following onset of symptoms, if present) [and possibly for longer in other specimen types].

Under emergency use authorization (EUA), ***[applicant name]*** plans to distribute the test or accept sample for testing with the ***[test name]*** for the detection of nucleic acid from 2019-nCoV in clinical specimens collected from individuals meeting CDC's 2019-nCoV clinical and/or epidemiological criteria. This EUA request for the ***[test name]*** is intended to expand domestic readiness within the United States and its territories by expanding diagnostic testing capabilities for 2019-nCoV during public health emergency.

FDA consulted with subject matter experts within HHS on the public health needs for diagnostic devices to detect 2019-nCoV nucleic acid. It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for 2019-nCoV detection during the public health emergency.

## M. APPROVED/CLEARED ALTERNATIVE PRODUCTS

Currently no methods for the detection of the 2019-nCoV have been approved/ cleared by FDA.

## N. RISKS AND BENEFITS:

**The Risks and Benefits section should be updated according to your specific device, some example language is given below but should be tailored to the device and the disease.**

Risks

The ***[test name]*** has been designed to minimize the likelihood of false test results. However, should false results occur, they may present risks to patients:

- False positive result:
  - A false positive 2019-nCoV result could [***update based on the pathogen***].
  - A false positive result in the context of the current public health emergency could lead to misallocation of resources used for surveillance and prevention.
  - A false positive result could delay correct diagnosis and initiation of appropriate treatment for the actual cause of patient illness.
- False negative result:
  - Although a negative result does not rule out 2019-nCoV infection, a false negative has the potential to result in initiation of inappropriate treatment and a delay in correct diagnosis.
  - A false negative result can trigger a waste of health care resources, as additional evaluations are pursued in the effort to establish the true diagnosis.
  - A false negative results can contribute to further spread of the disease.

Benefits

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The primary benefit of distributing the ***[test name]*** for clinical use is that it provides a relatively fast diagnostic method for symptomatic patients, which enables faster intervention.

- True positive test results provide support for the diagnosis of a 2019-nCoV infection. The results can be used in conjunction with clinical and epidemiological information to guide patient management.
- Distribution of the factsheets can help healthcare professionals and the public learn more about 2019-nCoV disease and how to avoid acquiring it.

Risk Assessment

- Negative results may not preclude a 2019-nCoV infection. It is emphasized that the ***[test name]*** should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure must be considered pivotal to making patient management decisions. A negative test should not be interpreted as definitive, if other aspects of the patient's clinical presentation or recent epidemiologic exposures indicate such is likely, and diagnostic tests for other diseases are negative.
- False negative results due to failure of PCR are minimized by the presence of controls that monitor nucleic acid extraction and PCR efficiency.
- Risk of patient discomfort or harm during sample collection is minimal.

Risk-Benefit Assessment

The risks posed by use of the ***[test name]*** are mitigated by:

- Use of the ***[test name]*** in conjunction with other laboratory, epidemiological, and clinical evaluation tools
- Distribution of Healthcare Provider and Patient fact sheets.
- Post-market studies/reporting or conditions of Authorization.

Based on these factors, the potential benefits from the use of the ***[test name]*** are expected to outweigh the risks.

## O. FACT SHEET FOR HEALTHCARE PROVIDERS AND PATIENTS:

**Include proposed Fact Sheets for Patients and Healthcare Providers**

## P. INSTRUCTIONS FOR USE/ PROPOSED LABELING/PACKAGE INSERT:

**Include Instructions for Use, Box Labels, Vial Labels and any other proposed labeling.**

## Q. RECORD KEEPING AND REPORTING INFORMATION TO FDA:

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[***Manufacturer name***] will track adverse events and report to FDA under 21 CFR Part 803. A website is available to report on adverse events, and this website is referenced in the Fact Sheet for Health Care providers as well as through the [***Manufacturer name***] Product Support website: [***Include link to Website***]. Each report of an adverse event will be processed according to [***Manufacturer name]***'s Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the FDA as required. Through a process of inventory control, [***Manufacturer name]*** will also maintain records of device usage/purchase. [***Manufacturer name]*** will collect information on the performance of the test, and report to FDA any suspected occurrence of false positive or false negative results of which [***Manufacturer name]*** becomes aware. [***Manufacturer name]*** will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

## R. ADMINISTRATIVE INFORMATION:

**Interactive Review Log:** Please use the table below to document interactive review with FDA and include interactions initiated by either FDA or yourself

| **Date** | **Type of Interaction** (phone/ email/ formal submission-DCC) | **Brief Description** (e.g., questions asked/ feedback from FDA received / any word documents included) |
|---|---|---|
| [X] | [X] | [X] |
| | | |
| | | |

## S. FDA ADMINISTRATIVE INFORMATION:

**This section will be finalized by the FDA Lead Reviewer upon completion of the review process and documents the interactive review of this submission and any conclusions resulting from the interactive review.**

1) **Summary of Interactive Review – Lead Reviewer to use this section to highlight any major issues solved during interactive review.**
2) **Final Conclusions for Interactive Review -** It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for [pathogen] detection during the public health emergency. **Conclusion should include an outline the unique features of the device compared to currently issued EUA's under the declaration, if applicable.**
3) **Upon competition of this section the Lead Reviewer should also sign this document and save the file as the final Decision Memorandum.**

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## APPENDIX A – Multiplex Panels Under EUA:

An emergency declaration by the HHS Secretary is typically specific for a pathogen/disease (i.e., there is a publicly declared health emergency involving a particular etiologic agent). Therefore, the EUA pathway is only applicable for testing patients with signs/symptoms/risk of exposure for that single agent in a given emergency. FDA has occasionally allowed limited additional target pathogens to be claimed for EUA devices, but panel members must be relevant to the event/disease outbreak subject of the specific emergency declaration. When determining whether to issue an EUA for a multiplex panel FDA takes into consideration the utility of the test (multiplex pathogen detection as an aid in differential diagnosis), clearance/approval status of IVDs for the other panel members, whether the proposed Intended Use fits within the HHS emergency declaration and the how the multiplex panel would fit into current public health authority patient testing algorithm recommendations. We recommend you contact FDA for specific feedback if you plan to claim multiple target analytes as part of your EUA test. If it is determined that a multiplex test is beneficial to the emergency response, please note that analytical and clinical evaluations for each of the target analytes will be required.

## APPENDIX B – General Study Design Recommendations for Reagent Stability:

- For EUAs you may follow the current FDA recognized CLSI Standard EP25 – Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline when evaluating the suitability of stability study designs. If you are planning to pursue a De Novo/510(k) for your device we recommend discussing in more detail your stability design to facilitate potential use of the EUA data in your regular premarket submission.
- Please note that use of only the positive controls is not acceptable for reagent stability evaluation because controls are usually formulated at a moderate positive level. For all the stability evaluations in addition to your external positive and negative controls and the no-template control you should include for the EUA evaluation at least one sample, that should be prepared by spiking negative clinical matrix at an analyte concentration of 3-5xLoD.
- If you are claiming multiple blood clinical specimen types in which similar LoDs are determined, you should use the most challenging clinical matrix for this study.
- Please note we typically recommend your stability study design includes the evaluation of at least 5 replicates. You should also evaluate, if available, 3 different lots of reagents.
- You should design your study to provide data for a timeframe that is about 10% longer than the one to be claimed – for example; a claim of 18 months should be supported by stability data out to 20 months and a claim of 7 days should include stability data out to 8 days.
- FDA considers 15-30°C to represent room temperature conditions. Ideally you should evaluate stability at both 15°C and 30°C, however, for the purposes of the EUA evaluation at 30°C is acceptable as the worse-case scenario.
- Shelf-Life Stability- Unopened kit:
    - You should evaluate real-time kit stability studies with unopened kits stored at the claimed storage temperature for your test.

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  - Accelerated stability evaluations for unopened kits is acceptable for EUA submissions while the real-time studies are on-going. However, please note real-time stability data is required to support regular pre-market submissions and for the final claim of an EUA.
- Shipping Stability - Unopened kit: Study should evaluate the anticipated handling and shipping times and temperatures expected for unopened kits.
- In-use/Opened Kit Stability: Depending on your device your stability study design should also support in-use stability of the kit reagents once the kit has been opened, e.g., storage at 2-8 $^{o}$C for 7 days. This includes on board stability once reagents have been placed on the instrument (if applicable).
- Inverted stability (if applicable): Study should support inverted stability for of kits.
- Freeze-thaw Stability: If you recommend aliquoting the reagents to meet the end-users needs following the initial thaw this recommendation should be supported by a freeze-thaw stability study, including the specific number of allowed freeze-thaw cycles.
- FDA analysis recommendations for real time stability studies are as follows:
  - Baseline of the study (t=0 of stability study) should not exceed a month from bottling
  - Clear baselines should be described (e.g., a month from bottling) for each stability claim under each study
  - Claims should be determined based on regression analysis. Any %change (%shift) from time zero (baseline) should be calculated between the target claim and the zero-time as (Ttest-Tbaseline)/ Tbaseline*100 with 95%CI using the regression equation obtained from plotting the mean values. When formulating your acceptance criteria for evaluating the shift from baseline you should consider the reproducibility of your device. However, generally, that the shift at the target claim due to storage cannot exceed 10-15%. The target stability is the next to last tested point that was within +/- 10% of time zero.
  - Acceptance criterion may be different, depending on the test samples analyte concentration distribution in the intended use population and the risk, in other words, the impact of false results to public health.

**APPENDIX C – Claiming Multiple Instruments and/or Extraction Methods:**

If you wish to claim multiple instruments and/or extraction methods for use with your test, please review the study recommendations provided below and contact FDA for any additional feedback. Please note that these analytical and clinical evaluation recommendations are based on the assumption that the elution volumes from the extraction methods and PCR volumes on the different RT-PCR instruments are identical.

- Limit of Detection (LoD): Please note that these studies should be repeated for each clinical matrix claimed in the Intended Use. Pick one RT-PCR instrument and determine the tentative LoD (using 5 replicates in 10-fold dilution) followed by the confirmatory LoD (20 replicates spiked at tentative LoD) for each extraction method on the chosen instrument. Note: If you detect 20/20 replicates in your confirmatory LOD study you should test the next lower concentration, using a 3-fold dilution, until

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you achieve a hit rate of <20/20.

- If the different extraction methods yield the same LoD (≤3xLOD) on the RT-PCR instrument chosen for initial testing, pick one extraction method for further LoD determination on the remaining RT-PCR instruments and follow the recommendations below.
- If the extraction methods do not yield the same LoD on the chosen RT-PCR instrument, please choose the extraction method with the worst LoD for further comparison of the LoD on all RT-PCR instruments.

For all other RT-PCR instruments you should use the following adaptive LoD study design:

- Please perform a refined tentative LoD study with 5 replicates at 0.5x, 1x, and 1.5 to 2x LoD. If you detect 4/5 replicates as positive at all the tested levels, you need to include the next higher concentration (i.e., 3x LoD). If you obtain 5/5 replicates at 0.5x LoD, you need to test the next lower concentration (i.e., 0.25x LoD). You will test in this manner until you find the lowest concentration that gives you 5/5 positive results for the tested RT-PCR instrument. This concentration should be used for a confirmatory LoD study for the given RT-PCR instrument using 20 replicates.

Final reported LoD: Please list all RT-PCR instruments with their respective LoDs if different LoDs are obtained. LoDs are considered comparable if they are between 1-3xLoD. These studies should be repeated for each clinical matrix claimed in the Intended Use.

- Interference Substances Studies (if applicable): Pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Inclusivity Testing: For the inclusivity testing, pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Exclusivity Testing: For exclusivity, you can perform this study using any extraction/instrument combination.

- Clinical study: If equivalency of the RT-PCR instruments is shown in an LoD study that tests and confirms that the LoD is the same or very similar for all of the RT-PCR instruments (between 2-3xLoD), then you can pick one RT-PCR instrument for your clinical study provided that the RT-PCR instruments in question are known to FDA for other *in vitro* diagnostic devices. If you find that one or more RT-PCR instruments machines has/have a different LoD, you should pick the extraction method / RT-PCR instrument combination with the worst LoD.

Note, if there are differences in the extraction input volume, extraction elution volume

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and PCR input volume (extracted nucleic acid) then the LoD should be confirmed, for each.

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/28/2020 8:57:19 AM
**To**: Gitterman, Steven [Steven.Gitterman@va.gov]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]
**Subject**: EUA Review Template_NAT_Novel Coronavirus 1.19.2020 (002).doc
**Attachments**: EUA Review Template_NAT_Novel Coronavirus 1.19.2020 (002).doc

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/28/2020 8:55:45 AM
**To:** Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]; Gitterman, Steven [Steven.Gitterman@va.gov]
**Subject:** Minimum criteria

1. Analytical Evaluation

a. LoD using viral genomic RNA or inactivated virus preferably in clinical matrix. Testing limiting dilution serious of 3 replicates and confirmation with 20 replicates from the extraction to result in most challenging matrix or if not obtainable contrived clinical matrix. Acceptance criteria 19/20.

b. Inclusivity (in silico analysis of primers and probe to demonstrate that the assay can detect all currently known SARS-CoV-2). Acceptance criteria: identifying 100% of published SARS-CoV-2 sequences.

c. Cross-reactivity (in silico analysis of primers and probe to potentially detect cross reactant of organisms that are usually present in respiratory specimens e.g., Flu, coronavirus 229E etc ). We also request laboratory testing of microorganisms that showed potentially cross reacting in in silico analysis (i.e., >80% homology between one of your primers or probes to any of the sequences of organisms usually present in respiratory specimens)

2. Clinical Evaluation – Contrived clinical study: You should test 40 negative and 40 positive contrived clinical samples. The samples should be prepared by spiking SARS-CoV2 viral RNA or inactivated virus into individual clinical upper and lower respiratory specimens collected from patients with signs and symptoms of respiratory infection. 80% of the samples can be upper respiratory specimens. Left-over archived specimens may be used to prepare the mock clinical samples, the majority can be upper respiratory specimens. Half (20) of the contrived positive samples should be prepared by spiking the SARS-CoV2 at 1X – 2x LoD and the remaining contrived positive samples should span the testing range of your assay and not higher than 5x LoD. Acceptance criteria: 95% for 1X – 2x LoD, 100% 5x LoD and negative specimens.

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**Sent:** 2/27/2020 10:10:55 PM
**To:** Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]
**Subject:** RE: Summary of information from Charles Chiu; SARS-CoV-2 CRISPR

For him I might be easier to directly connect him (b) (5)
(b) (5)

**From:** Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 9:33 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Summary of information from Charles Chiu; SARS-CoV-2 CRISPR

I was planning to just send Charles the email we finalized earlier today, (b) (5)
(b) (5) I don't have this information.

Thanks,

Joe

**From:** Briggs, Joseph
**Sent:** Thursday, February 27, 2020 9:01 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Summary of information from Charles Chiu; SARS-CoV-2 CRISPR

Hi Uwe,

I've attached the summary of our conversation with Charles Chiu today. There are links to the Mammoth Bio website as well as the white paper. Let me know if you'd like to discuss the questions he posed in his email. I'll be up for a while working on submissions.

Thanks,

Joe

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/27/2020 10:08:21 PM
**To:** Tucker, Angela (b) (6) @roche.com]
**Subject:** RE: SARS-CoV- 2 tests CE marked

Angela,

Thanks, very much appreciated.

BTW, you might know what is needed to get CE mark? Only analytical studies with In Virto Transcipts?

Uwe

**From:** Tucker, Angela <(b) (6) @roche.com>
**Sent:** Thursday, February 27, 2020 10:02 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** SARS-CoV- 2 tests CE marked

Dear Uwe,

As follow-up:

From Rita Hoady on my team:

These are all the manufacturers of CE-marked tests:
Frontline Genomics
CO-Diagnostics
Qiagen
Genesig
Novacyt
Primer Design (oligo's only)
(b) (4)

Angela G. Tucker
Vice President, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588-2722

Phone: +1 925 730-8277
Cell: + (b) (6)
Fax: +1 925 225-0207
Email: angela.tucker@roche.com

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/28/2020 10:41:36 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Minimal Criteria for test validation

Jeff and Tim,

The minimal criteria acceptable to validate the test to be developed by the target laboratories are listed below. We foresee that it will take 3-4 days for a CLIA-certified, high-complexity laboratory to complete these evaluations.
For item 1. a. below, Genomic RNA manufactured by UTMB, provided to us by NIAID/NIH or BEI is available for testing.

1. Analytical Evaluation

a. LoD using viral genomic RNA or inactivated virus preferably in clinical matrix. Testing limiting dilution serious of 3 replicates and confirmation with 20 replicates from the extraction to result in most challenging matrix or if not obtainable contrived clinical matrix. Acceptance criteria 19/20.

b. Inclusivity (in silico analysis of primers and probe to demonstrate that the assay can detect all currently known SARS-CoV-2). Acceptance criteria: identifying 100% of published SARS-CoV-2 sequences.

c. Cross-reactivity (in silico analysis of primers and probe to potentially detect cross reactant of organisms that are usually present in respiratory specimens e.g., Flu, coronavirus 229E etc ). We also request laboratory testing of microorganisms that showed potentially cross reacting in in silico analysis (i.e., >80% homology between one of your primers or probes to any of the sequences of organisms usually present in respiratory specimens)

2. Clinical Evaluation – Contrived clinical study: You should test 50 negative and 50 positive contrived clinical samples. The samples should be prepared by spiking SARS-CoV2 viral RNA or inactivated virus into individual clinical upper and lower respiratory specimens collected from patients with signs and symptoms of respiratory infection. 80% of the samples can be upper respiratory specimens. Left-over archived specimens may be used to prepare the mock clinical samples, the majority can be upper respiratory specimens. Half (25) of the contrived positive samples should be prepared by spiking the SARS-CoV2 at 1X – 2x LoD and the remaining contrived positive samples should span the testing range of your assay and not higher than 5x LoD. Acceptance criteria: 95% for 1X – 2x LoD, 100% 5x LoD and negative specimens.

Let me know if you have any questions.

Uwe

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/29/2020 9:09:43 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: LoD and clinical study

They can already do testing after validation with the new policy. So they will be happy.

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

-----Original Message-----
From: Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
Sent: Saturday, February 29, 2020 9:03 PM
To: Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Subject: RE: LoD and clinical study
Importance: High

They received the viral RNA and is generating testing data. (b) (5)
(b) (5) The new FDA guidance regarding LDTs allows them to offer the test, and then submit an EUA right? What guidance should we give to them? What if they submit he EUA tomorrow?
Li

-----Original Message-----
From: Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
Sent: Saturday, February 29, 2020 8:54 PM
To: Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Subject: FW: LoD and clinical study

It looks like (b) (5) See below.

-----Original Message-----
From: Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
Sent: Saturday, February 29, 2020 8:50 PM
To: Alex Greninger <agrening@uw.edu>
Subject: RE: LoD and clinical study

Hi Alex,

(b) (4)

With regard to the FDA new guidance, it allows CLIA high complexity labs to develop, validate, and offer an LDT under the current emergency without first submitting and obtaining an EUA. The lab should submit an EUA within 15 days of offering the test though.

Li

-----Original Message-----
From: Alex Greninger <agrening@uw.edu>
Sent: Saturday, February 29, 2020 8:24 PM

AMERICAN OVERSIGHT

To: Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
Subject: Re: LoD and clinical study

Hi Li,

Can you offer guidance on what we need to do if we need to update the instrument we perform our extractions on in order to increase testing? (b) (4)

(b) (4)

Does this require a completely new validation?

> On Feb 29, 2020, at 4:38 PM, Li, Li (CDRH) <Li.Li2@fda.hhs.gov> wrote:
>
> As stated in the template:
> If in silico analysis reveals ≥ 80% homology between the cross-reactivity microorganisms and your test primers/ probe(s), we recommend that you either perform (1) a microbial interference study with 2019-nCoV and the microorganisms that your test primers/ probe(s) have homology to, (2) as an alternative to the microbial interference study, you may provide justification as to why (e.g., amount of primer(s)/ probe(s) included in your master mix) the performance of your test would not be impacted by the presence of a causative agent of a clinically significant co-infection, or (3) explain why the in silico results are clinically irrelevant.
> So, you have all three options to address potential microbial interference.
>> 80% homology for any one primer or probe may negatively impact test performance with SARS-CoV-2 when in a clinically significant co-infection with an HCoV at high concentrations.
>
> Li
>
> -----Original Message-----
> From: Alex Greninger <agrening@uw.edu>
> Sent: Saturday, February 29, 2020 7:22 PM
> To: Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
> Subject: Re: LoD and clinical study
>
> And if one or more primers are >80% to an HCoV, we MUST do an interference study??? Or is it just recommended? If required, How many primers or probe need to be within 80%?
>
> Alex
>
>> On Feb 29, 2020, at 4:17 PM, Li, Li (CDRH) <Li.Li2@fda.hhs.gov> wrote:
>>
>> Hi Alex,
>>
>> Yes, you can use the same (b) (4) specimens for LoD confirmation and as a part of the mock clinical study. While pooled negative clinical matrix is acceptable for the LoD study (both range finding and confirmation), individual unique clinical specimens are needed for the mock clinical study.
>>
>> Li
>>
>> -----Original Message-----
>> From: Alex Greninger <agrening@uw.edu>
>> Sent: Saturday, February 29, 2020 4:20 PM
>> To: Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
>> Subject: LoD and clinical study
>>
>> Hi Li,
>>
>> Well, the virus made it to Seattle, so now our validation is a touch easier. Regarding the new FDA guidance, can we (b) (4)

(b) (4)

>>
>> alex
>

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 10:07:04 PM
**To**: CDRH-OIR-IVD-DMD (CDRH-OIR-IVD-DMD@fda.hhs.gov) [CDRH-OIR-IVD-DMD@fda.hhs.gov]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Briggs, Joseph (Joseph.Briggs@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Joseph.Briggsbaf]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Gagne, Stefan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34d09d8b5be419c8f5c441bc8ebc4f7-SXG]; Aihie, Irene [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad4eedb2f6c644b28a1ce3903f325790-Irene.Aihie]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]
**CC**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Fulmer, Sonja [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6136c44586e4a1ca8ce73d55803cfe5-Sonja.Fulme]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; CDRH-OCE-Division of Comms-MGRS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9166df93aa6c4a23a3f6661b21ae3e7c-CDRH-OCE-DH]; MacLennan, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e3684d6a36e4002bc07015b7506b803-Lori.MacLen]

**Subject**: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

**Congratulations!**

FDA just issued the Emergency Use Authorization for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel.
Thanks to the tireless and outstanding work of the DMD review team:

- **Himani Bisht, Li Li**, **Joseph Briggs** Reviewer, Viral Respiratory & HPV Branch,
- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*
- **Brittany Goldberg**, MD, Senior Medical Officer, and
- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, our communication team, and our senior leadership.

These have been incredible times and words cannot describe how grateful I am for your phenomenal dedication and extraordinary hard work that made this happen. You are an exceptional team to work with unprecedented commitment to public health!

Thank you!

My very kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 2:41:25 PM
**To**: Krueger, Brian [(b) (6) @LabCorp.com]; Eisenberg, Marcia [Eisenbm@LabCorp.com]
**CC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Humes, Rosemary (OS) (Rosemary.Humes@hhs.gov) [Rosemary.Humes@hhs.gov]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: RE: LabCorp update

**Importance**: High

Brian and Marcia,

We have a courier who can ship material to you today. Important next step:
Can you receive material on Sunday? If yes
Where would it need to be shipped to.

I copied Rosemary Humes, she ahs close contact to BEI and has facilitated the process.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/28/2020 3:07:59 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Shearstone, Peter E. [(b) (6) @thermofisher.com]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**CC:** Fenton, Tim [(b) (6) @thermofisher.com]; Kerr, Liz [(b) (6) @thermofisher.com]
**Subject:** RE: EUA Submission

Peter,
Thanks, we will start review today and will have a better timing after that.

Thanks, Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 28, 2020 at 2:01:59 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Shearstone, Peter E. <(b) (6) @thermofisher.com>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Fenton, Tim <(b) (6) @thermofisher.com>, Kerr, Liz <(b) (6) @thermofisher.com>
**Subject:** RE: EUA Submission

Thanks Peter, this is great news.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 12:51 PM
**To:** Shearstone, Peter E. <(b) (6) @thermofisher.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

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**Cc:** Fenton, Tim <(b) (6) @thermofisher.com>; Kerr, Liz <(b) (6) @thermofisher.com>
**Subject:** RE: EUA Submission

Adding Uwe who can better opine on timing of response.

---

**From:** Shearstone, Peter E. <peter.shearstone@thermofisher.com>
**Sent:** Friday, February 28, 2020 12:37 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Fenton, Tim <(b) (6) @thermofisher.com>; Kerr, Liz <(b) (6) @thermofisher.com>
**Subject:** EUA Submission

Dear Jeff, Tim and Wendi,

A quick update from Thermo Fisher's efforts on COVID-19.

We plan to submit the EUA pre-sub to Uwe between 7-8pm EST tonight.
Let me know when we could expect a response in order to keep moving.

Also :

1. We have received (b)(4) nd are initiating our contrived samples
2. We are working our controls strategy with our internal resources
3. We have currently manufactured (b)(4) eactions of the EUA assay for testing purposes. We will have a (b)(4) reaction size kits.
4. We have or will be sending kits to (b)(4) or testing.

Let me know what else you may need.

Best,
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) Mobile: (b) (6)
Internal extension 110-1333
(b) (6) @thermofisher.com

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**[Date]**

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**ATTN:** Division Director: Dr. Uwe Scherf**,** OHT7-OIR/OPEQ/CDRH/FDA

**RE:** Request for Pre-Emergency Use Authorization (Pre-EUA) of the [*Name of the Assay*]

**Dear Dr. Scherf,**

[***Name of the Company***] is submitting a Pre-Emergency Use (Pre-EUA) for the [***Name of the Medical Device Product***] so we can obtain feedback from FDA concerning the studies and/or testing outlined in our Pre-Emergency Use Authorization (Pre-EUA) submission package.

The [***Name of the Medical Device Product***] is [***brief description of the device***] and [***intended use***].

Attached to this letter is the first draft of our device EUA Interactive Review Template for FDA review as a Pre-EUA. One hard copy of the signed EUA Cover Letter and one electronic copy are enclosed. Also, these documents have been sent to you via email.

In case you should have any questions regarding the information provided and/or need additional information/data from us please contact me immediately either via email [_____] or phone [_____].

Sincerely,

[***Name***]

[***Signature block***]

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# EMERGENCY USE AUTHORIZATION (EUA)

## EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (2019-nCoV)

## GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow *[Text]* should be completed by the IVD developer (sponsor) as applicable to their specific test. Text in **bold** outlines the Food and Drug Administration (FDA) suggestions and clarifications for the sponsors' consideration when completing the required information in a specific section.

- This is a EUA interactive review template for Pre-EUA/EUA submissions concerning molecular-based single target tests for detection of 2019 Novel Coronavirus (2019-nCoV), Wuhan, China. If you are developing a multiplex molecular-based assay for the detection and differentiation of nucleic acids from a panel of microorganisms, please review Appendix A for FDA recommendations.

- This is a EUA interactive review template for Pre-EUA/EUA submissions and not a guidance document. The template is subject to change as we learn more about the 2019-nCoV disease and its risk-benefit profile. Recipients will receive notice and updated templates as they become available.

- This EUA interactive review template is an FDA internal document and any proprietary information provided within the template and during the interactive review process will remain confidential as it does in a regular FDA premarket submission.

- Feedback provided by FDA during the interactive review of your pre-EUA/EUA is subject to change as we learn more about the 2019-nCoV disease and the risk-benefit profile evolves to address unmet public health needs.

- Prior to a potential authorization FDA will require developers of molecular-based tests to assess traceability of their test to an FDA-recommended reference material panel if available at the time. Specific details about the traceability study and the FDA-recommended reference material panel will be provided by the Lead Reviewer assigned to the Pre-EUA submission once the analytical and clinical evaluation data has been reviewed and found to be acceptable.

- Please be reminded that tests for the detection of 2019-nCoV or 2019-nCoV infection must not be distributed and/or used for clinical diagnoses without premarket clearance, approval, or EUA by the FDA. Clinical samples for 2019-nCoV testing should be sent to the appropriate public health laboratories until the IVD device subject of this Pre-EUA submission has received authorization from the FDA.

- Clinical specimens may be required to support the EUA request. Furthermore, please note that applicable regulations for human subject protection do apply under the

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EUA. Please refer to the Clinical Evaluation section of this document for more details.

- If authorized, the EUA means that this 2019-nCoV IVD is temporarily authorized for use until the public health emergency is terminated or the EUA is revoked by the FDA.

    - FDA recommends that you consider registration and listing your EUA product once you have been issued an EUA. If this is problematic, please notify the Agency during your Pre-EUA.
    - The EUA is not a pathway to permanent marketing of your device. Therefore, we strongly recommend that you consider, in addition to an EUA, a traditional premarket submission for your IVD so that your device can still be legally marketed after termination of the emergency declaration. We recommend that you identify as soon as possible in the Pre-EUA review process any consideration of moving your product forward towards De Novo/510(k) clearance. If so some of our feedback to you may take such a long-term goal into consideration in order to prevent additional testing where it may not be needed. Therefore, please consider submitting a Pre-Submission to inquire what studies would be required for a premarket approval/ clearance of your 2019-nCoV IVD. Details on how to submit a Pre-Submission to the Agency are outlined in the FDA guidance document: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.* [ HYPERLINK "https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program" ]

## A. EXECUTIVE SUMMARY (as of X/XX/20XX)

## B. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the ***[test name]*** to ***[indicate labs, if applicable]*** for the *in vitro* qualitative detection of RNA from the 2019-nCoV in ***[add all claimed specimen types, e.g., nasopharyngeal/oropharyngeal swabs, sputa, BAL, stool, and serum, etc.]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated with 2019-nCoV infection) and CDC novel coronavirus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated) to aid in the diagnosis of 2019-nCoV infection.

## C. MEASURAND

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Specific nucleic acid sequences from the genome of the 2019-nCoV **[*please specify the targeted gene(s) of the pathogen*]**.

## D. APPLICANT

***[Official name, address and contact information of applicant]***

## E. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name - ***[test name]***
Established Name - ***[test name]***

## F. REGULATORY INFORMATION

***Approval/Clearance Status:***
The ***[test name]*** test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

***Product Code:***
[XXX – FDA will complete]

## G. PROPOSED INTENDED USE

***1) Intended Use:***
**The proposed IU will be finalized based on the data and recommendations from Public Health authorities at the time of authorization – example text is provided below for a qualitative molecular test that detects organism RNA but may be adapted according to the specific emergency situation addressed by the device.**

[***Test name***] is a [***specify test technology such as, real-time RT-PCR test***] intended for the qualitative detection of nucleic acid from the 2019-nCoV in [***describe all the specimen types***] from individuals meeting CDC 2019-nCoV clinical criteria (e.g., clinical signs and symptoms associated with 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated). Testing is limited to [***laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories***].

Results are for the identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in **[*name specimen type*]** during the acute phase of infection. Positive results

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are indicative of active infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The ***[test name]*** is intended for use by **[*include intended user, e.g., trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures*]**. The ***[test name]*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

***2) Special Conditions for Use Statements:***

For prescription use only
For in vitro diagnostic use only

***3) Special Instrument Requirements:***

The ***[test name]*** test is to be used with the [***list all RT-PCR Instruments, software requirements, automated extraction instruments***].

## H. DEVICE DESCRIPTION AND TEST PRINCIPLE

**Example text has been added under each of the sub-headings below for a fluorescence based rRT-PCR test for detection of organism RNA. If a different test principle is used by the test for the detection of a specific analyte please modify the description accordingly to capture the salient points in each of the sub-headings below. Please note that for new investigative technologies FDA may request additional detailed information so we can adequately assess the risks and benefits associated with the device.**

***1) Product Overview/Test Principle:***

**Describe the technology of the test and how this technology works to identify the measurand, the instruments employed/required to perform the test from sample collection to result (include all claimed extraction and PCR detection instruments), and the specimen types for which you claim to have specific performance characteristics as described below. If applicable, list all primer and probe sets and briefly describe what they detect. Please include the nucleic acid sequences for all primers and probes used in the test. Please indicate if the test uses biotin-Streptavidin/avidin chemistry in any of the steps for coupling reagents. Please note that an alignment with available reference genomes for different strains of the target pathogen is requested as part of the inclusivity evaluation (Section N).**

The ***[test name]*** is a real-time reverse transcription polymerase chain reaction (rRT - PCR) test. The 2019-nCoV primer and probe set(s) is designed to detect RNA from

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the 2019-nCoV in ***[list all the specimens]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated).

2) ***Description of Test Steps:***

**List and describe in detail all the steps of the test sequentially from specimen collection to detection.**

Nucleic acids are isolated and purified from ***[specimens]*** using ***[please describe the method(s) of extraction (please specify the specimen input volume for extraction and/or test, the nucleic acid elution volume and whether isolation/purification is manual and/or automated)].*** The purified nucleic acid is reverse transcribed using ***[enzyme mix/kits – please specify the input volume of purified nucleic acid added to the rRT-PCR reaction mix]*** into cDNA which is then subsequently amplified in ***[please describe the instrument(s) and enzyme mix]***. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by ***[please describe the detection instrument(s)]***.

3) ***Control Material(s) to be Used with [test name]:***

**List all control materials (provided with the test kit and/or required but not provided with the test kit and describe what they are, how they are expected to work, where in the testing process they are used, and the frequency of use. If a control is commercially available, provide supplier's name and catalog number or other identifier; if your device relies on external controls that are manufactured by a third party please note that these controls should also be validated within your analytical and clinical studies described below in Section (N).**

Controls that will be provided with the test kit include:

a) A "no template" (negative) control is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***

b) A positive template control is needed to ***[describe need]*** and is used ***[describe use – please specify the concentration of the positive control relative to the LoD of your test (note that ideally the positive control concentration should be such that it is close to the LoD of your test) and also specify frequency of use]***

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c) An extraction control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use].*** **Please note that if the no template control and positive control, are taken through the entire sample processing procedure, including the extraction, then a separate extraction control is not required**.

d) An internal control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use]***.

Controls that are required but not provided with the test kit include ***[describe control – provide recommended sources of the control materials – either a separate control kit for purchase that you the applicant develops or a control material that can be purchased from a third party].*** This/these control(s) is/are needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***.

**Please note that any control recommended to be used with your device (provided with the kit or not) needs to be validated in the context of your analytical and clinical study (i.e., you will need to run these controls as part of your studies). In instances where control material is not readily available through 3rd party vendors (which is often the case at the beginning of an outbreak) FDA may request that you include suitable control material with your device. Please note that external control materials are considered particularly important in the context of EUA devices because often GMP requirements for the manufacture of the EUA device are waived in emergency situations and reagent stability studies are limited. Hence the external controls offer some assurance of EUA test performance in the hands of the end user.**

## I. INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. **Please describe if a Ct cutoff is used as part of your testing algorithm and/or if the end user is required to review fluorescent curves for weakly positive samples before final interpretation. Although not typical for molecular-based tests, if the test result involves the use of an algorithm/calculation, for example a ratio value, when determining the final patient test result, please include a detailed description and any additional calibration materials that may be required.**

1) ***[Test name] Controls – Positive, Negative and Internal***

**Describe in detail the expected results generated, including acceptance criteria, for all the controls described in detail in Section H above. Describe the measured values (if applicable) for valid and invalid controls and outline the recommended actions the laboratory should take in the event of an invalid control result.**

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2) ***Examination and Interpretation of Patient Specimen Results:***

**Describe when clinical specimen test results should be assessed and outline the criteria for test validity**. **Example text**: Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

**Clearly indicate how to interpret numeric test values (if applicable) as positive or negative for presence of the 2019-nCoV. Indicate if the end user is required to review fluorescent curves for weakly positive samples before final interpretation and how to identify indeterminate/inconclusive results (if they exist) results and how the user should resolve them, e.g. if repeat testing may be required.**

**When applicable, provide a table clearly describing the possible combinations of test result values for each primer/probe set, and how they should be combined into a final interpretation of the result for your test. If the test produces result that will be used as part of a CDC recommended testing algorithm, please indicate what follow-up testing/process should be conducted, if applicable.**

## J. PRODUCT MANUFACTURING

**Please note that if you are developing a test for use at a single site (i.e., a laboratory developed test LDT), some of the information requested in this section may not be applicable. Please contact FDA for additional guidance for an emergency use LDT.**

The ***[test name]*** has been validated using only the components referenced in this submission and shall not be changed without prior concurrence from the FDA.

*1)* ***Overview of Manufacturing and Distribution:***

The product will be manufactured at [***manufacturer's name and FDA registration number (if applicable) or laboratory name if an LDT***] by [***manufacturer name, or laboratory name if an LDT***] personnel consistent with practices for the production of **[*types of devices*]** based on [***type of quality system****]. Material manufactured by [***manufacturer's name, or laboratory name if an LDT***] may be bottled and kitted by [***packager name***] manufacturing facility.

***Under the Emergency Use Authorization (EUA) most of the 21 CFR 820 Quality System Regulation (QSR) requirements can be waived for the duration of the EUA. FDA expects that developers follow comparable practices as much as possible and may consider previous compliance history when determining whether or not to waive certain QSR requirements for a specific product. Please note adverse events, as per 21 CFR Part 803, have to be reported for authorized devices (see Section R).**

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The current manufacturing capabilities include the ability to manufacture approximately **[*please insert the approximate number of units/products that can currently be manufactured per week at the manufacturing facility*]** products per week, however in the event of a surge in demand this could be increased to **[*please insert the approximate maximum number of units/products that could potentially be manufactured per week at the manufacturing facility if there was a surge in demand*]** product per week within a **[*please specify in weeks/months the expected timeframe required to increase product production if required*]** timeframe.

The product will be distributed by **[*please describe the distribution plan for the product and list all current distributors*]**.

2) ***Components Included with the Test***

Components manufactured by [***manufacturer's name and FDA registration number (if applicable)***] and supplied with the test include:

**List all components and reagents provided for your test, including a description of the primers and probes, volumes, concentrations, quantities, buffer components, etc.**

3) ***Components Required But Not Included with the Test***

Components required but not included with the test:

**List all components and reagents not included with the test that must be supplied by the user to perform the test, with specific supplier names and catalog numbers or other identifiers for obtaining these components and reagents. Please include here all specific consumables that were validated for use with your device, that are not interchangeable with other products and that are needed to guarantee device performance as established in the EUA validation studies listed in Section N below.**

4) ***Testing Capabilities***

**Briefly describe current sample throughput capacity, total time required to perform the test (from clinical specimen collection, specimen transport to result), and number of tests that can be performed per instrument run and per day.**

5) ***Reagent Stability:***

**Briefly describe stability test plan for *[test name]* reagents and include any accelerated stability information if available. Please note that reagent stability studies do not need to be completed at the time of EUA issuance, however the study design should be agreed upon during interactive review and the stability studies started immediately following authorization, if not before. When designing your stability study, we have some general recommendations that are outlined in Appendix B, for your consideration.**

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## K. PERFORMANCE EVALUATION

**If you plan to claim multiple target analytes to aid in differential diagnosis or you plan to claim multiple RT-PCR instruments and/or extraction methods, please refer to Appendix A and C, respectively, more information. Please note that any omission of a requested study in this document should be documented and justified.**

### *1) Analytical Sensitivity:*

a) *Limit of Detection (LoD):* **You should determine the LoD of the device utilizing the entire test system from sample preparation to detection for each clinical matrix claimed. Please note that claims for additional anticoagulants, for blood specimens, can be supported by a matrix equivalency study as outlined in Section N, subsection 3 below. The LoD is determined using dilutions of live propagated and titered 2019-nCoV stocks (CFU/mL or PFU/mL) spiked into a relevant clinical matrix. If wild-type virus is not available at the time of your validation studies, please contact FDA to discuss a potential alternative. Please note that if available please also provide Genomic Equivalent Copies (GEC)/mL units for the stock solutions used and include an explanation on how they were determined. Please note that LoD studies should be performed with live organisms, as described above. If you plan to use inactivated organism in your LoD determination you should describe how the material was inactivated and perform a study to determine whether the inactivation process impacted the LoD of the device.**

**First a tentative LoD must be established through limiting dilutions of the prepared material with 3-5 replicate measurements. Please note for all the analytical studies described in Section N that require replicate testing, one replicate equates to one independent extraction and PCR detection. Once a tentative LoD is established, the LoD should be confirmed by preparing at least 20 additional replicates at the LoD concentration and demonstrating that the organism was detected with a minimum 95% positivity (19/20). If this confirmatory study achieves a positivity of 100%, then a lower concentration needs to be tested (with 20 replicates) until <100% positivity is obtained.**

**Please use the following format when submitting LoD information and data:**

LoD studies determine the lowest detectable concentration of 2019-nCoV at which approximately 95% of all (true positive) replicates test positive. The LoD was determined by limiting dilution studies using characterized samples.

**List/describe the following in this section:**

- **Titers and strains of the 2019-nCoV stocks used for the LoD study and describe how the organism stocks were prepared and how the titers were determined.**

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- **The dilution factor and number of serial dilutions of the characterized 2019-nCoV that were tested to determine the LoD for each primer and probe set.**
- **The nucleic acid extraction/purification method.**
- **The real time PCR instrument.**

Serial dilutions of the characterized 2019-nCoV were then tested in **[*number of replicates (i.e., recommend that sample is extracted independently three-five times and each extraction tested once)*]** replicates. The lowest concentration at which all [*number of replicates*] replicates were positive was treated as the tentative LoD for each test. The LoD of each test was then confirmed by testing [*number of replicates (at least 20 recommended)*] with concentrations at the tentative limit of detection. The final LoD of each test was determined to be the lowest concentration resulting in positive detection of [*number of positive replicates (at least 19 out of 20 replicates)*]. [*Include analysis of LoD results, indicating the final LoD for each test*]

**Tentative LoD: [*Please provide a summary of the data for each strain tested]* example table 2019-nCoV stocks is provided below:**

| 2019-nCoV Strain Tested | Stock 2019-nCoV Titer | Serial 10-Fold Dilution Factor | Concentration in Dilution Tested [Include Units] | Replicate 1 $C_t$ | Replicate 2 $C_t$ | Replicate 3 $C_t$ | Replicate 4 $C_t$ | Replicate 5 $C_t$ | Call Rate | Lowest Concentration with Uniform Positivity per Analyte | Limit of Detection (LoD) per Virus Strain |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Example: [analyte]* | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

b) FDA Sensitivity Evaluation: The analytical sensitivity of the test has to be further assessed by evaluating an FDA-recommended reference material using an FDA developed protocol if applicable and/or when available. Details will be provided during the Pre-EUA interactive review.

c) *Reactivity/Inclusivity:* Reactivity of the ***[test name]*** was evaluated for additional isolates of 2019-nCoV.

**Reactivity: *[test name]* example table below**

| 2019-nCoV Strain/Isolate | Source/Sample Type* | Concentration | Ct** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

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| | | | |
|---|---|---|---|
| | | | |

***Please list source of material used for wet testing and sample type tested (i.e., organism – live or inactivated, purified nucleic acid – whole genome etc.).**
**** If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**At a minimum, the strain used in your LoD evaluation should be listed here (multiple isolates of the same 2019-nCoV strain that was used for the LoD studies can also be included if available). If additional isolates are not available at the time of your validation studies, please discuss with FDA. Each isolate should be tested at or near the LoD (no more than 3x LOD) of the test, spiked into clinical matrix utilizing the entire test system, including extraction. If you plan to claim more than one type of clinical matrix, we recommend that you perform this study in the most challenging clinical matrix, testing a minimum of 3 replicates. In addition, the wet testing should be accompanied by extensive inclusivity *in silico* analysis of the test primer and probes with all known strains/isolates (past/present) of 2019-nCoV (including the strain/isolate used for wet testing).**

## 2) *Analytical Specificity:*

a) *Cross-Reactivity:* Cross-reactivity of the ***[test name]*** was evaluated using both *in silico* analysis and by testing whole organisms **[*pathogen*]** (concentration) or purified nucleic acid from other ***[describe organisms]*** (concentration/reaction).

**Cross-Reactivity: *[test name]* example table for wet tested organisms below**

| Virus/Bacteria/Parasite | Strain | Source/ Sample type | Concentration | Ct Values* |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

***If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**Cross-reactivity studies are preformed to demonstrate that the test does not react with related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen. The FDA Tables 1 and 2, below are intended to recommend simulate testing of patients having infections with organisms which cause similar symptoms to those observed at the onset of 2019-nCoV infection. The FDA Tables also include other organisms and strains which have significant genetic similarity and therefore a higher likelihood of cross-reacting with 2019-nCoV specific reagents. Also included in the FDA Tables are recommended unclaimed organisms/strains which are likely to be endemic to the currently affected area should be included in cross-reactivity testing since these organisms/strains will be an important aspect of the differential diagnosis of 2019-nCoV infection.**

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**FDA Table 1 Cross-Reactivity: List of Organisms to be wet-tested and analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens**

| Other high priority pathogens from the same genetic family | High priority organisms likely in the circulating area |
|---|---|
| Human coronavirus 229E | Adenovirus (e.g. C1 Ad. 71) |
| Human coronavirus OC43 | Human Metapneumovirus (hMPV) |
| Human coronavirus HKU1 | Parainfluenza virus 1-4 |
| Human coronavirus NL63 | Influenza A |
| SARS-coronavirus | Influenza B |
| MERS-coronavirus | Enterovirus (e.g. EV68) |
| | Respiratory syncytial virus |
| | Rhinovirus |
| | *Chlamydia pneumonia* |
| | *Haemophilus influenzae* |
| | *Legionella pneumophila* |
| | *Mycobacterium tuberculosis* |
| | *Streptococus pneumonia* |
| | *Streptococcus pyogenes* |
| | *Bordetella pertussis* |
| | *Mycoplasma pneumoniae* |
| | *Pneumocystis jirovecii* (PJP) |
| | Pooled human nasal wash - *to represent diverse microbial flora in the human respiratory tract* |
| | |

**FDA Table 2 Cross-Reactivity: List of Organisms to be analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens:**

| Other high priority pathogens from the same genetic family | High priority organisms, including organisms commonly found in the clinical matrix |
|---|---|
| | Influenza C |
| | Parechovirus |
| | *Candida albicans* |
| | *Corynebacterium diphtheriae* |
| | *Legionella non-pneumophila* |
| | *Bacillus anthracis* (Anthrax) |
| | *Moraxella catarrhalis* |
| | *Neisseria elongate and meningitidis* |
| | *Pseudomonas aeruginosa* |
| | *Staphylococcus epidermis* |
| | *Staphylococcus salivarius* |
| | *Leptospirosis* |

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| | |
|---|---|
| | *Chlamydia psittaci* |
| | *Coxiella burnetii (Q-Fever)* |
| | *Streptococcus aureus* |
| | |

***In silico*** **analysis should be performed on all potentially cross-reactive organisms outlined in the FDA Tables 1 and 2 above. You should provide the result summary of the *in silico* blast analysis (tabular format) evaluating whether there is any significant amplification of non-target sequences that could either result is cross-reactivity or potentially interfere with the detectability of the actual target analyte. As such we are asking that you provide individual blast results (non-truncated alignments) for each of the primers and probes used in your device with potential cross-reacting organisms. Please provide for our review the percent sequence homology for each organism relative to the target analyte primers/probes in your test. Please use the example table below when presenting the results of *in silico* analysis in your submission:**

**Results of *In Silico* Analysis**

| Pathogen | Strain | GenBank Acc# | % Homology Test FP (i.e. 0-100%) | % Homology Test RP | % Homology Test Probe |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**The analysis should include multiple representative strains from GenBank for each organism. If *in silico* analysis reveals other potential cross-reactants (i.e., ≥80% homology between one of your primers or the probe to any of the sequences of listed potential cross reactants), you should carefully review the alignments and determine based on the positions of the homologous stretches and mismatches if additional cross-reactivity and/or interference (please refer to item b below – microbial interference studies) wet testing will be required to rule out cross-reactivity or interference of that organism that may affect the performance of your device. In these circumstances if wet-testing is omitted you should include an explanation as to why *in silico* generated data is not clinically relevant (irrelevant isolate, location/extent of match within primer/probe, etc.), or why the performance of your test would not be impacted.**

**Organisms in FDA Table 1 should be wet tested in addition to the *in silico* analysis. Omissions from wet-testing should be discussed with FDA and supported by a well-documented justification that includes a due diligence attempt to obtain the live or inactivated organisms (and/or purified nucleic acid – which is acceptable for cross reactivity evaluation for an EUA).**

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**The wet testing evaluation should reflect test specimens prepared at the highest clinically relevant level of organism (i.e., a minimum of $10^6$ CFU/ml or higher for bacteria and $10^5$ $TCID_{50}$/mL or PFU/ml or higher for viruses) and should be tested with a minimum of three replicates per organism test specimen. Test specimens can be prepared by spiking cultured isolates/inactivated organisms/ purified nucleic acids (whole genome) into negative clinical matrix and determining cross reactivity based on triplicate replicates. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix.**

**If you plan to claim non-blood or non-respiratory clinical specimen types for diagnostic use with your device, e.g., stool specimens, etc., please consult FDA for more information on additional organisms that may be recommended for cross-reactivity testing, common examples are provided below for stool specimens (FDA Table 3):**

**FDA Table 3: Organisms to be analyzed for non-blood clinical specimens:**

| **Stool** |
|---|
| *Escherichia coli* |
| *Lactobacillus* |
| *Bacillus* spp. |
| *Clostridium* Spp. |
| *Enterobacter* |
| *Enterococcus* |
| Fusobacterium |
| Bacteroidetes |
| Bifidobacterium |
| Ruminococcus |
| |

b) *Microbial Interference Studies:* **If *in silico* analysis reveals ≥ 80% homology between the cross-reactivity microorganisms and your test primers/ probe(s), we recommend that you either perform (1) a microbial interference study with 2019-nCoV and the microorganisms that your test primers/ probe(s) have homology to, (2) as an alternative to the microbial interference study, you may provide justification as to why (e.g., amount of primer(s)/ probe(s) included in your master mix) the performance of your test would not be impacted by the presence of a causative agent of a clinically significant co-infection, or (3) explain why the *in silico* results are clinically irrelevant. In the case of the microbial interference study, interference should be evaluated using samples spiked at a low 2019-nCoV concentration, at 3x LoD, and a high interferent level (either microorganisms or nucleic acids purified from them), to represent the worst-case scenario, with a minimum of 3 replicates. If you plan to claim more than**

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**one type of blood clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix. If the LoDs are similar in the blood clinical matrices the study should be performed in the most challenging matrix, i.e., whole blood. In addition, if you are claiming blood and non-blood clinical specimens you may be required to perform this study in more than one clinical matrix. If interference is observed at the level tested, an additional titration study should be performed to determine the highest microorganism interferent level the 2019-nCoV test can tolerate.**

**c)** *Endogenous Interference Substances Studies*: **The extent of testing for endogenous interference substances depends on the matrix that is claimed for the device as well as on the technology of the device, e.g., if a nucleic extraction procedure is performed prior to testing or not. For EUA we do not typically ask for interference studies for tests that use conventional PCR and/or well-established extraction methods prior to testing (e.g., Boom method and column-based extraction methods).**

**For extraction procedures that are new or for nucleic acid-based technologies that are different from conventional PCR (e.g., various isothermal methods), we expect testing of potential interferents. The impact of interfering substances should be evaluated over the expected clinical range of the potentially interfering substance. Potential sources of endogenous interference include, but are not limited to, the ones listed in the tables below. It is important to note that the evaluation of interference and the generation of false negative results should be done using samples containing the analyte at or near the LoD and should not exceed 3x LoD. You should test a minimum of 3 replicates per substance. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed between the different clinical matrices this may warrant this study being performed in more than one clinical matrix. Biotin interference poses a risk to laboratory tests that incorporate the free biotin-streptavidin capture method. Therefore, please review this safety communication [ HYPERLINK "https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication" ] and the following [ HYPERLINK "onenote:http://sharepoint.fda.gov/orgs/CDRH-IVD/Orgs/DMD/DMD%20OneNotes/Language/Analytical%20Studies/Interference.one" \l "DRAFT%20guidance%20-%20Testing%20for%20Biotin%20Interference%20in%20In%20Vitro%20Diagnostic%20Devices&section-id={39D67316-5AE2-4791-958F-9387D384D6FA}&page-id={9298F00C-7C39-43CB-9EBA-29E5BC08BB6E}&end" ] ([ HYPERLINK "http://sharepoint.fda.gov/orgs/CDRH-IVD/Orgs/DMD/_layouts/OneNote.aspx?id=%2Forgs%2FCDRH-IVD%2FOrgs%2FDMD%2FDMD%20OneNotes%2FLanguage&wd=target%28Analytical%20Studies%2FInterference.one%7C39D67316-5AE2-4791-958F-**

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**9387D384D6FA%2FDRAFT%20guidance%20-%20Testing%20for%20Biotin%20Interference%20in%20In%20Vitro%7C9298F00C-7C39-43CB-9EBA-29E5BC08BB6E%2F%29" ]) to determine if biotin interference testing may be warranted for your device. We also recommend you consult with FDA prior to initiating biotin interference testing, if applicable.**

**The tables below indicate the potentially interfering substances that may be found in blood and respiratory specimens. For other non-blood specimen types, such as stool, the list of substances could be expanded – please consult with FDA.**

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *positive* results:**

| Potential Interfering Substance | Concentration | Results (Detected X/3) |
|---|---|---|
| **Respiratory Specimens** | | |
| Mucin: bovine submaxillary gland, type I-S | | |
| Blood (human) | | |
| Nasal sprays or drops | | |
| Nasal corticosteroids | | |
| Nasal gel | | |
| FluMist | | |
| Homeopathic allergy relief medicine | | |
| Throat lozenges, oral anesthetic and analgesic | | |
| Anti-viral drugs | | |
| Antibiotic, nasal ointment | | |
| Antibacterial, systemic | | |
| **Blood Specimens** | | |
| Hemoglobin | 10 mg/mL* | |
| Bilirubin Conjugated | 0.4 mg/mL* | |
| Bilirubin Unconjugated | 0.4 mg/mL* | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | |
| Triglycerides | 15 mg/mL* | |
| Cholesterol | 4 mg/mL* | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | |
| Rheumatoid Factor | 2000 IU/mL* | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *negative* results:**

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| Potential Interfering Substance | Concentration* | Viral Strain Level (In multiples of LoD) | Results (Detected X/3) |
|---|---|---|---|
| **Respiratory Specimens** | | | |
| Mucin: bovine submaxillary gland, type I-S | | | |
| Blood (human) | | | |
| Nasal sprays or drops | | | |
| Nasal corticosteroids | | | |
| Nasal gel | | | |
| FluMist | | | |
| Homeopathic allergy relief medicine | | | |
| Throat lozenges, oral anesthetic and analgesic | | | |
| Anti-viral drugs | | | |
| Antibiotic, nasal ointment | | | |
| Antibacterial, systemic | | | |
| **Blood Specimens** | | | |
| Hemoglobin | 10 mg/mL* | | |
| Bilirubin Conjugated | 0.4 mg/mL* | | |
| Bilirubin Unconjugated | 0.4 mg/mL* | | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | | |
| Triglycerides | 15 mg/mL* | | |
| Cholesterol | 4 mg/mL* | | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | | |
| Rheumatoid Factor | 2000 IU/mL* | | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

### 3) *Matrix Equivalency (if applicable):*

**A matrix equivalency study may be used to support certain specimen type claims that were not evaluated during the clinical study (e.g., serum versus plasma, use of different anticoagulants, use of difference swab types or viral transport media, etc.). Please note that LoD and clinical specificity studies are required for all claimed matrices. The matrix in which the clinical studies are conducted is the comparator. All other matrices are to be shown to be equivalent to the comparator matrix. We request a minimum of 40 paired samples each obtained from individual persons; negative (10 samples), low positive (1.5-2xLoD, 20 samples), and moderate positive (5-10xLoD, 10 samples) samples should be tested. Positive samples are prepared by spiking paired negative clinical matrix with the same amount of target analyte. Please note that individual (and not pooled) samples should be used in this study.**

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4) ***Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method:***

**A comparative LoD study may be required to support use of a comparator method in your clinical evaluation that has not been validated with a specific specimen type. The comparative LoD study should be conducted testing the same dilution series using both, your test and the comparator you chose in parallel (to dilution endpoints for both tests), 3-5 replicates per dilution level are sufficient for this study.**

5) ***Specimen Stability and Fresh-frozen Testing:***

**A specimen stability study may be required to support specimen stability claims in the instructions for use outside of those typically outlined in CSLI standards. A fresh/frozen and/or freeze/thaw study may be required to support the use of frozen specimens if they are used as part of the clinical evaluation. Please consult with FDA concerning an appropriate study design prior to initiating any studies.**

6) ***Clinical Evaluation:***

**This section should describe the clinical study used to evaluate the performance of your test. Please note that the exact requirements for the clinical evaluation will be very dependent on, access to 2019-nCoV disease clinical specimens at the time of the studies and the nature of the emergency. Our general clinical study evaluation recommendations for respiratory and serum clinical specimens are outlined below. If you are interested in claiming additional specimen types, for example, stool, please contact FDA for current recommendations. Please note these clinical study recommendations may be subject to change as we continue to learn about the 2019-nCoV disease or as the risk benefit analysis changes.**

**The clinical performance in general should be evaluated for each unique claimed clinical specimen type - with the exception of claims that can be supported by a matrix equivalency study (outlined in Section 3 above). The performance characteristics should ideally be established using a clinical study with a limited number of prospective samples. If a prospective study is not feasible, an acceptable alternative would be to test retrospectively collected 2019-nCoV nucleic acid negative and positive specimens from patients, accompanied by some basic information such as, the specimen collection date, date of onset of symptoms (if present/known), tests used to identify 2019-nCoV nucleic acid positive specimens, etc. Depending on the nature of the disease, if no prospective or retrospective specimens are**

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**available at the time of your pre-EUA submission for the 2019-nCoV disease we may accept a fully contrived clinical evaluation. The clinical evaluation should be comprised of a minimum of 100 negative individually collected specimens and 50 individual positive specimens (prospective, retrospective and/or contrived). Use of pooled specimens are not acceptable for the clinical evaluation of your test. Please see FDA Table 5 for more details. Please note that if a fully contrived clinical study is used to support your Pre-EUA submission, additional clinical testing of a limited number of natural clinical positive specimens and potentially negative specimens from the endemic region, if available, may be required at the time when this Pre-EUA transitions to an EUA as a result of an Emergency declaration for 2019-nCoV disease.**

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## FDA Table 5: Clinical study Recommendations:

| Details | Study Including Prospective/ Retrospective Specimens | Fully Contrived Sample Study |
|---|---|---|
| Minimum Number of Positive Specimens | 50<br><br>The number of natural (prospective/retrospective) positive clinical specimens should be at least 25 (collected from symptomatic patients in the 2019-nCoV disease endemic region(s)) and, if necessary, may be supplemented with contrived samples to generate the total of 50 positive specimens. Contrived samples should be prepared as described in the fully contrived sample study column. | 50<br><br>The contrived positive samples should be made in individual negative clinical matrix collected from subjects from a non-endemic population (pooled matrix is not acceptable for the clinical evaluation). Please note that the negative clinical matrix used for spiking should be confirmed negative by your test device prior to spiking. Half of the contrived positive samples can be prepared by spiking the 2019-nCoV at LoD and the remaining contrived positive samples should cover the range of the test up to and not higher than 5 x LoD.<br><br>Negative respiratory specimens: Can be archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection.<br><br>Negative blood specimens: Can be collected from healthy subjects from non-endemic areas. |
| Minimum Number of Negative Specimens | 100<br><br>Note: In general, for EUA the 100 individual negative samples can be collected from; (1) archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection for respiratory specimens, and (2) healthy subjects from non-endemic areas for blood specimens, that are "expected 2019-nCoV disease negative". Note these negative specimens can be used to also prepare any contrived positive specimens used in support of the clinical evaluation of the test.<br><br>Please note this recommendation is dependent on the current outbreak situation and is subject to change as we learn more about the 2019-nCoV disease/outbreak. If the outbreak situation for 2019-nCoV disease is primarily outside of the continental U.S. (OUS) it may be beneficial to consider collecting negative specimens that represent 50% endemic and 50% non-endemic regions. If negative specimens are collected from the endemic region of the 2019-nCoV disease these should be tested with the same comparator chosen for the positive specimens (more details provided below). For non-endemic collected specimens you can compare to the expected "negative" result. | |
| Recommended Comparator Method | Positive: Positive percent agreement should be calculated in comparison to a EUA PCR test (please see the following website for the most recent list of FDA authorized 2019-nCoV | Positive: Compare to expected result.<br><br>Negative: See Minimum Number of Negative Specimens row |

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| | | |
|---|---|---|
| for percent agreement performance calculations | tests: [ HYPERLINK "https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm" ]. If no EUA test available at the time of your EUA submission, please consult with FDA about your choice of comparator method – which ideally should be a well validated PCR test with comparable sensitivity to your subject device. Please note that a well validated PCR test should include evaluation of the tests LoD, inclusivity, exclusivity, interference and any clinical testing.<br><br>Negative: See Minimum Number of Negative Specimens row | |
| Comparator Method Note 1 | Please note when using natural clinical specimens, the comparator method must be validated for the specimen type claimed – if not you should perform a Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method study, as explained above (Section 4), to support its use as a comparator method in your clinical study. | N/A |
| Comparator Method Note 2 | Any occurrences of false results should be investigated with an additional validated PCR test and/or targeted sequencing, and the results of the discordant analysis can be footnoted in your final performance table but cannot be used to change the final performance calculations. | |
| Natural Clinical Specimens IRB/Informed Consent Note | For clinical specimens collected to support the EUA request, please note that sample collection needs to adhere to all applicable rules of human subject protection; as such, sample collection needs IRB approval, which includes review of the informed consent forms. Samples need to be collected with informed consent. If leftover de-identified samples are used, FDA exercises enforcement discretion regarding the informed consent requirement if the specimen collection meets the criteria described in the FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable ([ HYPERLINK "http://www.fda.gov/cdrh/oivd/guidance/1588.pdf" ]).<br>**Note that IRB approval is still required even if leftover de-identified samples are used in your study.** | |
| Additional Studies Warning | N/A | If fully contrived samples were used in your Pre-EUA submission, additional testing of natural clinical specimens may be requested, if available, to support transition of the Pre-EUA to EUA as a result of an Emergency declaration. |
| Testing Approach Note 1 | Please note all clinical specimens (natural and contrived) should be evaluated in accordance with your proposed diagnostic algorithm, including retesting when appropriate. We understand the limited nature of natural specimens may preclude retesting. In instances were retesting is indicated but not performed, for the purposed of performance evaluation, initial results will be analyzed for performance and equivocal/indeterminate results count against your final performance. | |
| Testing Approach Note 2 | Specimens should be tested in a blinded fashion, e.g., positive and negative samples should be mixed and blinded to the end user, end user should also be blinded to the results of any comparator method testing. | |

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**When you describe your clinical study please indicate/include:**

- **How the specimens were generated/collect/sourced**
- **If the study was fully prospective, mix of prospective, retrospective and/or contrived or fully contrived**
- **The rationale for the concentrations/specimens selected (if using contrived or 3-party sourced specimens)**
- **The total number of specimens tested**
- **The specimen types (clinical matrix)**
- **A summary of the study results**

**In the case of real-time PCR tests, please provide the line data in an Excel file as part of the Pre-EUA submission for each specimen (please indicate for each specimen if it was prospective, retrospective or contrived and the clinical matrix it represents); the data should include the $C_T$ values (for the specimen and the controls) and call/result for your device and, in the case of the natural clinical specimens, the comparator method results should be included as well.**

## L. UNMET NEED ADDRESSED BY THE PRODUCT

**This section will be finalized by FDA based on the state of the emergency at the time of authorization and based on recommendations from Public Health authorities at that time. Example text is provided below but may be adapted according to the specific emergency situation that is addressed by the device and the need at the specific time of the outbreak.**

[Outline background of pathogen, disease and current outbreak]

[Outline details of the disease such as the following:

- likely sources of transmission
- likely symptoms – if any
- Prevalence of symptomatic disease (what fraction of infection results in symptomatic disease)]

Laboratories in the United States are in need of diagnostic tools for use in the 2019-nCoV emergency for rapid diagnosis of acute 2019-nCoV infection.

A public health emergency has been declared by the Secretary of Health and Human Services (HHS) on [Month Day, YEAR] justifying the authorization of emergency use of *in vitro* diagnostic tests for detection of 2019-nCoV and/or diagnosis of 2019-nCoV infection.

The ***[test name]*** can augment clinically important laboratory evidence for individuals with active infection. The 2019-nCoV nucleic acid is generally detectable in [name

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specimen type] during the acute phase of infection (approximately [7] days following onset of symptoms, if present) [and possibly for longer in other specimen types].

Under emergency use authorization (EUA), ***[applicant name]*** plans to distribute the test or accept sample for testing with the ***[test name]*** for the detection of nucleic acid from 2019-nCoV in clinical specimens collected from individuals meeting CDC's 2019-nCoV clinical and/or epidemiological criteria. This EUA request for the ***[test name]*** is intended to expand domestic readiness within the United States and its territories by expanding diagnostic testing capabilities for 2019-nCoV during public health emergency.

FDA consulted with subject matter experts within HHS on the public health needs for diagnostic devices to detect 2019-nCoV nucleic acid. It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for 2019-nCoV detection during the public health emergency.

## M. APPROVED/CLEARED ALTERNATIVE PRODUCTS

Currently no methods for the detection of the 2019-nCoV have been approved/ cleared by FDA.

## N. RISKS AND BENEFITS:

**The Risks and Benefits section should be updated according to your specific device, some example language is given below but should be tailored to the device and the disease.**

Risks

The ***[test name]*** has been designed to minimize the likelihood of false test results. However, should false results occur, they may present risks to patients:

- False positive result:
  - A false positive 2019-nCoV result could [***update based on the pathogen***].
  - A false positive result in the context of the current public health emergency could lead to misallocation of resources used for surveillance and prevention.
  - A false positive result could delay correct diagnosis and initiation of appropriate treatment for the actual cause of patient illness.
- False negative result:
  - Although a negative result does not rule out 2019-nCoV infection, a false negative has the potential to result in initiation of inappropriate treatment and a delay in correct diagnosis.
  - A false negative result can trigger a waste of health care resources, as additional evaluations are pursued in the effort to establish the true diagnosis.
  - A false negative results can contribute to further spread of the disease.

Benefits

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The primary benefit of distributing the ***[test name]*** for clinical use is that it provides a relatively fast diagnostic method for symptomatic patients, which enables faster intervention.

- True positive test results provide support for the diagnosis of a 2019-nCoV infection. The results can be used in conjunction with clinical and epidemiological information to guide patient management.
- Distribution of the factsheets can help healthcare professionals and the public learn more about 2019-nCoV disease and how to avoid acquiring it.

Risk Assessment

- Negative results may not preclude a 2019-nCoV infection. It is emphasized that the ***[test name]*** should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure must be considered pivotal to making patient management decisions. A negative test should not be interpreted as definitive, if other aspects of the patient's clinical presentation or recent epidemiologic exposures indicate such is likely, and diagnostic tests for other diseases are negative.
- False negative results due to failure of PCR are minimized by the presence of controls that monitor nucleic acid extraction and PCR efficiency.
- Risk of patient discomfort or harm during sample collection is minimal.

Risk-Benefit Assessment

The risks posed by use of the ***[test name]*** are mitigated by:

- Use of the ***[test name]*** in conjunction with other laboratory, epidemiological, and clinical evaluation tools
- Distribution of Healthcare Provider and Patient fact sheets.
- Post-market studies/reporting or conditions of Authorization.

Based on these factors, the potential benefits from the use of the ***[test name]*** are expected to outweigh the risks.

## O. FACT SHEET FOR HEALTHCARE PROVIDERS AND PATIENTS:

**Include proposed Fact Sheets for Patients and Healthcare Providers**

## P. INSTRUCTIONS FOR USE/ PROPOSED LABELING/PACKAGE INSERT:

**Include Instructions for Use, Box Labels, Vial Labels and any other proposed labeling.**

## Q. RECORD KEEPING AND REPORTING INFORMATION TO FDA:

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[***Manufacturer name***] will track adverse events and report to FDA under 21 CFR Part 803. A website is available to report on adverse events, and this website is referenced in the Fact Sheet for Health Care providers as well as through the [***Manufacturer name***] Product Support website: [***Include link to Website***]. Each report of an adverse event will be processed according to [***Manufacturer name]***'s Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the FDA as required. Through a process of inventory control, [***Manufacturer name]*** will also maintain records of device usage/purchase. [***Manufacturer name]*** will collect information on the performance of the test, and report to FDA any suspected occurrence of false positive or false negative results of which [***Manufacturer name]*** becomes aware. [***Manufacturer name]*** will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

## R. ADMINISTRATIVE INFORMATION:

**Interactive Review Log:** Please use the table below to document interactive review with FDA and include interactions initiated by either FDA or yourself

| **Date** | **Type of Interaction** (phone/ email/ formal submission-DCC) | **Brief Description** (e.g., questions asked/ feedback from FDA received / any word documents included) |
|---|---|---|
| [X] | [X] | [X] |
| | | |
| | | |

## S. FDA ADMINISTRATIVE INFORMATION:

**This section will be finalized by the FDA Lead Reviewer upon completion of the review process and documents the interactive review of this submission and any conclusions resulting from the interactive review.**

1) **Summary of Interactive Review – Lead Reviewer to use this section to highlight any major issues solved during interactive review.**
2) **Final Conclusions for Interactive Review -** It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for [pathogen] detection during the public health emergency. **Conclusion should include an outline the unique features of the device compared to currently issued EUA's under the declaration, if applicable.**
3) **Upon competition of this section the Lead Reviewer should also sign this document and save the file as the final Decision Memorandum.**

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## APPENDIX A – Multiplex Panels Under EUA:

An emergency declaration by the HHS Secretary is typically specific for a pathogen/disease (i.e., there is a publicly declared health emergency involving a particular etiologic agent). Therefore, the EUA pathway is only applicable for testing patients with signs/symptoms/risk of exposure for that single agent in a given emergency. FDA has occasionally allowed limited additional target pathogens to be claimed for EUA devices, but panel members must be relevant to the event/disease outbreak subject of the specific emergency declaration. When determining whether to issue an EUA for a multiplex panel FDA takes into consideration the utility of the test (multiplex pathogen detection as an aid in differential diagnosis), clearance/approval status of IVDs for the other panel members, whether the proposed Intended Use fits within the HHS emergency declaration and the how the multiplex panel would fit into current public health authority patient testing algorithm recommendations. We recommend you contact FDA for specific feedback if you plan to claim multiple target analytes as part of your EUA test. If it is determined that a multiplex test is beneficial to the emergency response, please note that analytical and clinical evaluations for each of the target analytes will be required.

## APPENDIX B – General Study Design Recommendations for Reagent Stability:

- For EUAs you may follow the current FDA recognized CLSI Standard EP25 – Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline when evaluating the suitability of stability study designs. If you are planning to pursue a De Novo/510(k) for your device we recommend discussing in more detail your stability design to facilitate potential use of the EUA data in your regular premarket submission.
- Please note that use of only the positive controls is not acceptable for reagent stability evaluation because controls are usually formulated at a moderate positive level. For all the stability evaluations in addition to your external positive and negative controls and the no-template control you should include for the EUA evaluation at least one sample, that should be prepared by spiking negative clinical matrix at an analyte concentration of 3-5xLoD.
- If you are claiming multiple blood clinical specimen types in which similar LoDs are determined, you should use the most challenging clinical matrix for this study.
- Please note we typically recommend your stability study design includes the evaluation of at least 5 replicates. You should also evaluate, if available, 3 different lots of reagents.
- You should design your study to provide data for a timeframe that is about 10% longer than the one to be claimed – for example; a claim of 18 months should be supported by stability data out to 20 months and a claim of 7 days should include stability data out to 8 days.
- FDA considers 15-30°C to represent room temperature conditions. Ideally you should evaluate stability at both 15°C and 30°C, however, for the purposes of the EUA evaluation at 30°C is acceptable as the worse-case scenario.
- Shelf-Life Stability- Unopened kit:
    - You should evaluate real-time kit stability studies with unopened kits stored at the claimed storage temperature for your test.

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  - Accelerated stability evaluations for unopened kits is acceptable for EUA submissions while the real-time studies are on-going. However, please note real-time stability data is required to support regular pre-market submissions and for the final claim of an EUA.
- Shipping Stability - Unopened kit: Study should evaluate the anticipated handling and shipping times and temperatures expected for unopened kits.
- In-use/Opened Kit Stability: Depending on your device your stability study design should also support in-use stability of the kit reagents once the kit has been opened, e.g., storage at 2-8 $^{o}$C for 7 days. This includes on board stability once reagents have been placed on the instrument (if applicable).
- Inverted stability (if applicable): Study should support inverted stability for of kits.
- Freeze-thaw Stability: If you recommend aliquoting the reagents to meet the end-users needs following the initial thaw this recommendation should be supported by a freeze-thaw stability study, including the specific number of allowed freeze-thaw cycles.
- FDA analysis recommendations for real time stability studies are as follows:
  - Baseline of the study (t=0 of stability study) should not exceed a month from bottling
  - Clear baselines should be described (e.g., a month from bottling) for each stability claim under each study
  - Claims should be determined based on regression analysis. Any %change (%shift) from time zero (baseline) should be calculated between the target claim and the zero-time as (Ttest-Tbaseline)/ Tbaseline*100 with 95%CI using the regression equation obtained from plotting the mean values. When formulating your acceptance criteria for evaluating the shift from baseline you should consider the reproducibility of your device. However, generally, that the shift at the target claim due to storage cannot exceed 10-15%. The target stability is the next to last tested point that was within +/- 10% of time zero.
  - Acceptance criterion may be different, depending on the test samples analyte concentration distribution in the intended use population and the risk, in other words, the impact of false results to public health.

**APPENDIX C – Claiming Multiple Instruments and/or Extraction Methods:**

If you wish to claim multiple instruments and/or extraction methods for use with your test, please review the study recommendations provided below and contact FDA for any additional feedback. Please note that these analytical and clinical evaluation recommendations are based on the assumption that the elution volumes from the extraction methods and PCR volumes on the different RT-PCR instruments are identical.

- Limit of Detection (LoD): Please note that these studies should be repeated for each clinical matrix claimed in the Intended Use. Pick one RT-PCR instrument and determine the tentative LoD (using 5 replicates in 10-fold dilution) followed by the confirmatory LoD (20 replicates spiked at tentative LoD) for each extraction method on the chosen instrument. Note: If you detect 20/20 replicates in your confirmatory LOD study you should test the next lower concentration, using a 3-fold dilution, until

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you achieve a hit rate of <20/20.

- If the different extraction methods yield the same LoD (≤3xLOD) on the RT-PCR instrument chosen for initial testing, pick one extraction method for further LoD determination on the remaining RT-PCR instruments and follow the recommendations below.
- If the extraction methods do not yield the same LoD on the chosen RT-PCR instrument, please choose the extraction method with the worst LoD for further comparison of the LoD on all RT-PCR instruments.

For all other RT-PCR instruments you should use the following adaptive LoD study design:

- Please perform a refined tentative LoD study with 5 replicates at 0.5x, 1x, and 1.5 to 2x LoD. If you detect 4/5 replicates as positive at all the tested levels, you need to include the next higher concentration (i.e., 3x LoD). If you obtain 5/5 replicates at 0.5x LoD, you need to test the next lower concentration (i.e., 0.25x LoD). You will test in this manner until you find the lowest concentration that gives you 5/5 positive results for the tested RT-PCR instrument. This concentration should be used for a confirmatory LoD study for the given RT-PCR instrument using 20 replicates.

Final reported LoD: Please list all RT-PCR instruments with their respective LoDs if different LoDs are obtained. LoDs are considered comparable if they are between 1-3xLoD. These studies should be repeated for each clinical matrix claimed in the Intended Use.

- Interference Substances Studies (if applicable): Pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Inclusivity Testing: For the inclusivity testing, pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Exclusivity Testing: For exclusivity, you can perform this study using any extraction/instrument combination.

- Clinical study: If equivalency of the RT-PCR instruments is shown in an LoD study that tests and confirms that the LoD is the same or very similar for all of the RT-PCR instruments (between 2-3xLoD), then you can pick one RT-PCR instrument for your clinical study provided that the RT-PCR instruments in question are known to FDA for other *in vitro* diagnostic devices. If you find that one or more RT-PCR instruments machines has/have a different LoD, you should pick the extraction method / RT-PCR instrument combination with the worst LoD.

Note, if there are differences in the extraction input volume, extraction elution volume

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and PCR input volume (extracted nucleic acid) then the LoD should be confirmed, for each.

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/27/2020 10:01:31 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject:** FW: Pre-EUA IVD template request
**Attachments:** Draft cover letter for Sponsor 01212020.docx; EUA Review Template_NAT_Novel Coronavirus 1.19.2020.doc

FYI

---

**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:03 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Pre-EUA IVD template request

FYI – see information in red in the email below and:

(b) (4)

[redacted]

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
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**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:50 PM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** RE: Pre-EUA IVD template request

Dear Jill,

Thank you very much for reaching out to us about the test you have validated at Wadsworth Center, NYS Department of Health it was very nice to chat with you. As discussed please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [formally - 2019-novel coronavirus (2019-nCoV)]. I suggest the first step is to populate this draft template with the validation information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center). The Pre-EUA review is an interactive process, so we will provide feedback after receiving and reviewing the information provided. The draft review template is a shared "work-in-progress" document which you will populate with information and data as obtained and which we will review and provide feedback to you. **Please make sure to capture in the EUA review template that you performed the validation using the (b) (4) primer/probes sets, sensitivity was evaluated with the positive control material provided in the CDC EUA test kit and that validation studies were performed used the commercial primer/probe materials using the CDC EUA Protocol (please be sure to include information the extraction method and instrument used).**

I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of SARS-CoV-2 to FDA (it includes the address for the Document Control Center). Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under Section A (type of submission) please check "other" and specify Pre-EUA; please also complete Sections B, C, F and G. For G please use the information provided in this link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=3669.

One hard copy of the signed EUA Cover Letter and one electronic copy (CD or thumb drive) of you Pre-EUA submission package should be enclosed in your Pre-EUA submission package mailed to FDA (recommend FedEx). In addition to mailing your Pre-EUA package to FDA we also request that you submit the package to the review division via electronic mail (including the EUA Review Template in MS word) to myself Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;
- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please let me know if you have ANY questions I am happy to assist if you are not sure about certain sections in the template.
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311

AMERICAN OVERSIGHT

Kim.Sapsford@fda.hhs.gov






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---

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Tuesday, February 25, 2020 1:08 PM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** Pre-EUA IVD template request

At your earliest convenience, I wish to request a copy of the most recent EUA review template relevant to an assay for the SARS-CoV-2 pathogen.
The IVD that we will submit is completely based on the CDC protocol released to public health laboratories earlier in February except that the Wadsworth Center, New York State's public health laboratory has used commercially-derived primers and probes in place of the reagents provided by the CDC.
Thank you,

**Jill Taylor, Ph.D.**
Director

Wadsworth Center, NYS Department of Health
Room E-260, Biggs Laboratory
(518) 474-3157 | jill.taylor@health.ny.gov
www.wadsworth.org




AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 3/1/2020 3:55:57 PM
**To:** (b) (4)
**CC:** Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Woodson, Sara E (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=943c7f4ea27947828174a33d354394e1-HHS-sara.wo]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** RE: requesting SARS-CoV-2 genetic material

(b) (4)

FDA confirms that Dr. Li from ScienCell should obtain 2 vials from the FDA allotments. Please let me know if you have any questions.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** (b) (4)
**Sent:** Friday, February 28, 2020 5:49 PM
**To:** Daniel Li <yli@sciencellonline.com>; Woodson, Sara E (NIH) <sara.woodson@nih.gov>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** Re: requesting SARS-CoV-2 genetic material

Hello Daniel, thank you.

Sara, can you please confirm that this group is to receive from the allotment made for the FDA? If not I will send a different preparation.

(b) (4)

AMERICAN OVERSIGHT

**From:** Daniel Li <yli@sciencellonline.com>
**Sent:** Friday, February 28, 2020 4:30 PM
**To:** (b) (4)
**Cc:** 'Bisht, Himani' <Himani.Bisht@fda.hhs.gov>
**Subject:** requesting SARS-CoV-2 genetic material

**WARNING:** This email originated from outside of (b) (4) email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

(b) (4)

Thank you for taking my call regarding the availability of SARS-Cov-2 genetic material. Per our conversation, I hereby send you a confirmation email that we would like to get an aliquot of SARS-Cov-2 genetic material from (b) (4) Since we are actively working with FDA on an EUA application, I include Dr. Himani Bisht in the conversation.

Please kindly instruct us on how to proceed.

Best regards,
Daniel

**Yongjiang Daniel Li, PhD**
ASSOCIATE DIRECTOR, MOLECULAR BIOLOGY DIVISION

ScienCell Research Laboratories

ScienCell Research Laboratories
1610 Faraday Ave I Carlsbad, CA 92008
(760) 602-8549 x(b) (6) **Direct** I (b) (6) **Fax**
yli@sciencellonline.com I www.sciencellonline.com

PROMOTIONS

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/28/2020 8:35:59 AM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**CC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]
**Subject**: RE: Two pre-EUA questions....advice please

Elizabeth,

We do not know yet, it is our understanding that it would be shared between (b) (4), (b) (5) and New Nork State (Wadsworth) PHL labs.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:24 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: Two pre-EUA questions....advice please

Jeff, Do we need to prepare a (b) (5) and tie to other announcements that may soon come?

Uwe, Do we expect the request/authorization (b) (5)
(b) (5)

Elizabeth

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:46 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>;

AMERICA'S OVERSIGHT

Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: Two pre-EUA questions....advice please

Jeff,

Yes, we are preparing the getting this authorization done asap.

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:38 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** Fwd: Two pre-EUA questions....advice please

Uwe,

Can your folks please put together our piece of the EUA package together today and bring OCET into the loop so our review of the NYS submission and authorization of the EUA, if supported by the evidence, can occur within the next 24 hours, or sooner?

Jeff

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** February 28, 2020 at 7:22:46 AM EST
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>, McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>, Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>, Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>, Rakeman, Jennifer <(b) (6) @health.nyc.gov>, Hutton, Brad J (HEALTH) <(b) (6) @health.ny.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Two pre-EUA questions....advice please

Excellent thanks Jill

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

AMERICAN OVERSIGHT

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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Friday, February 28, 2020 7:19 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <(b) (6) @health.nyc.gov>; Hutton, Brad J (HEALTH) <(b) (6) @health.ny.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Two pre-EUA questions....advice please

Thank you so much Kim. This is exactly what we needed to know. We are working very hard and it is our intention to submit today.
Jill

Sent from my iPhone

On Feb 28, 2020, at 7:15 AM, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov> wrote:

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Jill,

Thank you for your questions. Since we know the issues around the CDC assay – if New York would like to include the N3 manufactured by either (b)(4) we will certainly consider that.

GMP can be waived for EUA so this is not a concern.

I would recommend submitting today, please call Uwe or Tamara if you have any questions as I will be out of the office for most of the day:

| | | | |
|---|---|---|---|
| Uwe Scherf | DMD – Division Director | Uwe.Scherf@fda.hhs.gov | 301-796-5456 |
| Tamara Feldblyum | DMD – Branch Chief | Tamara.Feldblyum@fda.hhs.gov | 301-796-6195 |

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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<image002.jpg.secure>

<image003.jpg.secure>

<image004.jpg.secure>

<image005.jpg.secure>

<image006.jpg.secure>

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---

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Thursday, February 27, 2020 10:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <(b) (6) @health.nyc.gov>; Hutton, Brad J (HEALTH) <(b) (6) @health.ny.gov>
**Subject:** Two pre-EUA questions....advice please

Hello Kim,
We are having an internal discussion at Wadsworth on strategy and need some advice please.
I am also copying this email to Dr. Jen Rakeman who directs the NYC lab as the answers will affect her strategy also.

(b)(4)

Could you advise whether it is essential that we use primers and probes that are made under GMP conditions.

Thank you for your patience with us as we learn the FDA process.
Best wishes
Jill and Colleagues.

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/29/2020 6:14:38 PM
**To:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: EUA200003_Review Memo NewYork SARS-nCoV Real_Time RT-PCR Panel_29FEB2020_Final.doc

Thank you all. Just spoke with Kristen, if we cannot find another way and we need to have the (b) (5) (b) (5) Stay tuned. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov
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---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 5:53 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>
**Subject:** RE: EUA200003_Review Memo NewYork SARS-nCoV Real_Time RT-PCR Panel_29FEB2020_Final.doc

Here is the final with the e-mail included

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 5:30 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** EUA200003_Review Memo NewYork SARS-nCoV Real_Time RT-PCR Panel_29FEB2020_Final.doc

For your records, the document just with the email missing. Uwe

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 9:56:34 PM
**To**: Taylor, Jill (HEALTH) [jill.taylor@health.ny.gov]
**CC**: St. George, Kirsten (HEALTH) [kirsten.st.george@health.ny.gov]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Dear Jill,

Is has been an absolute pleasure to work with you and your team. This has been an important step to protect public health.

Kind rewards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Saturday, February 29, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy

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<Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Thank you so much Uwe. Being able to work with you and your FDA colleagues has been a privilege. We are grateful that the FDA is with us as we work to protect our citizens.
Very best wishes,
Jill

Sent from my iPhone

On Feb 29, 2020, at 9:35 PM, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov> wrote:

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Drs. Taylor and St. George,

It is a pleasure to inform you that your submission for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issued an Emergency Use Authorization.

Attached please find the electronic version of the signed letter. Please confirm the receipt of the letter.

Congratulations, it has been a pleasure to work with you and your team.

Kind regards,
Uwe Scherf

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Saturday, February 29, 2020 6:02 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** RE: Material to discuss for 1 PM
**Importance:** High

AMERICAN OVERSIGHT

Here is the new letter

Please let me know if it OK or if you need adjustments

Best, Kirsten

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george

<image001.png.secure>

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:09 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** RE: Material to discuss for 1 PM

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Kirsten

Please find attached Draft EUA request cover letter you can use.

You can delete the hard copy part as you EUA submission is already logged in

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

<image002.png.secure>

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<image003.jpg.secure>
<image004.jpg.secure>

<image005.jpg.secure>

<image006.jpg.secure>

<image007.jpg.secure>

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:56 PM
**To:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Material to discuss for 1 PM

Kristen,

We would like to go over the following documents with you during our 1 PM call:

Intended Use

Instructions for Use

And discuss the Fact Sheets

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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<NYS DOH EUA Letter of Authorization 02292020 FINAL.pdf.secure>

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 6:04:53 PM
**To**: Seligson, Edie D. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39c00b63d10740d4a0f8a8296522a657-EDP]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Pagan Motta, Monica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39552e3b45c741f19b0bebbf796d96c2-Monica.Paga]; Gagne, Stefan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34d09d8b5be419c8f5c441bc8ebc4f7-SXG]; Aihie, Irene [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad4eedb2f6c644b28a1ce3903f325790-Irene.Aihie]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Fulmer, Sonja [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6136c44586e4a1ca8ce73d55803cfe5-Sonja.Fulme]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; CDRH-OCE-Division of Comms-MGRS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9166df93aa6c4a23a3f6661b21ae3e7c-CDRH-OCE-DH]; MacLennan, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e3684d6a36e4002bc07015b7506b803-Lori.MacLen]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Paulos, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]; Roberts, Michelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1c09da5d79049fb902729d7e8328a34-Michelle.Ro]; Price, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f6e66e367574338b48eca70c18edda5-William.Pri]
**Subject**: RE: Communications Rollout: COVID-19 Guidance and EUA Template

Unfortunately not, it will still take some time. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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uwe.scherf@fda.hhs.gov

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**From:** Seligson, Edie D. <Edie.Seligson@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 5:38 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Gagne, Stefan <Stefan.Gagne@fda.hhs.gov>; Aihie, Irene <Irene.Aihie@fda.hhs.gov>; Witters, Alicia

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<Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; CDRH-OCE-Division of Comms-MGRS <CDRH-OCE-DivisionofComms-MGRS@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Roberts, Michelle <Michelle.Roberts1@fda.hhs.gov>; Price, William <William.Price@fda.hhs.gov>
**Subject:** RE: Communications Rollout: COVID-19 Guidance and EUA Template

Stefan has prepared the content. We are standing by to add the files. Are we expecting them around 7:00PM?

**Edie Seligson**
*Chief, Web and Graphics Branch*

**Center for Devices and Radiological Health**
**Office of Communication and Education**
**Division of Communication**
**U.S. Food and Drug Administration**
Tel: 301-796-5768
edie.seligson@fda.hhs.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 4:32 PM
**To:** Seligson, Edie D. <Edie.Seligson@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Gagne, Stefan <Stefan.Gagne@fda.hhs.gov>; Aihie, Irene <Irene.Aihie@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; CDRH-OCE-Division of Comms-MGRS <CDRH-OCE-DivisionofComms-MGRS@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Roberts, Michelle <Michelle.Roberts1@fda.hhs.gov>; Price, William <William.Price@fda.hhs.gov>
**Subject:** RE: Communications Rollout: COVID-19 Guidance and EUA Template

Thanks Edie

Yes I will submit the form shortly

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*
Bacterial Respiratory and Medical Countermeasures Branch

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Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov






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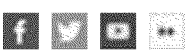
**From:** Seligson, Edie D. <Edie.Seligson@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 4:30 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Gagne, Stefan <Stefan.Gagne@fda.hhs.gov>; Aihie, Irene <Irene.Aihie@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; CDRH-OCE-Division of Comms-MGRS <CDRH-OCE-DivisionofComms-MGRS@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Roberts, Michelle <Michelle.Roberts1@fda.hhs.gov>; Price, William <William.Price@fda.hhs.gov>
**Subject:** RE: Communications Rollout: COVID-19 Guidance and EUA Template

Yes Kim that would be fine. Go ahead and submit the request. We'll prep for posting and wait for the files. Are you submitting now? If so I'll alert Stefan.

**Edie Seligson**
*Chief, Web and Graphics Branch*

**Center for Devices and Radiological Health**
**Office of Communication and Education**
**Division of Communication**
**U.S. Food and Drug Administration**
Tel: 301-796-5768
edie.seligson@fda.hhs.gov



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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 4:13 PM
**To:** Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Gagne, Stefan <Stefan.Gagne@fda.hhs.gov>; Aihie, Irene <Irene.Aihie@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Seligson, Edie D. <Edie.Seligson@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; CDRH-OCE-Division of Comms-MGRS <CDRH-OCE-DivisionofComms-MGRS@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Roberts, Michelle <Michelle.Roberts1@fda.hhs.gov>; Price, William <William.Price@fda.hhs.gov>
**Subject:** RE: Communications Rollout: COVID-19 Guidance and EUA Template

Dear Monica, Edie and Stefan

I have the draft CDRH Web and Graphics Request Form for the Wadsworth NYSDOH EUA submission – do you want me to submit it now and I can follow up with clarifications and files once it is authorized?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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-----Original Appointment-----
**From:** Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 4:03 PM
**To:** Gagne, Stefan; Aihie, Irene; Witters, Alicia; Seligson, Edie D.; Caccomo, Stephanie; Scherf, Uwe; Fulmer, Sonja; Hillebrenner, Elizabeth J; Tomasello, Jennifer; CDRH-OCE-Division of Comms-MGRS; MacLennan, Lori; Sapsford, Kim E; Shuren, Jeff
**Cc:** Paulos, Lauren; Roberts, Michelle; Price, William
**Subject:** Communications Rollout: COVID-19 Guidance and EUA Template
**When:** Saturday, February 29, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
**Where:** **This is not a meeting, just a calendar hold so that we meet our goal

****This is not a meeting, just a calendar hold so that we meet our goal.**

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*Please note: Rollout timeline may change based on when webstaff receives the cleared guidance. Please allow ~one hour for staff to prep the web postings prior to rollout.

**Before rollout –**

- Webinar scheduled and calendar hold sent (Irene/Monica) - Complete
- Cleared guidance is sent to webstaff and staged (Sonja/Stefan) - Complete
- OEA web updates staged: FDA EUA page and FDA coronavirus page (Chris/Edie) - Complete
- Webinar announcement is staged (Stefan) - Complete

**2/29/20 –**
**10:00 AM**

- Guidance is posted (Stefan) - Complete
- Press Release is Live (Chris/Stephanie) - Complete
- Web update to CDRH EUA page and EUA template Word document is posted (Stefan) - Complete
- Webinar webpage is live (Stefan) - Complete
- OEA Web Updates live: FDA EUA page and FDA coronavirus page - Complete

**~11:00 AM**

- FDA Email for Press Release is sent (Stephanie) - Complete
- CDRH External Email is sent to stakeholder list and subscription lists (Stefan/Monica) - Complete
- Agency and CDRH Twitter and Linkedin (Alicia/Abby/Brad) - Complete

**Later in the day**

- (~7:00pm) EUA NYS package is sent to webstaff (Uwe/Kim)
- EUA package is posted to CDRH EUA webpage (Stefan)
- OEA Web Update to FDA EUA webpage (Jan/Lori)
- Agency and CDRH Twitter (Alicia/Abby/Brad)

**3/2/20 –**

- 12:00-12:30PM - Webinar Prep Meeting (Leads/Policy/CDRH Comms)
- 3:00-4:00PM - Conduct webinar (Leads/Policy/CDRH Comms)

**Web Assets:**

- Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia-prior
- Press Release: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics
- CDRH EUA webpage: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
- CDRH EUA Template: https://www.fda.gov/media/135658/download
- Webinar webpage: https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia
- FDA EUA webpage: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- FDA Coronavirus page: https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-covid-19

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/29/2020 11:41:06 AM
**To:** Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: language

Here also the language for the conditions of authorization:

A. Authorized laboratories will include with reports of the results of the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

B. Authorized laboratories will perform the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel as outlined in the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel Instructions for Use. Deviations from the authorized procedures, including the authorized RT-PCR instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel are not permitted.

C. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

D. Authorized laboratories will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Wadsworth Center NYSDOH (Include contact email@xx.xxv) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

E. All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:39 AM

**To:** Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** language

New York State Wadsworth Center's analytical and clinical validity is supported by reference to the analytical and clinical data listed in the CDC's 2019 nCoV EUA authorization for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 9:42:24 AM
**To**: Schlottmann, Silke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e336124318b94b659ff7a2c244ce4c18-Silke.Schlo]
**Subject**: RE: IDT Technologies - Draft IFU and Draft EUA Letter

Can you still take your computer in case things change? Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**From:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:39 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: IDT Technologies - Draft IFU and Draft EUA Letter

Ok. Thanks. I started updating the IDT IFU based on my conversation with you. Only missing section is the performance section. I am attaching it as the most recent IFU version (Just in case things change throughout the day).
I will go to my kids tournament then WITHOUT taking my computer. Call me if you need me; I will check emails around 7 pm when I am back.

Best
Silke

**Silke Schlottmann**
*Scientific Reviewer*

Hepatitis and General Virology Branch
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR) | OHT7

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Ph: (301) 796-9551
Silke.Schlottmann@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:23 AM
**To:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IDT Technologies - Draft IFU and Draft EUA Letter

Silke and Kim,

I just got different direction because CDC is willing to work this out. There is NO need to work on these document now.

I will touch base with you when we have restrategized

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:20 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IDT Technologies - Draft IFU and Draft EUA Letter
**Importance:** High

Kim.
I just had a call with Uwe. He wants the Documents finished this weekend. I will work on it but need to know the following:
(b) (4), (b) (5)

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(b) (4), (b) (5)

Again, if IDT sends us anything this weekend. Here are my numbers: (b)(6) cell, best for today) and (b)(6) (b)(6) home, better for most of tomorrow!)

Also, it would be good if I can get a contact at IDT for any questions.

Best
Silke

**Silke Schlottmann**
*Scientific Reviewer*

Hepatitis and General Virology Branch
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR) | OHT7

CDRH | Food and Drug Administration
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Ph: (301) 796-9551
Silke.Schlottmann@fda.hhs.gov






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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:44 PM
**To:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IDT Technologies - Draft IFU and Draft EUA Letter

Thanks very much Silke

Best regards
Kim

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 6:24 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** IDT Technologies - Draft IFU and Draft EUA Letter

Kim.

Please find attached the Draft Authorization Letter and the DRAFT IFU for IDT as far as it is possible to complete them. I will do the EUA template on Monday.

I marked in yellow or with a comment everything that IDT needs to verify or that requires updating based on future information – a lot of things are unknown at this point.
(b) (5)

We can discuss next week.

Hope you can enjoy the weekend with your parents.
Best

Silke

**Silke Schlottmann**
*Scientific Reviewer*

Hepatitis and General Virology Branch
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR) | OHT7

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 5:12 PM
**To:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** CDC 3 primer test

Dear Silke,

Please find attached the authorized instructions for use and FDA Letter of Authorization for CDC for the 3 primer test and CDC's EUA .

I guess leave the performance part blank for now

Cheers

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Kim.Sapsford@fda.hhs.gov




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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/28/2020 8:14:18 PM
**To**: Pagan Motta, Monica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39552e3b45c741f19b0bebbf796d96c2-Monica.Paga]; Gagne, Stefan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34d09d8b5be419c8f5c441bc8ebc4f7-SXG]; Aihie, Irene [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad4eedb2f6c644b28a1ce3903f325790-Irene.Aihie]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]; Seligson, Edie D. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39c00b63d10740d4a0f8a8296522a657-EDP]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Fulmer, Sonja [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6136c44586e4a1ca8ce73d55803cfe5-Sonja.Fulme]
**Subject**: RE: [tentative] Communications Rollout: COVID-19 Guidance and EUA

The EUA package will not be ready at 10 AM. We need to rewrite and confirm with Wadsworth several documents. Uwe

-----Original Appointment-----
**From:** Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:10 PM
**To:** Gagne, Stefan; Aihie, Irene; Witters, Alicia; Seligson, Edie D.; Caccomo, Stephanie; Scherf, Uwe; Fulmer, Sonja
**Subject:** [tentative] Communications Rollout: COVID-19 Guidance and EUA
**When:** Saturday, February 29, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
**Where:** **This is not a meeting, just a calendar hold so that we meet our goal

**This is not a meeting, just a calendar hold so that we meet our goal.

*Rollout timeline may change based on clearance of the guidance.

**Before rollout (~2/28/20) –**

- Cleared guidance is sent to webstaff and prepped in the system (Sonja/Stefan)
- EUA NY authorization package submitted to webstaff (Uwe)
- Webinar scheduled and calendar hold sent (Irene)

**2/29/20 –**
**10:00 AM**

- Guidance is posted (Stefan)
- EUA template Word document is posted (Stefan/Edie)
- EUA NY authorization package (Uwe/Stefan)

**10:30 AM**

- External Email is sent (Monica/Stefan)
- FDA Posts Press Release about Guidance
- EUA NY authorization package OMA Tweets and CDRH Tweets (Irene A./Stephanie)

**3/2/20 –**

- 10:00 AM - Post ICS file and reminder email about webinar (Irene)
- 3:00-4:00PM - Conduct webinar (All)

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Links to Drafts:
TBD

Web Assets:
TBD

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

# *Welcome to today's FDA/CDRH Webinar*

*Thank you for your patience while additional time is provided for participants to join the call.*

**Please connect to the audio portion of the webinar now:**
**U.S. Callers: 1-888-946-7601**

**International Callers: 1-312-470-7136**

**Conference Number: PWXW9976446**
**Passcode: 6470708**

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# Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency: Immediately in Effect Guidance

Timothy Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health

March 2, 2020

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# Agenda

- Background
- Summary of Immediately In Effect Guidance
- Questions and Answers



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# Objective

- Explain policy for molecular diagnostics testing in high-complexity Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories prior to emergency use authorization for coronavirus disease-2019 (COVID-19) during the public health emergency.

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# Background

- Guidance issued February 29, 2020 describes a policy regarding certain ~~enabling~~ laboratories ~~to~~ immediately usinge ~~tests~~ they developed and validated in order to achieve more rapid testing capacity in the U.S.
- To address the COVID-19 public health emergency, the FDA has determined that prior public participation for this guidance is not feasible or appropriate and ~~is~~ issueding this guidance without prior public comment.
- This guidance document is immediately in effect, but it remains subject to comment in accordance with the FDA's good guidance practices.

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# Scope

- The new policy is limited to:
  - Laboratories certified to perform high complexity testing, consistent with the requirements under the Clinical Laboratory Improvement Amendments (CLIA)
  - Molecular diagnostics for SARS-CoV-2
  - The duration of the current public health emergency declaration for SARS-CoV-2
- The new policy does NOT impact:
  - Requirements under the Clinical Laboratory Improvement Amendments (CLIA)
  - CDC recommendations for who should be tested



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# Policy

The guidance includes recommendations regarding:

- Validating newly developed SARS-CoV-2 tests prior to clinical use
- Notifying FDA when clinical use of a validated test begins
- Confirming the first 5 positive and negative samples with an EUA authorized test
- Indicating in test reports that the test has been validated but independent review by FDA is not yet complete
- Submiting an EUA within 15 days of initiating testing
- Steps to take if any specimens fail confirmatory testing or if FDA is unable to authorize the EUA~~, stop testing and issuinge corrected test reports indicating prior results may not be valid~~

7

(b)(5) internal deliberative

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# Test Validation

- The guidance includes recommendations regarding the ~~Validation should meet~~ minimal testing to be performed for validation ~~recommendations outlined in the guidance for~~:
  - Limit of Detection (LoD)
  - Clinical Evaluation
  - Inclusivity
  - Cross-Reactivity

- Limited viral materials are available
  - FDA, BARDA, and CDC prioritize and coordinate shipments to labs when ready to validate



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# Limit of Detection

- Generally defined as the lowest concentration at which 19/20 replicates are positive

- Methods:
  - Recommend testing dilution series with 3 replicates per concentration (range finding) and
  - confirming final concentration with 20 replicates (around initially identified LoD only)

- Samples:
  - pooled negative clinicals samples or artificial matrix
  - if multiple specimen types are intended, ~~evaluate~~ most challenging should be evaluated (e.g., sputum)

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# Clinical Evaluation

- Recommend testing at least 30 contrived reactive specimens and 30 non-reactive specimens
  - Contrived reactive specimens can be created by spiking viral RNA or inactivated virus into leftover clinical specimens
  - Twenty (20) of the contrived specimens should be spiked at a concentration of 1x-2x LoD, with the remainder of specimens spanning the assay testing range.

- FDA generally defines acceptable performance:
  - 95% agreement at 1x-2x LoD and
  - 100% agreement at all other concentrations and for negative specimens

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# Inclusivity

- Recommend conducting an *in silico* analysis of the percent identity matches against publicly available SARS-CoV-2 sequences that can be detected by the proposed molecular assay.
- 100% of published SARS-CoV-2 sequences should be detectable with the selected primers and probes



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# Cross-Reactivity

- Recommend conducting an *in silico* analysis of the assay primer and probes compared to common respiratory flora and other viral pathogens ~~is sufficient~~
- There should be >80% homology between one of the primers/probes and any sequence present in the targeted microorganism
- Recommend following recognized laboratory procedures for any additional cross-reactivity testing in the context of the sample types intended for testing



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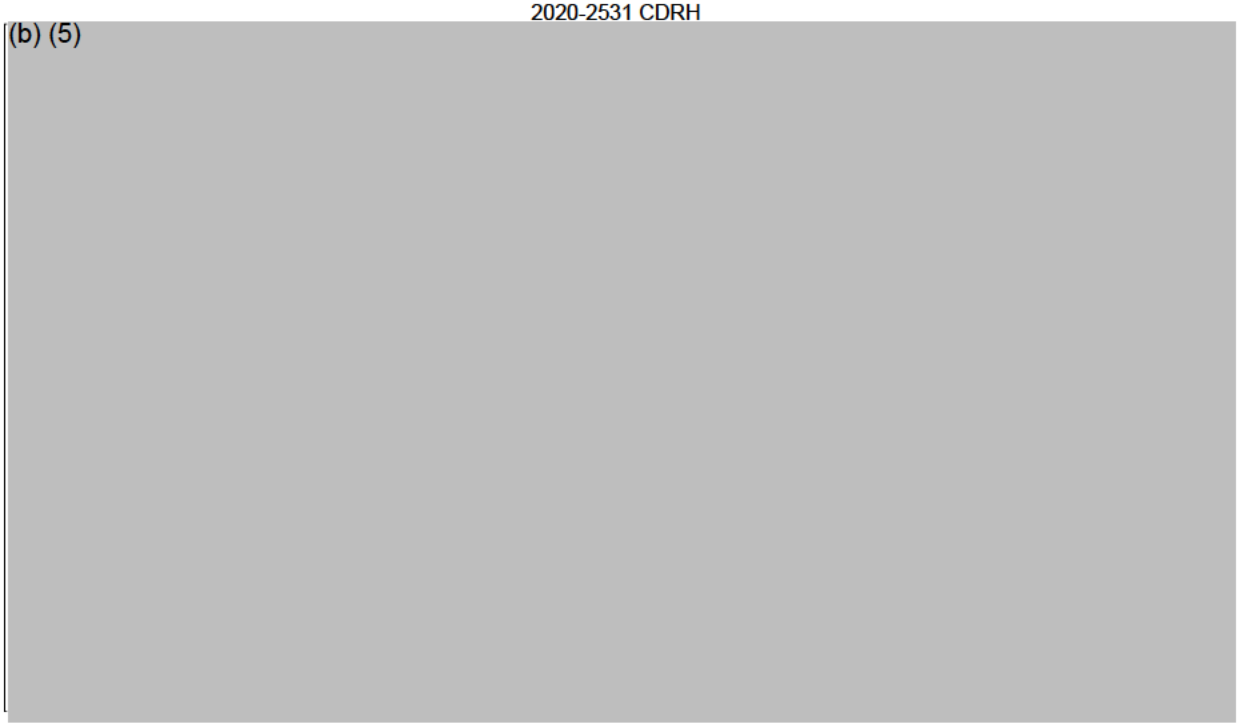
# Status of EUA Tests

- CDC EUA authorization Feb 4, 2020
  - Covers CDC-qualified IDT 2019-nCoV Kit Lot#0000500383
  - Additional IDT lots undergoing qualification by CDC
- NYS Wadsworth Center EUA Authorization Feb 29, 2020
- CDC, FDA and BARDA are working with multiple IVD manufacturers and laboratories to enable additional EUA authorizations as soon as possible; monitor at:
  https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019

13

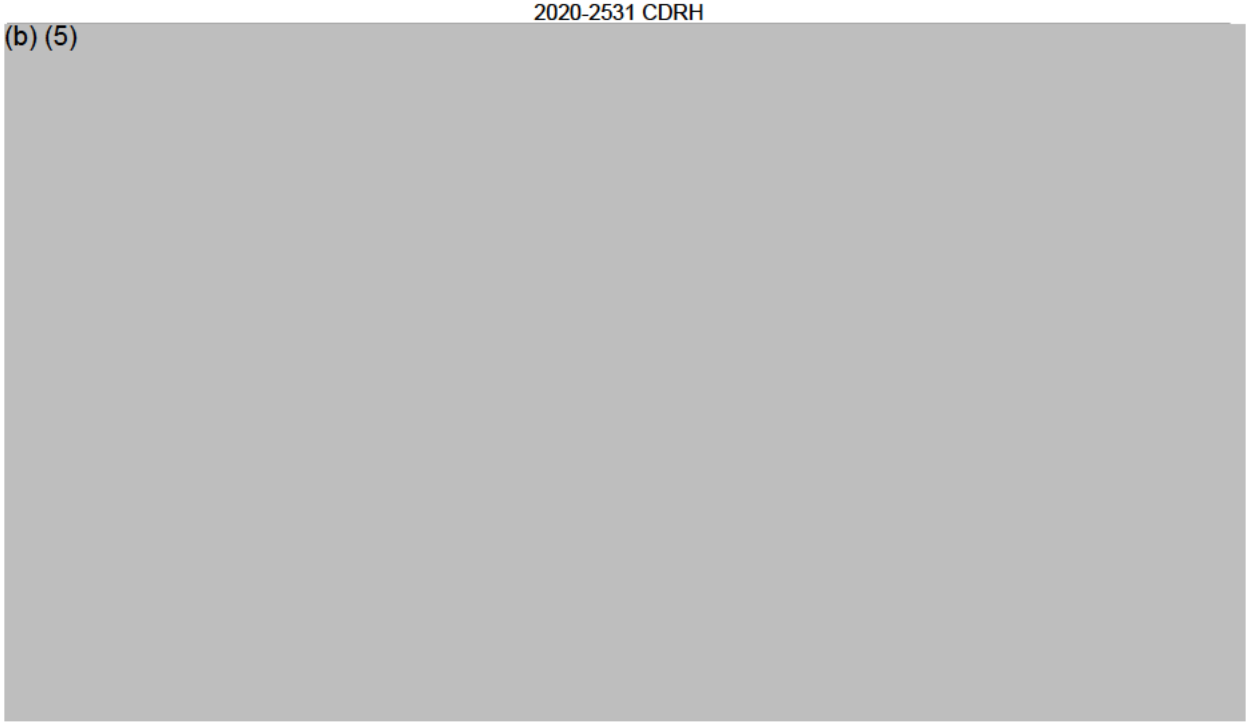
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(b) (5)



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(b) (5)



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# Submissions to FDA

- **Notification** of clinical use of a validated test should be directed to CDRH-EUA-Templates@fda.hhs.gov and should include:
  - name of the laboratory
  - name of the lab director
  - address
  - contact person

- **EUA** should be submitted within 15 days of initiating clinical testing to OIR-Operations@fda.hhs.gov and should include:
  - Form 3514 available at: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf
  - Completed EUA template available at: https://www.fda.gov/media/135658/download

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Mention: Under normal circumstances, an EUA should be mailed to our document control center. Due to the extenuating circumstances, we will waive this requirement and accept submissions via email.

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# Resources

- COVID-19 Guidance Document: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia-prior
- General EUA Guidance Document: https://www.fda.gov/media/97321/download
- FDA's Novel Coronavirus (COVID – 19) webpage: https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-covid-19

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# Questions?

For questions on the guidance and accelerated EUA template, or if you wish to consider use an alternative specimen type, contact the Division of Microbiology devices at (301) 348-1778 or: CDRH-EUA-Templates@fda.hhs.gov.

Slide Presentation, Transcript and Webinar Recording will be available at:
http://www.fda.gov/training/cdrhlearn
Under Heading [Insert respective webpage heading]

18

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 3/1/2020 8:39:20 PM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**CC**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]; Pagan Motta, Monica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39552e3b45c741f19b0bebbf796d96c2-Monica.Paga]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx
**Attachments**: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe_MB TimUwe.pptx

I am sorry, but on slide 9 it need to read 'should be evaluated' see attached file.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 8:32 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Hi Elizabeth,

See attached with my comment on slide 13. Deleted an "s" on slide 9. Rest of the changes look acceptable to me.

Thanks!

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Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Jennifer.Campbell@fda.hhs.gov

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---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 8:06 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Tim, just following up to see if you can respond to Marcy's question on the IDT qualified kits? See slide 13 where she asked: (b) (5) let's discuss.

Uwe and Tim, do you have any technical concerns with the other edits? If not I will proceed to clean the deck so Jeff can share with the Commissioner's office before tomorrow.

Elizabeth

---

**From:** Hillebrenner, Elizabeth J
**Sent:** Sunday, March 1, 2020 3:11 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Marcy, thank you!

Tim, Uwe, I flipped through quickly but think it needs your review. In particular Marcy has a question on the IDT qualified kits.

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Elizabeth

---

**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 3:08 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Thanks Elizabeth! I included some suggested edits (in red on the slides, and in the comments for 1 slide) in the attached. I tried to explain my thinking in comment bubbles, but happy to discuss further if you have any questions/concerns.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 11:57 AM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Hi Marcy,

Attached is an updated webinar deck for your review. I will be out for an hour but otherwise available to answer questions. Thanks for all your help!

Elizabeth

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/28/2020 5:50:43 PM
**To**: St. George, Kirsten (HEALTH) [kirsten.st.george@health.ny.gov]
**Subject**: RE: the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

**Importance**: High

Kristen,

Can you please give me a call, we have some quick questions regarding the submission. 301-796-5456.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Friday, February 28, 2020 3:56 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; oir-policy <CDRH-OIR-POPS@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Subject:** RE: the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

Sincerely appreciate your guidance Kim

Kind regards, Kirsten

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george




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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 3:24 PM
**To:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; oir-policy <CDRH-OIR-POPS@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Subject:** RE: the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Kirsten and Jill

We acknowledge receipt of your EUA request.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Friday, February 28, 2020 3:21 PM
**To:** oir-policy <CDRH-OIR-POPS@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Subject:** the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

In the attached files, please find the following documents for the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

1. Cover letter from the Wadsworth Center Director, Dr. Jill Taylor
2. Completed form 3514
3. Wadsworth Center EUA Interactive Review Submission for Molecular-Based test for SARS-CoV-2
4. Associated appendices to the submission:

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a. Oligo spec sheets from manufacturer
b. Transcript spec sheet from manufacturer
c. NYSDOH SOP for lot to lot verification testing
d. NYSDOH SOP for the New York State SARS-CoV-2 real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel
e. NYSDOH Info for Patients on New York State SARS-CoV-2 real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel
f. NYSDOH Info for Healthcare Providers on New York State SARS-CoV-2 real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george




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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

# *Welcome to today's FDA/CDRH Webinar*

*Thank you for your patience while additional time is provided for participants to join the call.*

**Please connect to the audio portion of the webinar now:**
**U.S. Callers: 1-888-946-7601**

**International Callers: 1-312-470-7136**

**Conference Number: PWXW9976446**
**Passcode: 6470708**

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# Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency: Immediately in Effect Guidance

Timothy Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health

March 2, 2020

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# Agenda

- Background
- Summary of Immediately In Effect Guidance
- Questions and Answers



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# Objective

- Explain policy for molecular diagnostics testing in high-complexity Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories prior to emergency use authorization for coronavirus disease-2019 (COVID-19) during the public health emergency.



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# Background

- Guidance issued February 29, 2020 describes a policy enabling laboratories to immediately use tests they developed and validated in order to achieve more rapid testing capacity in the U.S.
- To address the COVID-19 public health emergency, the FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment.
- This guidance document is immediately in effect, but it remains subject to comment in accordance with the FDA's good guidance practices.

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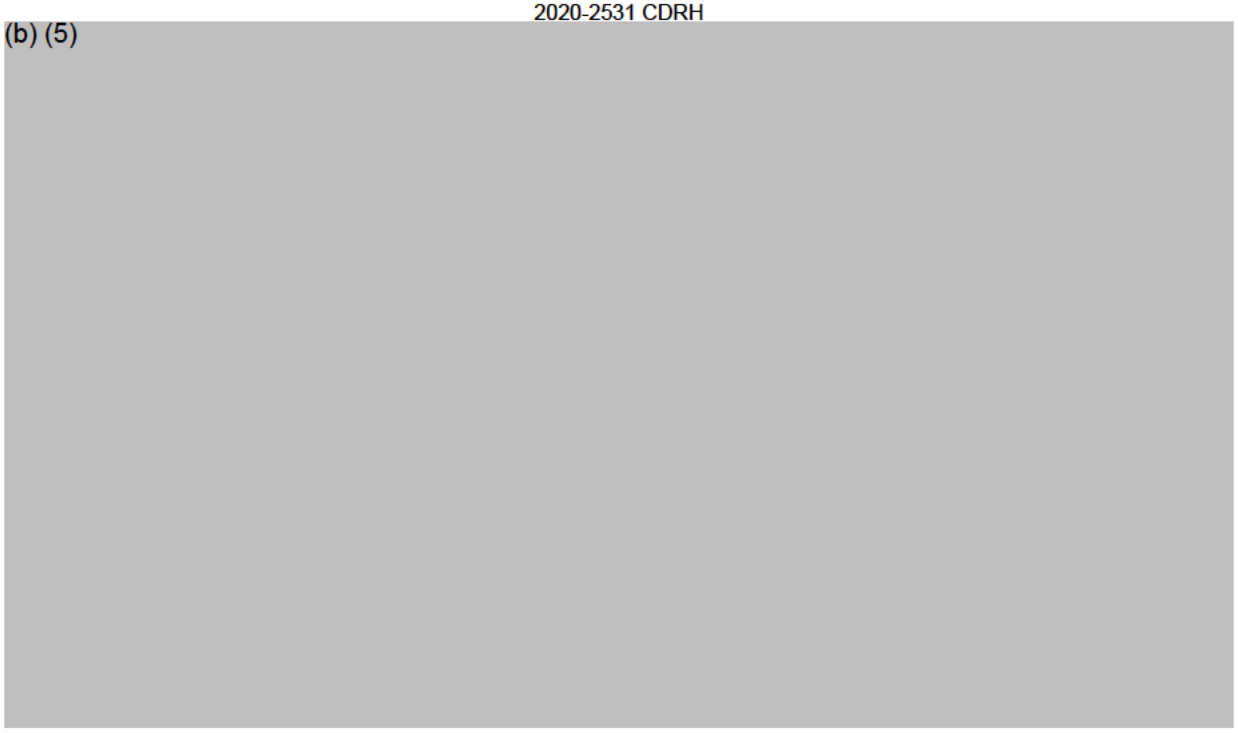
# Scope

- The new policy is limited to:
  - Laboratories certified to perform high complexity testing, consistent with the requirements under the Clinical Laboratory Improvement Amendments (CLIA)
  - Molecular diagnostics for SARS-CoV-2 ~~COVID-19~~
  - The duration of the current public health emergency declaration for SARS-CoV-2 ~~COVID-19~~
- The new policy does NOT impact:
  - Requirements under the Clinical Laboratory Improvement Amendments (CLIA)
  - CDC recommendations for who should be tested



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(b) (5)



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# Policy

- Labs should complete validation of newly developed SARS-CoV-2 ~~COVID-19~~ tests prior to clinical use
- Labs should notify FDA when clinical use of a validated test begins
- Labs should confirm the first 5 positive and negative samples with an EUA authorized test
- Test reports should indicate the test has been validated but independent review by FDA is not yet complete
- Labs should submit an EUA within 15 days of initiating testing
- If any specimens fail confirmatory testing or if FDA is unable to authorize the EUA, labs should stop testing and issue corrected test reports indicating prior results may not be valid

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(b) (5)



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# Policy

Validation should meet minimal recommendations outlined in the guidance for:

- Limit of Detection (LoD)
- Clinical Evaluation
- Inclusivity
- Cross-Reactivity



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# Limit of Detection

- Defined as the lowest concentration at which 19/20 replicates are positive
- Methods:
  - test dilution series with 3 replicates per concentration (range finding)
  - confirm final concentration with 20 replicates (around initially identified LoD only)
- Samples:
  - may use contrived samples (i.e., spiking RNA or inactivated virus into artificial or real clinical matrix)
  - if multiple specimen types are intended, evaluate most challenging (e.g., sputum)

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# Clinical Evaluation

- Test at least 30 contrived reactive specimens and 30 non-reactive specimens
  - Contrived reactive specimens can be created by spiking viral RNA or inactivated virus into leftover clinical specimens
  - Twenty (20) of the contrived specimens should be spiked at a concentration of 1x-2x LoD, with the remainder of specimens spanning the assay testing range.

- Acceptable performance:
  - 95% agreement at 1x-2x LoD and
  - 100% agreement at all other concentrations and for negative specimens

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# Inclusivity

- Conduct an *in silico* analysis of the percent identity matches against publicly available SARS-CoV-2 sequences that can be detected by the proposed molecular assay.
- 100% of published SARS-CoV-2 sequences should be detectable with the selected primers and probes



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# Cross-Reactivity

- Conduct an *in silico* analysis of the assay primer and probes compared to common respiratory flora and other viral pathogens is sufficient
- There should be >80% homology between one of the primers/probes and any sequence present in the targeted microorganism
- Follow recognized laboratory procedures for any additional cross-reactivity testing in the context of the sample types intended for testing



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# Additional Updates

- NYS Wadsworth Center rec'd EUA Authorization for their LDT 29FEB2020.

(b) (5)

- IDT 2019-nCoV Kit Lot#0000500383 has been lot qualified by the CDC under the CDC's EUA authorization and is available for distribution. Stay tuned for additional IDT lots to be qualified as they become available.
- The CDC, FDA and BARDA are working with multiple other IVD manufacturers and Laboratories enable additional EUA authorizations as soon as possible, so stay tuned. We will make this information known.
- (b) (5)

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## Submissions to FDA

- **Notification** of clinical use of a validated test should be directed to CDRH-EUA-Templates@fda.hhs.gov and should include:
  - name of the laboratory
  - name of the lab director
  - address
  - contact person

- **EUA** should be submitted within 15 days of initiating clinical testing to OIR-Operations@fda.hhs.gov and should include:
  - Form 3514 available at: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf
  - Completed EUA template available at: https://www.fda.gov/media/135658/download

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Mention: Under normal circumstances, an EUA should be mailed to our document control center. Due to the extenuating circumstances, we will waive this requirement and accept submissions via email.

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# Resources

- COVID-19 Guidance Document: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia-prior

- General EUA Guidance Document: https://www.fda.gov/media/97321/download

- Novel Coronavirus (COVID – 19) webpage: https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-covid-19



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# Questions?

For questions on the guidance and accelerated EUA template, or if you wish to consider use an alternative specimen type, contact the Division of Microbiology devices at (301) 348-1778 or: CDRH-EUA-Templates@fda.hhs.gov.

Division of Industry and Consumer Education: DICE@fda.hhs.gov

EH note: I would take out DICE since our audience is labs; not industry or consumers. I think we just want the labs going straight to the EUA mailbox and should not confuse them with too many places to go

Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn

Under Heading [Insert respective webpage heading]

17

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 3/1/2020 9:16:18 AM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]; Pagan Motta, Monica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39552e3b45c741f19b0bebbf796d96c2-Monica.Paga]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: EUA COVID-19 Lab Tests - Webinar deck.pptx
**Attachments**: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.pptx

Here my comments on the slides.

Uwe

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 9:03 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Thank you Tim!

I have some questions about one of your additions: Are (b) (5), (b) (4) (b) (5), (b) (4) (b) (5) (b) (5)

Also standing by for any edits Uwe may have.

Elizabeth

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** March 1, 2020 at 8:40:06 AM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>, Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Good morning,

I made some minor edits and added an update slide near the end, see attached. Uwe is working on making sure viral and disease names are all correct and double checking the content at well. Thanks!

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Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:40 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Happy to delete that slide, but note that Dan asked us to include it (attached). Do we know if CDC is planning their own slides? I thought they would just be on to answer questions.

I will send to Marcy and Claire in parallel while we sort this out.

Elizabeth

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:34 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Elizabeth,

They look good. I wouldn't include the CDC criteria in Tim's presentation. Dan is welcome to use slides if he wants to discuss the CDC criteria after Tim finishes his presentation.

I agree they need to go to OCC and then shared with OC. I can share them with OC once OCC finishes their review.

Jeff

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:16 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** EUA COVID-19 Lab Tests - Webinar deck.pptx

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Jeff and Tim,
Attached are draft slides for the webinar Monday for your review. I think they will may to go through OCC as well.
Elizabeth

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/29/2020 11:38:59 AM
**To:** Hwang, Leroy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5da97657ec944cebf943616bd848105-Leroy.Hwang]
**Subject:** RE: no update from Co-diagnostics yet

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:27 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: no update from Co-diagnostics yet

I still didn't receive anything from co-diagnostics yet. If we don't get anything by Monday I'll call them again.

Leroy

---

**From:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Date:** February 28, 2020 at 4:35:09 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** no update from Co-diagnostics yet

Uwe,

I haven't received the CE-IVD labeling or validation summary from Co-diagnostics yet. I will be checking my emails tonight to see if they sent anything and forward them to you, when I receive them.

Leroy

---

**From:** Chad Apuli <(b) (6) @codiagnostics.com>
**Sent:** Friday, February 28, 2020 11:42 AM
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>; Cecilia Hutchins <(b) (6) @codiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: CE-IVD Logix Smart 2019-nCoV product

Dr. Hwang,

AMERICAN OVERSIGHT

We would love to talk. Once Cecilia gets into the office we will give you a call then, or if it works better for you, we can set up a call later today.

Thanks,
Chad

---

**From:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 9:30 AM
**To:** Cecilia Hutchins <(b) (6) @codiagnostics.com>; Chad Apuli <(b) (6)@codiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** CE-IVD Logix Smart 2019-nCoV product

Ms. Hutchins and Mr. Apuli,

I had just called and left a voice message for Ms. Hutchins, but wasn't sure if it would reach you. We are very interested in the Logix Smart COVID-19 CE-IVD product offered by your company and would like to ask if you could provide some information regarding the product. I was wondering if it would be possible to call me (240) 402-6427 today to discuss. Thank you.

Sincerely,

**Leroy N. Hwang, Ph.D.**
*Team Lead, Post-market Compliance Group*

Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3266 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (240) 402-6427
leroy.hwang@fda.hhs.gov





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---

**From:** Hwang, Leroy
**Sent:** Friday, February 28, 2020 8:05 AM
**To:** 'Andrew Benson' <(b) (6) @codiagnostics.com>
**Cc:** Cecilia Hutchins <(b) (6) @codiagnostics.com>; Chad Apuli <(b) (6)@codiagnostics.com>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>
**Subject:** RE: RUO Logix Smart 2019-nCoV Kit

Mr. Benson,

AMERICAN OVERSIGHT

Thank you for providing your proposal to address our concerns. We agree to the proposed solution. It will be acceptable if you added the statement for the News releases in question and any future News releases discussing your CE-IVD product. In review of the updated website information for the CE-IVD COVID-19 product and the RUO product, it appears that you have added appropriate statements clarifying that the CE-IVD product is for export only and not available for sale in the U.S. and the RUO product contains the required "For research use only. Not for use in diagnostic procedures" statement as required by 21CFR809.10(c)(2)(i).

If these actions are implemented, it would adequately address our remaining concerns regarding your firm's statements labeling for the Logix Smart 2019-nCoV Kit product.

We again thank you for your cooperation in addressing these concerns and we look forward to your pre-EUA submission for your test.

Sincerely,

**Leroy N. Hwang, Ph.D.**
*Team Lead, Post-market Compliance Group*

Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: (240) 402-6427
leroy.hwang@fda.hhs.gov






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**From:** Andrew Benson <(b) (6) @codiagnostics.com>
**Sent:** Thursday, February 27, 2020 6:36 PM
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Cc:** Cecilia Hutchins <(b) (6) @codiagnostics.com>; Chad Apuli <(b) (6)@codiagnostics.com>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>
**Subject:** Re: RUO Logix Smart 2019-nCoV Kit

Dear Dr. Hwang,

Would it be acceptable if we edited the releases in question to include the following verbiage, above the Company disclaimer for each release?:

*The Logix Smart™ 2019-nCoV kit is for Research Use Only. Not for use in diagnostic procedures.*

*This product is for export only and not available for sale in the U.S.*

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The page for our CE-IVD COVID-19 product is now live on the website, which hopefully helps to clarify that there are two distinct products (the RUO and the IVD) and to eliminate confusion. This page also does state "This product is for export only and is not for sale in the United States."

Thank you for taking the time to reach out. If you can confirm that the disclaimer as described above will work, Cecilia will add it into our Corrective Action report and the changes will be made immediately.

Best regards,

**Andrew Benson | Head of Corporate Communications**

CO-DIAGNOSTICS, INC
*Tailor-Made Life Saving Solutions*
2401 S Foothill Dr. Ste. D
Salt Lake City, UT 84109
www.codiagnostics.com
(b) (6) codiagnostics.com

On Thu, Feb 27, 2020 at 5:08 AM Hwang, Leroy <Leroy.Hwang@fda.hhs.gov> wrote:

> Ms. Hutchins,
>
> A Friday (2/28) response would be fine. Again, if you have any questions regarding our recommendations, feel free to schedule a phone call.
>
> Sincerely,
>
> **Leroy N. Hwang, Ph.D.**
> *Team Lead, Post-market Compliance Group*
>
> Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
> Office of Product Evaluation and Quality
>
> CDRH | Food and Drug Administration
> White Oak, Bldg. 66, Rm. 3266 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
> Ph: (240) 402-6427
> leroy.hwang@fda.hhs.gov
> FDA U.S. FOOD & DRUG ADMINISTRATION
>
> ***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:*** https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Cecilia Hutchins <(b) (6) @codiagnostics.com>
**Sent:** Wednesday, February 26, 2020 6:35 PM
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>; Chad Apuli <(b) (6) @codiagnostics.com>

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**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>; Andrew Benson <(b) (6)@codiagnostics.com>
**Subject:** Re: RUO Logix Smart 2019-nCoV Kit

Dr. Hwang,

I'm sorry to hear that the FDA still has concerns about the previous press releases.
We have been trying our best to be in compliance with the federal regulations.
We also understand that there is a lot of misunderstanding in the general public nowadays than in the normal operations of the IVD industry.
The review process for updates to the website has become more lengthy with the newly implemented process.
Please, allow us some time to discuss internally and provide a more accurate answer to the raised concerns.
I'll be able to provide the answer and hopefully have all corrective actions completed by Friday.

Sincerely,

**Cecilia Hutchins | Head of Regulatory Affairs**

***Tailor-Made Life Saving Solutions***
**2401 S. Foothill Dr., Suite D**
**Salt Lake City, Utah 84109**
**www.codiagnostics.com**
(b) (6) **@codiagnostics.com**

---

**From:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 10:25 AM
**To:** Cecilia Hutchins <(b) (6) @codiagnostics.com>; Chad Apuli <(b) (6)@codiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>; Andrew Benson <(b) (6)@codiagnostics.com>
**Subject:** RUO Logix Smart 2019-nCoV Kit

Ms. Hutchins,

In review of the information provided, we still have some remaining concerns with regards to News Releases that are still accessible through your firm's website. Specifically, the February 6, 2020, and February 10, 2020 News releases that were highlighted previously are still accessible and still contain statements which are of concern to FDA. We realize that these statements were made in the past, prior to FDA communication with your firm, so the statements made by representatives of your company cannot be changed. However, we would request that you either remove reference to the previous news releases from your firm's website, or add a disclaimer statement to include as part of those previous news releases that the products are for Research Use Only (in the U.S.) and Not for use in diagnostic procedures.

From our review of the updated information on your firm's website, it also appears that Co-Diagnostics has recently (February 24, 2020) announced CE-IVD mark for the Logix Smart COVID-19 Test. So as to prevent confusion from U.S. customers, we would also recommend that you clearly indicate that this product is available for Export only and not currently available in the U.S. We would request that you add this disclaimer

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statement to future press releases or statements regarding the CE-IVD product until a EUA is granted for the U.S.

We request that you provide an updated list of planned corrective actions to address these remaining issues to us by Friday, February 28, 2020. If you would like to discuss specific proposals for wording for your updates, we would be happy to review through email or discuss over the phone.

We thank you for your cooperation in addressing these concerns and we look forward to your pre-EUA submission for your test. Please let me know if you have any questions regarding this communication.

Sincerely,

**Leroy N. Hwang, Ph.D.**
*Team Lead, Post-market Compliance Group*

Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: (240) 402-6427

leroy.hwang@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 9:50:49 PM
**To**: Pagan Motta, Monica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39552e3b45c741f19b0bebbf796d96c2-Monica.Paga]; Gagne, Stefan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34d09d8b5be419c8f5c441bc8ebc4f7-SXG]; Aihie, Irene [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad4eedb2f6c644b28a1ce3903f325790-Irene.Aihie]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]; Seligson, Edie D. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39c00b63d10740d4a0f8a8296522a657-EDP]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Fulmer, Sonja [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6136c44586e4a1ca8ce73d55803cfe5-Sonja.Fulme]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; CDRH-OCE-Division of Comms-MGRS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9166df93aa6c4a23a3f6661b21ae3e7c-CDRH-OCE-DH]; MacLennan, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e3684d6a36e4002bc07015b7506b803-Lori.MacLen]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Paulos, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]; Roberts, Michelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1c09da5d79049fb902729d7e8328a34-Michelle.Ro]; Price, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f6e66e367574338b48eca70c18edda5-William.Pri]
**Subject**: RE: Communications Rollout: COVID-19 Guidance, EUA Template and Granting NYS EUA

Dear Monica,

The signed Emergency Authorization Letter for New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel package has just been send to Wadsworth Center.

Dr. Kristen St. George has confirmed the receipt of the letter.

Thanks you all for your incredible work getting this done today.

Kind regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*
OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

-----Original Appointment-----
**From:** Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:22 PM
**To:** Gagne, Stefan; Aihie, Irene; Witters, Alicia; Seligson, Edie D.; Caccomo, Stephanie; Scherf, Uwe; Fulmer, Sonja; Hillebrenner, Elizabeth J; Tomasello, Jennifer; CDRH-OCE-Division of Comms-MGRS; MacLennan, Lori; Sapsford, Kim E; Shuren, Jeff
**Cc:** Paulos, Lauren; Roberts, Michelle; Price, William
**Subject:** Communications Rollout: COVID-19 Guidance, EUA Template and Granting NYS EUA
**When:** Sunday, March 1, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
**Where:** **This is not a meeting, just a calendar hold so that we meet our goal

****This is not a meeting, just a calendar hold so that we meet our goal.**

*Please note: Rollout timeline may change based on when webstaff receives the cleared guidance. Please allow ~one hour for staff to prep the web postings prior to rollout.

**Before rollout –**

- Webinar scheduled and calendar hold sent (Irene/Monica) - Complete
- Cleared guidance is sent to webstaff and staged (Sonja/Stefan) - Complete
- OEA web updates staged: FDA EUA page and FDA coronavirus page (Chris/Edie) - Complete
- Webinar announcement is staged (Stefan) - Complete

**2/29/20 –**
**10:00 AM**

- Guidance is posted (Stefan) - Complete
- Press Release is Live (Chris/Stephanie) - Complete
- Web update to CDRH EUA page and EUA template Word document is posted (Stefan) - Complete
- Webinar webpage is live (Stefan) - Complete
- OEA Web Updates live: FDA EUA page and FDA coronavirus page - Complete

**~11:00 AM**

- FDA Email for Press Release is sent (Stephanie) - Complete
- CDRH External Email is sent to stakeholder list and subscription lists (Stefan/Monica) - Complete
- Agency and CDRH Twitter and Linkedin (Alicia/Abby/Brad) - Complete

**3/1/20 –**

**Before 10:00 AM**

- EUA NYS package is sent to webstaff (Uwe/Kim)

**10:00 AM**

- EUA package is posted to CDRH EUA webpage (Stefan)
- OEA Web Update to FDA EUA webpage (Jan/Lori)
- Agency and CDRH Twitter (Alicia/Abby/Brad)

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**3/2/20 –**

- 12:00-12:30PM - Webinar Prep Meeting (Leads/Policy/CDRH Comms)
- 3:00-4:00PM - Conduct webinar (Leads/Policy/CDRH Comms)

**Web Assets:**

- Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia-prior
- Press Release: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics
- CDRH EUA webpage: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
- CDRH EUA Template: https://www.fda.gov/media/135658/download
- Webinar webpage: https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia
- FDA EUA webpage: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- FDA Coronavirus page: https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-covid-19

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 11:38:45 AM
**To**: Briggs, Joseph (Joseph.Briggs@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Joseph.Briggsbaf]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: language

New York State Wadsworth Center's analytical and clinical validity is supported by reference to the analytical and clinical data listed in the CDC's 2019 nCoV EUA authorization for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 3/1/2020 9:12:48 AM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]; Pagan Motta, Monica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39552e3b45c741f19b0bebbf796d96c2-Monica.Paga]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Elizabeth, this is a good point, they will not have enough for hundreds of labs so some prioritization will be needed. It might be better to work through us.

Uwe

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 9:03 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Thank you Tim!

I have some questions about one of your additions: Are (b) (4), (b) (5) (b) (4), (b) (5) (b) (5) (b) (5) ?

Also standing by for any edits Uwe may have.

Elizabeth

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** March 1, 2020 at 8:40:06 AM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>, Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Good morning,

I made some minor edits and added an update slide near the end, see attached. Uwe is working on making sure viral and disease names are all correct and double checking the content at well. Thanks!

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Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Jennifer.Campbell@fda.hhs.gov

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---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:40 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Happy to delete that slide, but note that Dan asked us to include it (attached). Do we know if CDC is planning their own slides? I thought they would just be on to answer questions.

I will send to Marcy and Claire in parallel while we sort this out.

Elizabeth

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:34 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Elizabeth,

They look good. I wouldn't include the CDC criteria in Tim's presentation. Dan is welcome to use slides if he wants to discuss the CDC criteria after Tim finishes his presentation.

I agree they need to go to OCC and then shared with OC. I can share them with OC once OCC finishes their review.

Jeff

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:16 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** EUA COVID-19 Lab Tests - Webinar deck.pptx

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Jeff and Tim,
Attached are draft slides for the webinar Monday for your review. I think they will may to go through OCC as well.
Elizabeth

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/29/2020 9:23:04 AM
**To:** Schlottmann, Silke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e336124318b94b659ff7a2c244ce4c18-Silke.Schlo]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: IDT Technologies - Draft IFU and Draft EUA Letter

Silke and Kim,

I just got different direction because CDC is willing to work this out. There is NO need to work on these document now.

I will touch base with you when we have restrategized

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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---

**From:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:20 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IDT Technologies - Draft IFU and Draft EUA Letter
**Importance:** High

Kim.
I just had a call with Uwe. He wants the Documents finished this weekend. I will work on it but need to know the following:
(b) (5), (b) (4)

Again, if IDT sends us anything this weekend. Here are my numbers: (b) (6) cell, best for today) and (b) (6) (b) (6) home, better for most of tomorrow!)

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Also, it would be good if I can get a contact at IDT for any questions.

Best
Silke

**Silke Schlottmann**
*Scientific Reviewer*

Hepatitis and General Virology Branch
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR) | OHT7

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:44 PM
**To:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IDT Technologies - Draft IFU and Draft EUA Letter

Thanks very much Silke

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov






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---

**From:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 6:24 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** IDT Technologies - Draft IFU and Draft EUA Letter

Kim.

Please find attached the Draft Authorization Letter and the DRAFT IFU for IDT as far as it is possible to complete them. I will do the EUA template on Monday.

I marked in yellow or with a comment everything that IDT needs to verify or that requires updating based on future information – a lot of things are unknown at this point.

(b) (5)

We can discuss next week.

Hope you can enjoy the weekend with your parents.
Best

Silke

**Silke Schlottmann**
*Scientific Reviewer*

Hepatitis and General Virology Branch
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR) | OHT7

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Silke.Schlottmann@fda.hhs.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 5:12 PM
**To:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** CDC 3 primer test

Dear Silke,

Please find attached the authorized instructions for use and FDA Letter of Authorization for CDC for the 3 primer test and CDC's EUA .

I guess leave the performance part blank for now

Cheers

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov





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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/28/2020 8:18:14 AM
**To**: Taylor, Jill (HEALTH) [jill.taylor@health.ny.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; St. George, Kirsten (HEALTH) [kirsten.st.george@health.ny.gov]; McDonough, Kathleen A (HEALTH) [kathleen.mcdonough@health.ny.gov]; Egan, Christina T (HEALTH) [christina.egan@health.ny.gov]; Derbyshire, Victoria (HEALTH) [victoria.derbyshire@health.ny.gov]; Rakeman, Jennifer [jrakeman@health.nyc.gov]; Hutton, Brad J (HEALTH) [brad.hutton@health.ny.gov]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Two pre-EUA questions....advice please

Dear Jill,

Please submit your submission as an EUA rather than an pre-EUIA request to the following mailbox OIR-Operations@fda.hhs.gov to assure a smooth process.

Please include in your EUA submission package:

- The populated EUA Review Template draft (MS Word Document)
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf [fda.gov]) - under Section A (type of submission) please check "other" and specify Pre-EUA; please also complete Sections B, C, F and G. For G please use the information provided in this link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=3671

Please submit your EUA package to FDA via electronic mail (including the EUA Review Template in MS word) to Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;
- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov
- OIR-Operations@fda.hhs.gov – This will ensure that you can skip the step of mailing your submission to us and still get it logged into our system.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Friday, February 28, 2020 7:38 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <(b) (6) @health.nyc.gov>; Hutton, Brad J (HEALTH) <(b) (6) @health.ny.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Two pre-EUA questions....advice please

Jeff,
Thank you for your note. Kim, and FDA are being very helpful and responsive and we really appreciate that. We are working very hard to submit our application to the FDA today.
Jill
Sent from my iPhone

On Feb 28, 2020, at 7:18 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Jill,

We saw Dr. Zucker on CNN last night and also wanted to check if there is anything else we can do to be helpful. Please let us know. You are welcome to reach out to me, as well, at any time.

Best regards,

Jeff

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:15 AM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Two pre-EUA questions....advice please

Dear Jill,

Thank you for your questions. Since we know the issues around the CDC assay – if New York would like to include the N3 manufactured by either (b) (4) we will certainly consider that.

GMP can be waived for EUA so this is not a concern.

I would recommend submitting today, please call Uwe or Tamara if you have any questions as I will be out of the office for most of the day.

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| | | | |
|---|---|---|---|
| Uwe Scherf | DMD – Division Director | Uwe.Scherf@fda.hhs.gov | 301-796-5456 |
| Tamara Feldblyum | DMD – Branch Chief | Tamara.Feldblyum@fda.hhs.gov | 301-796-6195 |

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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<image011.jpg.secure>

<image012.jpg.secure>

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---

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Thursday, February 27, 2020 10:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; McDonough, Kathleen A (HEALTH) <kathleen.mcdonough@health.ny.gov>; Egan, Christina T (HEALTH) <christina.egan@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Rakeman, Jennifer <(b) (6) @health.nyc.gov>; Hutton, Brad J (HEALTH) <(b) (6) @health.ny.gov>
**Subject:** Two pre-EUA questions....advice please

Hello Kim,
We are having an internal discussion at Wadsworth on strategy and need some advice please.
I am also copying this email to Dr. Jen Rakeman who directs the NYC lab as the answers will affect her strategy also.

(b)(4)

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(b)(4)

Could you advise (b)(4)

Thank you for your patience with us as we learn the FDA process.
Best wishes
Jill and Colleagues.

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/29/2020 9:18:41 AM
**To:** Beanan, Maureen J (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0873f9e5a4c34d8eb1ce164b6a19185c-HHS-beananm]; Humes, Rosemary (OS) (Rosemary.Humes@hhs.gov) [Rosemary.Humes@hhs.gov]
**CC:** Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** SARS-CoV-2 Extracted nucleic acid

**Importance:** High

Maureen and Rosemary,

I just heard that a shipment of SARS-CoV-2 extracted nucleic acid to (b)(4)

FDA supports the request o(b)(4) to obtain extracted nucleic acid from the reserved (b) ials set aside for FDA.

It is important that (b)(4) eceives this material today to perform testing.

FDA supports the request of (b)(4) o obtain extracted nucleic acid from the reserved (b) ials set aside for FDA.

Please let me know if you have any questions.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/29/2020 3:29:28 PM
**To:** Krueger, Brian [(b) (6)@LabCorp.com]
**Subject:** RE: RE: RE: LabCorp update

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Krueger, Brian <Kruegeb@LabCorp.com>
**Sent:** Saturday, February 29, 2020 3:28 PM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Burns, Ayla <(b) (6)@LabCorp.com>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: RE: LabCorp update

Hi Dr. Scherf,

Ayla's cell is below:
(b) (6)

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---

**From:** Krueger, Brian <(b) (6)@LabCorp.com>
**Sent:** Saturday, February 29, 2020 2:12:31 PM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Burns, Ayla <(b) (6) LabCorp.com>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: [External] RE: RE: LabCorp update

Hi Dr. Scherf,

I'm sorry I missed your call. We have a team at the lab working tomorrow to prepare samples in anticipation of receipt of this virus.

Ayla Burns
(b) (6)

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Phone: (b) (6)

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 1:41:25 PM
**To:** Krueger, Brian <(b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** [External] RE: RE: LabCorp update

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Brian and Marcia,

We have a courier who can ship material to you today. Important next step:
Can you receive material on Sunday? If yes
Where would it need to be shipped to.

I copied Rosemary Humes, she ahs close contact to BEI and has facilitated the process.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 1:41:25 PM
**To:** Krueger, Brian <(b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** [External] RE: RE: LabCorp update

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**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 1:41:25 PM
**To:** Krueger, Brian <(b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** [External] RE: RE: LabCorp update

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Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 9:45:21 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Saturday, February 29, 2020 9:42 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Dear Dr. Scherf,

This is confirmation of receipt of the letter, notifying Emergency Use Authorization of the New York State SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel.

Our sincere thanks. It has been an absolute pleasure working with you and your team.

With kind regards, Kirsten St. George

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george




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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:35 PM
**To:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

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Dear Drs. Taylor and St. George,

It is a pleasure to inform you that your submission for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issued an Emergency Use Authorization.

Attached please find the electronic version of the signed letter. Please confirm the receipt of the letter.

Congratulations, it has been a pleasure to work with you and your team.

Kind regards,
Uwe Scherf

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Saturday, February 29, 2020 6:02 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** RE: Material to discuss for 1 PM
**Importance:** High

Here is the new letter

Please let me know if it OK or if you need adjustments

AMERICAN OVERSIGHT

Best, Kirsten

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george




**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:09 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** RE: Material to discuss for 1 PM

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Dear Kirsten

Please find attached Draft EUA request cover letter you can use.

You can delete the hard copy part as you EUA submission is already logged in

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:56 PM
**To:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Material to discuss for 1 PM

Kristen,

We would like to go over the following documents with you during our 1 PM call:

Intended Use

Instructions for Use

And discuss the Fact Sheets

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 3/1/2020 11:38:56 AM
**To**: Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject**: RE: requesting SARS-CoV-2 genetic material

Himani,

Just to make sure, so they established a real assay defining a specimen type, an extraction method, and an instrument.

Uwe

---

**From:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 10:27 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: requesting SARS-CoV-2 genetic material

Yes, last time they responded saying that the have kits ready for shipping and they are ready for the required validation.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 8:22 AM
**To:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: requesting SARS-CoV-2 genetic material

Himani,

Are they ready to test for an EUA?

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:35 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara

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<Tamara.Feldblyum@fda.hhs.gov>
**Subject:** FW: requesting SARS-CoV-2 genetic material

ScienCell contacted (b) (4) for the virus material after our email. They copied me on their latest conversation with (b) (4)

I know ScienCell is on our priority list as they have CDC like assay for commercial distribution. Does (b) (4) have companies names from us? It appears so from their email , please see below.

Can we help ScienCell to receive the material for their validation studies.

Best,
Himani

---

**From:** (b) (4)
**Sent:** Friday, February 28, 2020 5:49 PM
**To:** Daniel Li <yli@sciencellonline.com>; Woodson, Sara E (NIH) <sara.woodson@nih.gov>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** Re: requesting SARS-CoV-2 genetic material

Hello Daniel, thank you.

Sara, can you please confirm that this group is to receive from the allotment made for the FDA? If not I will send a different preparation.

(b) (4)

---

**From:** Daniel Li <yli@sciencellonline.com>
**Sent:** Friday, February 28, 2020 4:30 PM
**To:** (b) (4)
**Cc:** 'Bisht, Himani' <Himani.Bisht@fda.hhs.gov>
**Subject:** requesting SARS-CoV-2 genetic material

**WARNING:** This email originated from outside of (b) (4) email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear (b) (4) ,

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Thank you for taking my call regarding the availability of SARS-Cov-2 genetic material. Per our conversation, I hereby send you a confirmation email that we would like to get an aliquot of SARS-Cov-2 genetic material from(b) (4) Since we are actively working with FDA on an EUA application, I include Dr. Himani Bisht in the conversation.

Please kindly instruct us on how to proceed.

Best regards,
Daniel

**Yongjiang Daniel Li, PhD**
ASSOCIATE DIRECTOR, MOLECULAR BIOLOGY DIVISION

ScienCell Research Laboratories

ScienCell Research Laboratories
1610 Faraday Ave I Carlsbad, CA 92008
(760) 602-8549 x(b) (6)**Direct** I (b) (6)
yli@sciencellonline.com I www.sciencellonline.com




AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/28/2020 11:20:31 AM
**To:** Hwang, Leroy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5da97657ec944cebf943616bd848105-Leroy.Hwang]
**Subject:** FW: RUO Logix Smart 2019-nCoV Kit

You are right, no phone number, sorry for the confusion. Uwe

---

**From:** Cecilia Hutchins <(b) (6) @codiagnostics.com>
**Sent:** Wednesday, February 26, 2020 6:35 PM
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>; Chad Apuli <(b) (6)@codiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>; Andrew Benson <(b) (6)@codiagnostics.com>
**Subject:** Re: RUO Logix Smart 2019-nCoV Kit

Dr. Hwang,

I'm sorry to hear that the FDA still has concerns about the previous press releases.
We have been trying our best to be in compliance with the federal regulations.
We also understand that there is a lot of misunderstanding in the general public nowadays than in the normal operations of the IVD industry.
The review process for updates to the website has become more lengthy with the newly implemented process.
Please, allow us some time to discuss internally and provide a more accurate answer to the raised concerns.
I'll be able to provide the answer and hopefully have all corrective actions completed by Friday.

Sincerely,

**Cecilia Hutchins | Head of Regulatory Affairs**

***Tailor-Made Life Saving Solutions***
**2401 S. Foothill Dr., Suite D**
**Salt Lake City, Utah 84109**
**www.codiagnostics.com**
(b) (6) @codiagnostics.com

---

**From:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 10:25 AM
**To:** Cecilia Hutchins <(b) (6) @codiagnostics.com>; Chad Apuli <(b) (6)@codiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>; Andrew Benson <(b) (6)@codiagnostics.com>
**Subject:** RUO Logix Smart 2019-nCoV Kit

Ms. Hutchins,

AMERICAN OVERSIGHT

In review of the information provided, we still have some remaining concerns with regards to News Releases that are still accessible through your firm's website. Specifically, the February 6, 2020, and February 10, 2020 News releases that were highlighted previously are still accessible and still contain statements which are of concern to FDA. We realize that these statements were made in the past, prior to FDA communication with your firm, so the statements made by representatives of your company cannot be changed. However, we would request that you either remove reference to the previous news releases from your firm's website, or add a disclaimer statement to include as part of those previous news releases that the products are for Research Use Only (in the U.S.) and Not for use in diagnostic procedures.

From our review of the updated information on your firm's website, it also appears that Co-Diagnostics has recently (February 24, 2020) announced CE-IVD mark for the Logix Smart COVID-19 Test. So as to prevent confusion from U.S. customers, we would also recommend that you clearly indicate that this product is available for Export only and not currently available in the U.S. We would request that you add this disclaimer statement to future press releases or statements regarding the CE-IVD product until a EUA is granted for the U.S.

We request that you provide an updated list of planned corrective actions to address these remaining issues to us by Friday, February 28, 2020. If you would like to discuss specific proposals for wording for your updates, we would be happy to review through email or discuss over the phone.

We thank you for your cooperation in addressing these concerns and we look forward to your pre-EUA submission for your test. Please let me know if you have any questions regarding this communication.

Sincerely,

**Leroy N. Hwang, Ph.D.**
*Team Lead, Post-market Compliance Group*

Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3266 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (240) 402-6427
leroy.hwang@fda.hhs.gov






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---

**From:** Cecilia Hutchins <(b) (6) @codiagnostics.com>
**Sent:** Friday, February 14, 2020 5:07 PM
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>; Chad Apuli <(b) (6)@codiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>; Andrew Benson <(b) (6) @codiagnostics.com>
**Subject:** Re: RUO Logix Smart 2019-nCoV Kit - request for teleconference

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Dear Dr. Hwang,

See enclosed our response to the raised concerns about the labeling of Logix Smart 2019-nCoV.
I hope our response, and actions taken and planned to suffice on correcting and preventing this issue from happening in the future.
I can provide an update once all planned actions are completed.

Sincerely,

**Cecilia Hutchins | Regulatory Liaison**

***Tailor-Made Life Saving Solutions***
**2401 S. Foothill Dr., Suite D**
**Salt Lake City, Utah 84109**
**www.codiagnostics.com**
(b) (6) **@codiagnostics.com**

---

**From:** Cecilia Hutchins <(b) (6) @codiagnostics.com>
**Sent:** Tuesday, February 11, 2020 2:18 PM
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>; Chad Apuli <(b) (6)@codiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>
**Subject:** Re: RUO Logix Smart 2019-nCoV Kit - request for teleconference

Dear Leroy,

Thank you for bringing these issues to us, as we discussed in the teleconference, our intentions were never to violate the federal regulations.
We'll take the following actions:

- Work on the corrective actions immediately to fix and clarify the discussed concerns.
- Plan the necessary actions to prevent this issue from happening in the future.

We'll submit the list of corrective and preventive actions as soon as possible and before Friday, the 14th.
Again, I would like to thank you for bringing this issue to our attention, as a startup and small company we have a serious commitment to improving our processes and compliance with the federal regulations. This feedback exchange is very valuable to us.

Sincerely,

**Cecilia Hutchins | Regulatory Liaison**

***Tailor-Made Life Saving Solutions***
**2401 S. Foothill Dr., Suite D**
**Salt Lake City, Utah 84109**
**www.codiagnostics.com**
(b) (6) **@codiagnostics.com**

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**From:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 1:26 PM
**To:** Chad Apuli <(b) (6)@codiagnostics.com>; Cecilia Hutchins <(b) (6) @codiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>
**Subject:** RE: RUO Logix Smart 2019-nCoV Kit - request for teleconference

Cecilia and Chad,

Please find below the summary of today's (02/11/2020) teleconference.

FDA acknowledges that Co-Diagnostics have requested the Pre-EUA template (on 2/1/2020) and are working with the premarket review team. But as indicated in the email your firm has received from FDA with the EUA template:
"Please be reminded that in the U.S. a test for the detection of 2019-nCoV or to diagnose 2019-nCoV infection must not be distributed and/or used for clinical diagnosis without premarket clearance, approval, or EUA by the FDA."

In review of the Website information regarding the RUO Logix Smart 2019-nCoV Kit product and News releases on your firm's website, FDA has identified a number of concerns with regards to the statements made with respect to this product, which appear inconsistent with Research Use Only (RUO) products. As a reminder, **Per 21CFR809.10(c)(i)** - For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: **"For Research Use Only. Not for use in diagnostic procedures."**

For more information regarding RUO products, please find the link to the FDA guidance on this subject.
https://www.fda.gov/media/87374/download

Specific concerns include:

Website for the RUO Logix Smart 2019-nCoV Kit product states –

- current features – "CoPrimer technology has shown enhanced specificity when compared to other products on the market." – specificity implies a performance claim.
- current features – "Components are sold for Research Use Only to appropriate customers, to meet the needs of the emergency market." – inconsistent with research use only and implies use for screening/diagnosis
- Intended Use – "The kit is available for Research Use Only and is not licensed for diagnostic procedures." - Inconsistent with 809.10(c)(i) which requires labeling bear the following statement, prominently placed, "**For Research Use Only. Not for use in diagnostic procedures.**"

News release (2/6/2020) statements -

- "(RUO) CoPrimer test for the 2019-nCoV coronavirus is ready for sale to appropriate laboratories, hospitals, and institutions in need of a solution to the current coronavirus epidemic." – implies use for diagnostic/screening purposes, not laboratory research.
- "Co-Diagnostics believes that the test's unique design will provide enhanced accuracy when detecting the presence of the coronavirus, including improved specificity over tests designed on a different platform." – specificity/performance claim.

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- "Increased specificity is one of the hallmarks of tests build using our patented CoPrimer platform." – performance claim.
- "Sales and shipments of products will be fulfilled…to customers who have the capacity to utilize RUO to slow the spread of this epidemic." – suggests use for diagnostic/screening purposes.

News release (2/10/2020) statements –

- "Co-Diagnostics, Inc.…announced today sales of its screening test designed to identify the presence of the novel coronavirus. – implies use for screening purposes.
- "We are pleased to be able to offer a product to this market that excels in being both sensitive and specific, the two benchmarks for accuracy in molecular diagnostics." – performance claims and implies use for diagnostic purposes.
- "We believe the way that Co-Diagnostics can be most helpful in this ongoing situation is by providing diagnostic solutions that are affordable and accessible in any market in the world." – Implies diagnostic use for RUO.
- "Doing so also provides a compelling proof-of-concept that the Company's unique process and patented technology could quickly and efficiently be applied to address the diagnostic needs associated with other emergencies, including potential mutations of the coronavirus." – implies diagnostic use

As clarified on the call, although some of the statements made are not specifically citing the RUO Logix Smart 2019-nCoV Kit product, when statements are made in association with a press release regarding the product or associated with the product on your firm's website, it links the claim to use of the RUO product.

We request that your firm take immediate corrective action to resolve these identified concerns and identify actions to avoid future issues with regards to the RUO Logix Smart 2019-nCoV coronavirus product and its labeling. We ask that you provide a list of planned actions to address these concerns by Friday, February 14, 2020.

Please also note that under the current HHS EUA declaration, LDTs should not be used for clinical diagnoses without FDA's approval, clearance, or authorization during an emergency declaration. For more information, please find links to information regarding EUA below. **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua**

Please let me know if you have any questions.

Sincerely,

**Leroy N. Hwang, Ph.D.**
*Team Lead, Post-market Compliance Group*

Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3266 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (240) 402-6427
leroy.hwang@fda.hhs.gov




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**From:** Chad Apuli <(b) (6)@codiagnostics.com>
**Sent:** Tuesday, February 11, 2020 2:01 PM
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>; Cecilia Hutchins <(b) (6) @codiagnostics.com>
**Subject:** Re: RUO Logix Smart 2019-nCoV Kit - request for teleconference

Leroy,

We will be able to meet at 12:30 MST (2:30 EST). Here is the GoToMeeting info. We look forward to talking with you.

Co-Diagnostics and FDA 2019-nCoV Meeting
Tue, Feb 11, 2020 12:30 PM - 1:00 PM (MST)

**Please join my meeting from your computer, tablet or smartphone.**
https://global.gotomeeting.com/join/443045253

**You can also dial in using your phone.**
United States: +1 (872) 240-3412

**Access Code:** (b) (6)

New to GoToMeeting? Get the app now and be ready when your first meeting starts:
https://global.gotomeeting.com/install/443045253

Thanks,
Chad

---

**From:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 11:22 AM
**To:** Chad Apuli <(b) (6) @codiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>; Cecilia Hutchins <(b) (6) @codiagnostics.com>
**Subject:** RE: RUO Logix Smart 2019-nCoV Kit - request for teleconference

Chad,

Thanks for the quick response. When you have arranged for the time for the call on your side, please just let us know and send the call-in number for us.

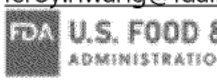
Sincerely,

AMERICAN OVERSIGHT

**Leroy N. Hwang, Ph.D.**
*Team Lead, Post-market Compliance Group*

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---

**From:** Chad Apuli <(b) (6)@codiagnostics.com>
**Sent:** Tuesday, February 11, 2020 1:21 PM
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>; info <info@codiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>; Cecilia Hutchins <(b) (6) @codiagnostics.com>
**Subject:** Re: RUO Logix Smart 2019-nCoV Kit - request for teleconference

Dr. Hwang,

Thanks for reaching out. I apologize as Cecilia's son is sick, and she is currently at a Dr.'s appointment with him. We should be able to have the call soon, but I'll respond shortly with a specific time.

Again, my apologies.

Regards,

Chad

---

**From:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 11:14 AM
**To:** Chad Apuli <(b) (6) @codiagnostics.com>; info <info@codiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Thornton, Keith <Keith.Thornton@fda.hhs.gov>; Cecilia Hutchins <(b) (6) @codiagnostics.com>
**Subject:** FW: RUO Logix Smart 2019-nCoV Kit - request for teleconference

Mr. Apuli,

We had previously reached out to your colleague Ms. Hutchins with regards to a request for a teleconference with your firm. We have yet to receive any responses with regards to this request. Could you please contact us to arrange for this discussion. Again we are available for discussion between now (1.15pm) and 3pm EST.

AMERICAN OVERSIGHT

Sincerely,

**Leroy N. Hwang, Ph.D.**
*Team Lead, Post-market Compliance Group*

Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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leroy.hwang@fda.hhs.gov





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---

**From:** Hwang, Leroy
**Sent:** Tuesday, February 11, 2020 9:53 AM
**To:** '(b) (6) @codiagnostics.com' <(b) (6) @codiagnostics.com>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RUO Logix Smart 2019-nCoV Kit - request for teleconference

Ms. Hutchins,

In review of your firm's website and News release statements regarding the Research Use Only (RUO) Logix Smart 2019-nCoV coronavirus test, we have some concerns regarding your firm's statements which have been made regarding this product in the context of the current HHS Emergency Use Authorization (EUA) declaration. We would request a teleconference this afternoon to discuss our concerns. We are available between the hours of 12.30pm and 3.00pm EST. Please let us know your availability for this discussion.

Sincerely,

**Leroy N. Hwang, Ph.D.**
*Team Lead, Post-market Compliance Group*

Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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leroy.hwang@fda.hhs.gov



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 10:59:36 AM
**To**: Plante, Kenneth S. [ksplante@UTMB.EDU]; Chiu, Charles [Charles.Chiu@ucsf.edu]; Weaver, Scott [sweaver@UTMB.EDU]; Lawal, Adeola [adlawal@UTMB.EDU]; Plante, Jessica A. [japlante@UTMB.EDU]; Newton, Je t'aime M. [jmnewton@utmb.edu]; Brocard, Anne-Sophie [anbrocar@utmb.edu]; Woodson, Sara E (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=943c7f4ea27947828174a33d354394e1-HHS-sara.wo]; Mirchandani, Divya [dimircha@UTMB.EDU]; Scharton, Dionna [dischart@UTMB.EDU]; Blakeman, David S. [dsblakem@UTMB.EDU]
**CC**: Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: SARS-CoV-2-CRISPR diagnostic assay -- request for quantified COVID-19 RNA for FDA EUA approval

Dear Kenneth,

I authorize to send you (b) vials of genetic material from the FDA lot to Dr. Charles Chiu, M.D./Ph.D.
Professor, Laboratory Medicine and Medicine / Infectious Diseases Director, UCSF-Abbott Viral Diagnostics and Discovery Center

Please let me know if you have any questions.

Thanks,

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Plante, Kenneth S. <ksplante@UTMB.EDU>
**Sent:** Saturday, February 29, 2020 10:44 AM
**To:** Chiu, Charles <Charles.Chiu@ucsf.edu>; Weaver, Scott <sweaver@UTMB.EDU>; Lawal, Adeola <adlawal@UTMB.EDU>; Plante, Jessica A. <japlante@UTMB.EDU>; Newton, Je t'aime M. <jmnewton@utmb.edu>; Brocard, Anne-Sophie <anbrocar@utmb.edu>; Woodson, Sara E (NIH) <(b) (6) @nih.gov>; Mirchandani, Divya <dimircha@UTMB.EDU>; Scharton, Dionna <dischart@UTMB.EDU>; Blakeman, David S. <dsblakem@UTMB.EDU>
**Cc:** Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: SARS-CoV-2-CRISPR diagnostic assay -- request for quantified COVID-19 RNA for FDA EUA approval

The paperwork will come from Ade.

Ken

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Kenneth Plante PhD.
Associate Director, Curator

World Reference Center for Emerging Viruses and Arboviruses
Department of Microbiology and Immunology
University of Texas Medical Branch
301 University Blvd. Rte. 0609
Galveston, TX 77555
O-(409) 747-2432
C-(b) (6)
F-(409) 747-2429
https://www.utmb.edu/wrceva/

---

**From:** Chiu, Charles <Charles.Chiu@ucsf.edu>
**Sent:** Saturday, February 29, 2020 9:39 AM
**To:** Plante, Kenneth S. <ksplante@UTMB.EDU>; Weaver, Scott <sweaver@UTMB.EDU>; Lawal, Adeola <adlawal@UTMB.EDU>; Plante, Jessica A. <japlante@UTMB.EDU>; Newton, Je t'aime M. <jmnewton@utmb.edu>; Brocard, Anne-Sophie <anbrocar@utmb.edu>; Woodson, Sara (NIH/NIAID) [E] <sara.woodson@nih.gov>; Mirchandani, Divya <dimircha@UTMB.EDU>; Scharton, Dionna <dischart@UTMB.EDU>; Blakeman, David S. <dsblakem@UTMB.EDU>
**Cc:** Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; uwe.scherf@fda.hhs.gov <uwe.scherf@fda.hhs.gov>
**Subject:** Re: SARS-CoV-2-CRISPR diagnostic assay -- request for quantified COVID-19 RNA for FDA EUA approval

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Hi Kenneth,

Thanks for your call and prompt reply! I don't see the attached forms – can you send them again?

I am also cc'ing Dr. Joseph Briggs and Dr. Uwe Scherf from the FDA as an FYI.

Thanks,
Charles

---

Dr. Charles Chiu, M.D./Ph.D.
Professor, Laboratory Medicine and Medicine / Infectious Diseases
Director, UCSF-Abbott Viral Diagnostics and Discovery Center
Associate Director, UCSF Clinical Microbiology Laboratory
UCSF School of Medicine
(415) 514-8219 (office)
(b) (6) (cell)
charles.chiu@ucsf.edu (e-mail)

---

---

**From:** "Plante, Kenneth S." <ksplante@UTMB.EDU>
**Date:** Saturday, February 29, 2020 at 7:28 AM
**To:** Charles Chiu <Charles.Chiu@ucsf.edu>, "Weaver, Scott" <sweaver@UTMB.EDU>, "Lawal, Adeola" <adlawal@UTMB.EDU>, "Plante, Jessica A." <japlante@UTMB.EDU>, "Newton, Je t'aime M." <jmnewton@utmb.edu>, "Brocard, Anne-Sophie" <anbrocar@utmb.edu>, "Woodson, Sara (NIH/NIAID) [E]" <(b) (6)@nih.gov>, "Mirchandani, Divya" <dimircha@UTMB.EDU>, "Scharton, Dionna" <dischart@UTMB.EDU>, "Blakeman, David S." <dsblakem@UTMB.EDU>
**Subject:** Re: SARS-CoV-2-CRISPR diagnostic assay -- request for quantified COVID-19 RNA for FDA EUA approval

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Hello Charles,

We would be happy to send you (b) (4) vials of genetic material. Sara I am setting aside 2 of the FDA lot initially but I need clarification ASAP

Charles, please fill these forms out in their entirety and return them to everyone in this email chain.

Thanks

Kenneth Plante PhD.
Associate Director, Curator
World Reference Center for Emerging Viruses and Arboviruses
Department of Microbiology and Immunology
University of Texas Medical Branch
301 University Blvd. Rte. 0609
Galveston, TX 77555
O-(409) 747-2432
(b) (6)
F-(409) 747-2429
https://www.utmb.edu/wrceva/

---

**From:** Chiu, Charles <Charles.Chiu@ucsf.edu>
**Sent:** Saturday, February 29, 2020 9:13 AM
**To:** Plante, Kenneth S. <ksplante@UTMB.EDU>
**Subject:** SARS-CoV-2-CRISPR diagnostic assay -- request for quantified COVID-19 RNA for FDA EUA approval

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Dear Dr. Plante,

We have developed a SARS-CoV-2 CRISPR-Cas12 based assay to diagnose COVID-19 infection in 30 minutes. We are looking to obtain quantified viral RNA to use in spiking studies in support of an FDA EUA application (please see correspondence below). Can you send us some quantified viral RNA? We urgently need additional diagnostic tests for COVID-19 especially given the recent cases of community transmission here in California.

I can be reached anytime at (b) (6) cell / text) or (b) (6) (pager).

Thanks for your consideration.

Best regards,
Charles

---

Dr. Charles Chiu, M.D./Ph.D.
Professor, Laboratory Medicine and Medicine / Infectious Diseases
Director, UCSF-Abbott Viral Diagnostics and Discovery Center
Associate Director, UCSF Clinical Microbiology Laboratory
UCSF School of Medicine
(415) 514-8219 (office)
(b) (6) (cell)
charles.chiu@ucsf.edu (e-mail)

---

AMERICAN OVERSIGHT

**From:** Chiu, Charles <Charles.Chiu@ucsf.edu>
**Sent:** Friday, February 28, 2020 4:27 PM
**To:** Wayne Deng <(b) (6) >; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>
**Cc:** Deng, Xian Ding <(b) (6) @ucsf.edu>
**Subject:** Re: SARS-CoV-2-CRISPR diagnostic assay white paper
**Importance:** High

Hi Joe,

Can you share some RNA with us? We aren't registered as level 3 yet with BEI. How else do you recommend that we get the COVID-19 RNA?

Thanks,
Charles

---

Dr. Charles Chiu, M.D./Ph.D.
Professor, Laboratory Medicine and Medicine / Infectious Diseases
Director, UCSF-Abbott Viral Diagnostics and Discovery Center
Associate Director, UCSF Clinical Microbiology Laboratory
UCSF School of Medicine
(415) 514-8219 (office)
(b) (6)
charles.chiu@ucsf.edu (e-mail)

---

**From:** Wayne Deng <(b) (6) @gmail.com>
**Date:** Friday, February 28, 2020 at 12:51 PM
**To:** Charles Chiu <Charles.Chiu@ucsf.edu>
**Cc:** Xian Ding Deng <(b) (6) Deng@ucsf.edu>
**Subject:** Re: SARS-CoV-2-CRISPR diagnostic assay white paper

It needs level 2, DONT know how long take to upgrade to level 2.

Can you get some RNA aliquot from Joe?

Wayne

Sent from my iPhone

On Feb 28, 2020, at 6:11 AM, Chiu, Charles <Charles.Chiu@ucsf.edu> wrote:

hi Wayne - can we order the extracted RNA ASAP from Bei?

Thanks,
Charles

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Sent from my iPhone

Begin forwarded message:

**From:** "Briggs, Joseph" <Joseph.Briggs@fda.hhs.gov>
**Date:** February 28, 2020 at 5:52:28 AM PST
**To:** "Chiu, Charles" <Charles.Chiu@ucsf.edu>
**Cc:** "Scherf, Uwe" <Uwe.Scherf@fda.hhs.gov>, Rachel Nosowsky <(b) (6) @ucop.edu>, Janice Chen <(b) (6)@mammothbiosci.com>, Janice Chen <(b) (6) @mammoth.bio>
**Subject: RE: SARS-CoV-2-CRISPR diagnostic assay white paper**

Hi Charles,

I have the following updated information for the Pre-EUA template and sources of extracted viral RNA. If you have trouble acquiring the material please let us know:

Due to the limited availability of CDC reagents for the detection of SARS-CoV2 (2019-nCoV) and the growing need for testing suspected cases of the COVID-19, FDA revised the study designs required to support an EUA submission for tests intended for the detection of SARS-CoV2.
The current minimum requirements for demonstrating the performance of the new assays are:

1. Analytical Sensitivity (LoD) using viral genomic RNA or inactivated virus preferably in clinical matrix as described in the EUA Template (if BSL-3 facilities are available live virus can also be used in this study). If viral genomic RNA is used in the LoD study, the clinical or simulated matrix should be mixed with the lysis buffer from the extraction kit validated for use with your test prior to the addition of RNA to mitigate the risk of RNA degradation in clinical or simulated matrix. The sample to lysis buffer ratio should be the same as when extracting and purifying nucleic acids from clinical specimens. The volume of the initial viral genomic RNA dilutions used to build the contrived specimens for testing should be kept as low as possible to maximumly preserve the characteristics of the natural clinical specimen matrixes. If lysis buffer is not used for your assay, then other methods to prevent RNA degradation may be helpful (e.g., use of RNasin). For the initial dilution of viral genomic RNA, the diluent should be able to maintain RNA stability e.g., using certified RNase-free consumables and reagents, carrier RNA or tRNA, etc.

2. Reactivity/Inclusivity as described in the EUA Template

3. Analytical Specificity studies as described in the EUA Template

4. Matrix Equivalency Study (if applicable)

5. Comparative LoD of your comparator assay if testing natural clinical samples as described in the EUA Template

6. Specimen stability and fresh vs. frozen studies (if applicable)

7. Clinical Evaluation – Contrived clinical study: You should test 50 negative and 50 positive contrived clinical samples. The samples should be prepared by spiking SARS-CoV2 viral RNA or inactivated virus into individual clinical specimens collected from patients with signs and symptoms of respiratory infection (if BSL-3 facilities are available live virus can also be used to prepare contrived clinical samples). Left-over archived specimens may be used to prepare the mock clinical samples. Half (25) of the contrived positive samples should be prepared by spiking the SARS-CoV2 at 1X – 2x LoD and the remaining contrived positive samples should span the testing range of your assay and not higher than 5x LoD. Consider mixing the clinical matrix with the lysis buffer from the extraction kit validated for use with your test prior to the addition of viral RNA to mitigate the risk of RNA degradation. The sample to lysis buffer ratio should be the same as when extracting and purifying nucleic acids from clinical specimens. The volume of the initial viral genomic RNA

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dilutions used to build the contrived clinical specimens for testing should be kept as low as possible to maximumly preserve the characteristics of the natural clinical specimen matrix.

For a source of extracted viral RNA please contact:

Kenneth Plante PhD.
Associate Director, Curator
World Reference Center for Emerging Viruses and Arboviruses
Department of Microbiology and Immunology
University of Texas Medical Branch
301 University Blvd. Rte. 0609
Galveston, TX 77555
O-(409) 747-2432
C-(b) (6)
F-(409) 747-2429
https://www.utmb.edu/wrceva/

Please also find attached information for extracted viral RNA from BEI.

Best regards,

Joe

---

**From:** Chiu, Charles <Charles.Chiu@ucsf.edu>
**Sent:** Thursday, February 27, 2020 8:44 PM
**To:** Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rachel Nosowsky <Rachel.Nosowsky@ucop.edu>; Janice Chen <(b) (6)@mammothbiosci.com>; Janice Chen <(b) (6)@mammoth.bio>
**Subject:** Re: SARS-CoV-2-CRISPR diagnostic assay white paper
**Importance:** High

Dear Joe and Uwe,

Thanks for the conversation and the initial feedback! I am wondering what you additional items you need from us to move forward with a potential FDA EUA application?

https://mammoth.bio/2020/02/15/white-paper-a-protocol-for-rapid-detection-of-sars-cov-2-using-crispr-sars-cov-2-detectr/

Here are 2 immediate questions that I have –

(b)(4)

I'm also cc'ing Rachel Nosowsky from UCOP and Janice Chen from Mammoth Biosciences, Inc. regarding this.

Best regards,
Charles

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---

Dr. Charles Chiu, M.D./Ph.D.
Professor, Laboratory Medicine and Medicine / Infectious Diseases
Director, UCSF-Abbott Viral Diagnostics and Discovery Center
Associate Director, UCSF Clinical Microbiology Laboratory
UCSF School of Medicine
(415) 514-8219 (office)
(b) (6) cell)
charles.chiu@ucsf.edu (e-mail)

---

**From:** "Briggs, Joseph" <Joseph.Briggs@fda.hhs.gov>
**Date:** Thursday, February 27, 2020 at 5:37 PM
**To:** Charles Chiu <Charles.Chiu@ucsf.edu>
**Cc:** "Scherf, Uwe" <Uwe.Scherf@fda.hhs.gov>
**Subject:** SARS-CoV-2-CRISPR diagnostic assay white paper

Hi Charles,

It was a pleasure speaking with you today regarding the exciting work you're doing to develop a SARS-CoV-2-CRISPR diagnostic assay. We would greatly appreciate if you could send us the white paper you mentioned on our phone call earlier today. We will be in touch shortly with information about the extracted viral RNA we discussed.

Best,

Joe
**Joseph Briggs, Ph.D.**
*Scientific Reviewer*

**DMD: Division of Microbiology Devices | OHT7: Office of *In Vitro* Diagnostics and Radiological Health**
**Office of Product Evaluation and Quality**
**CDRH | Food and Drug Administration**
**White Oak, Bldg. 66, Rm. 3274 | 10903 New Hampshire Avenue | Silver Spring, MD 20993**

Tel: 240-402-7942
Joseph.Briggs@fda.hhs.gov

<image001.png>

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<BEI-SARS-CoV2 Info.pdf>
<BEI_PI for SARS-CoV2.pdf>

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 3/1/2020 10:03:14 PM
**To:** St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** FW: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Don,

Here the numbers to track for the Wadsworth EUA. If you DPOM can take care of these tracking that will free the burden of the reviewer tremendously.

Current capacity at the Wadsworth Center for SARS-CoV-2 real-time RT-PCR testing is (b)(4) specimens per week.

We will be working in the coming weeks to enhance that with some additional automation, with the goal to increase capacity to (b)(4) per week. That is our capacity for influenza testing.

Thanks, Uwe

---

**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Saturday, February 29, 2020 10:15 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Subject:** RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Dear Dr. Stenzel,

Current capacity at the Wadsworth Center for SARS-CoV-2 real-time RT-PCR testing is (b)(4) specimens per week.

We will be working in the coming weeks to enhance that with some additional automation, with the goal to increase capacity to (b)(4) per week. That is our capacity for influenza testing.

Kind regards, Kirsten

AMERICAN OVERSIGHT

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george




---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:54 PM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

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Drs. Taylor and St. George,

You are most welcome! We are curious, what is your lab's weekly capacity for Coronavirus test volume? We are trying to keep track of this number nationwide.

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Saturday, February 29, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Thank you so much Uwe. Being able to work with you and your FDA colleagues has been a privilege. We are grateful that the FDA is with us as we work to protect our citizens.
Very best wishes,
Jill

Sent from my iPhone

On Feb 29, 2020, at 9:35 PM, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov> wrote:

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Drs. Taylor and St. George,

It is a pleasure to inform you that your submission for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issued an Emergency Use Authorization.

Attached please find the electronic version of the signed letter. Please confirm the receipt of the letter.

Congratulations, it has been a pleasure to work with you and your team.

Kind regards,
Uwe Scherf

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Saturday, February 29, 2020 6:02 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara

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<Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** RE: Material to discuss for 1 PM
**Importance:** High

Here is the new letter

Please let me know if it OK or if you need adjustments

Best, Kirsten

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george

<image001.png.secure>

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:09 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** RE: Material to discuss for 1 PM

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Kirsten

Please find attached Draft EUA request cover letter you can use.

You can delete the hard copy part as you EUA submission is already logged in

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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<image007.jpg.secure>

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:56 PM
**To:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Material to discuss for 1 PM

Kristen,

We would like to go over the following documents with you during our 1 PM call:

Intended Use

Instructions for Use

And discuss the Fact Sheets

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

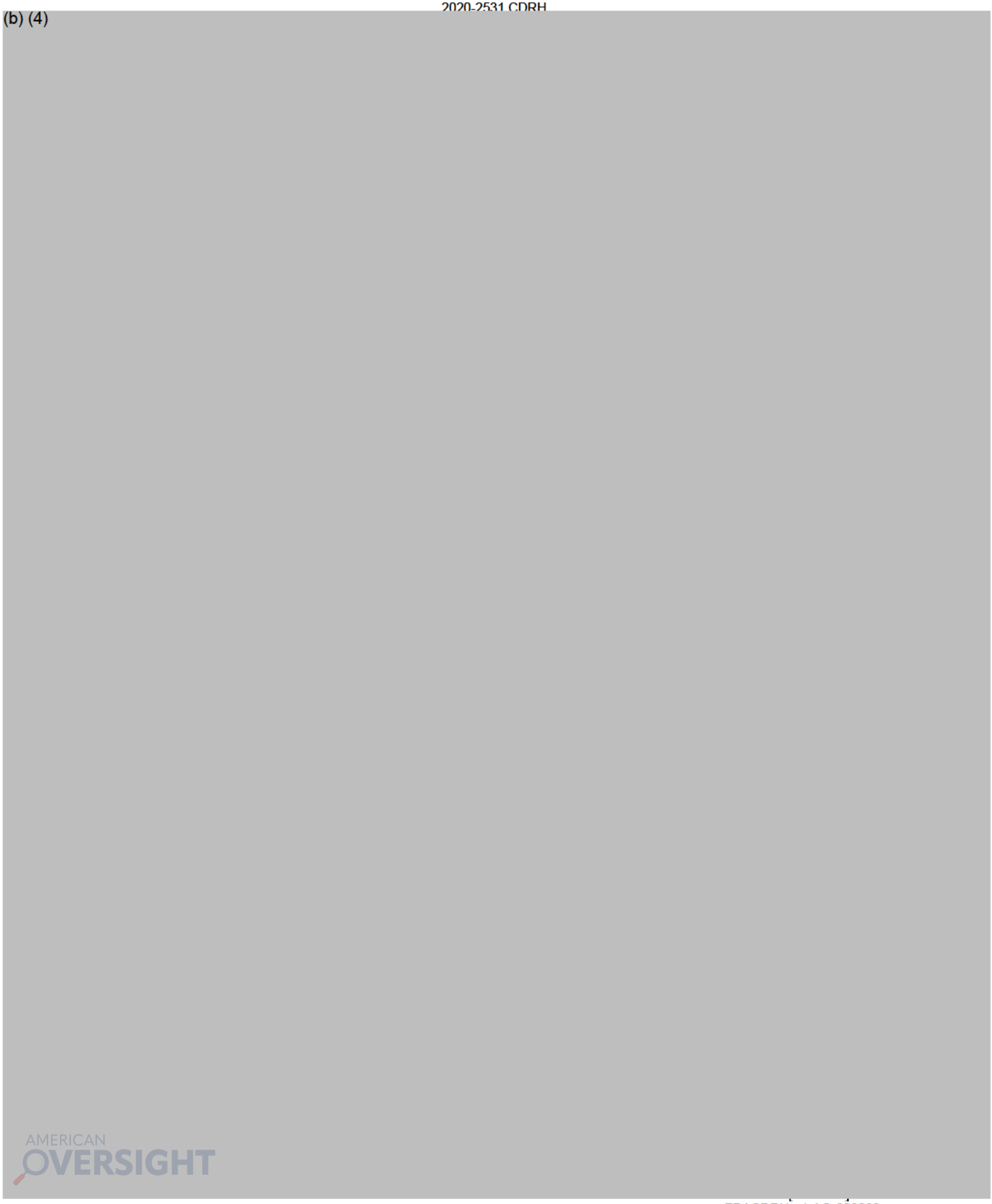
OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

<NYS DOH EUA Letter of Authorization 02292020 FINAL.pdf.secure>

AMERICAN OVERSIGHT

(b) (4)



AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

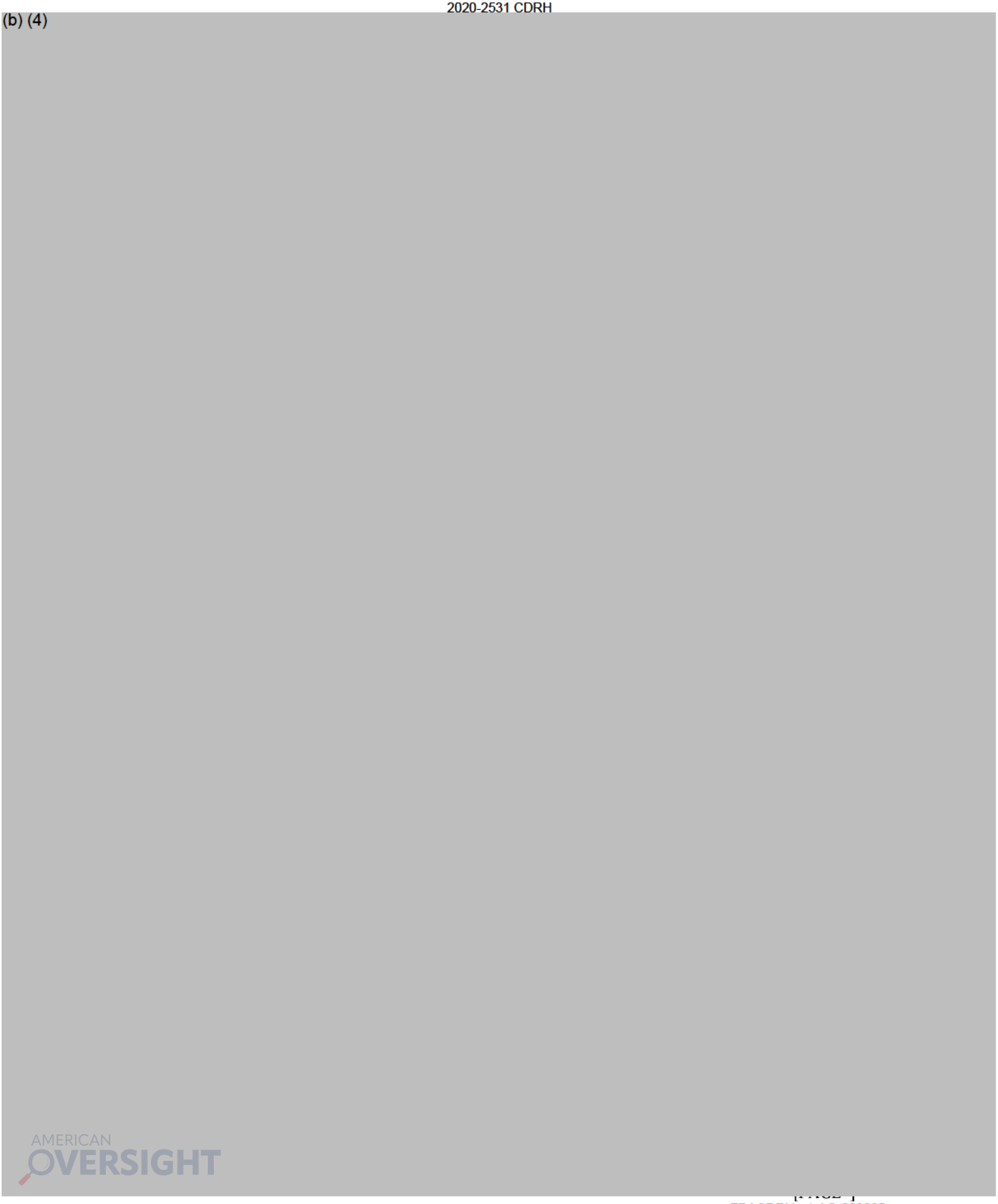
(b) (4)

AMERICAN OVERSIGHT

(b) (4)

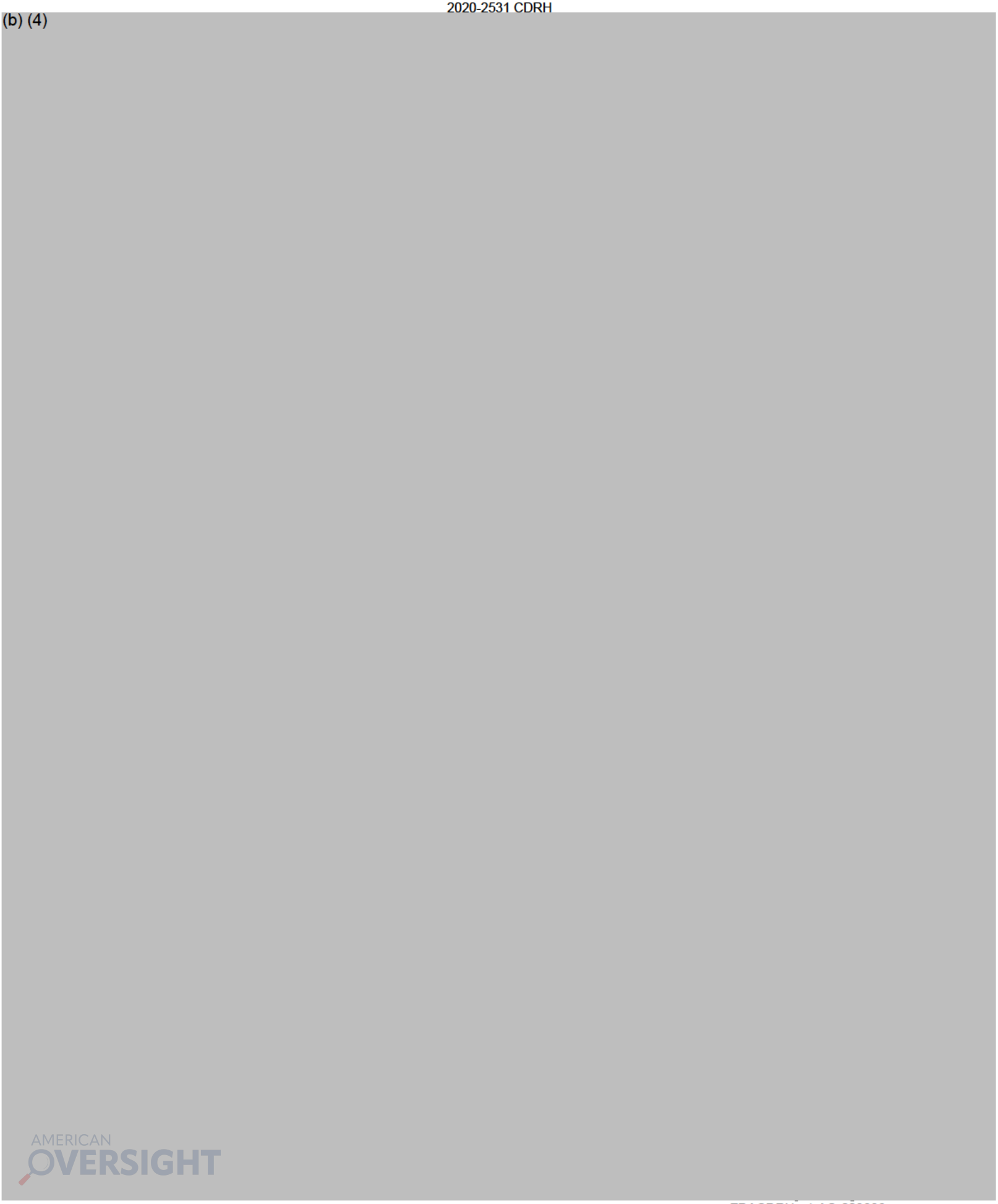
AMERICAN OVERSIGHT

(b) (4)



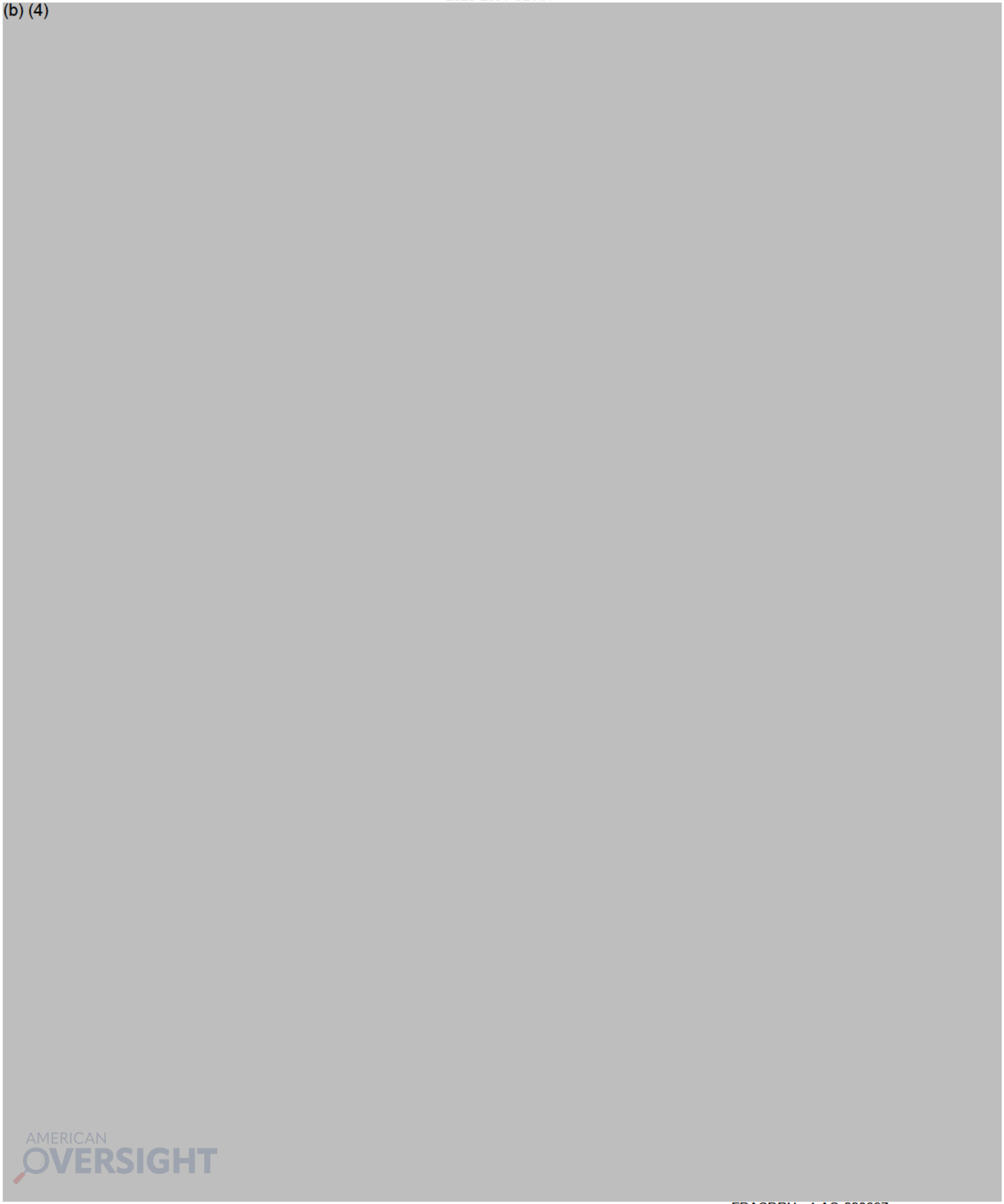
AMERICAN OVERSIGHT

(b) (4)



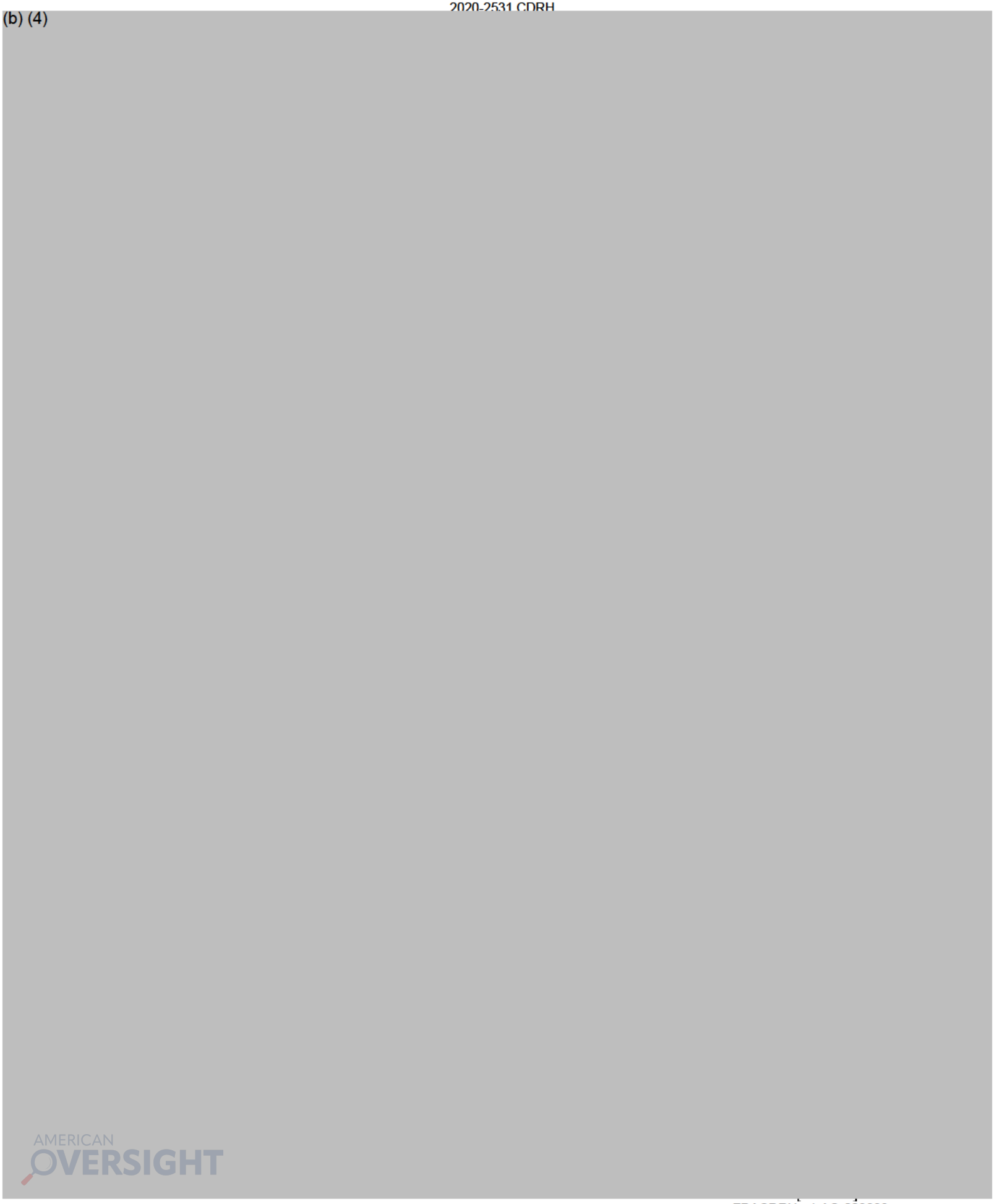
AMERICAN OVERSIGHT

(b) (4)



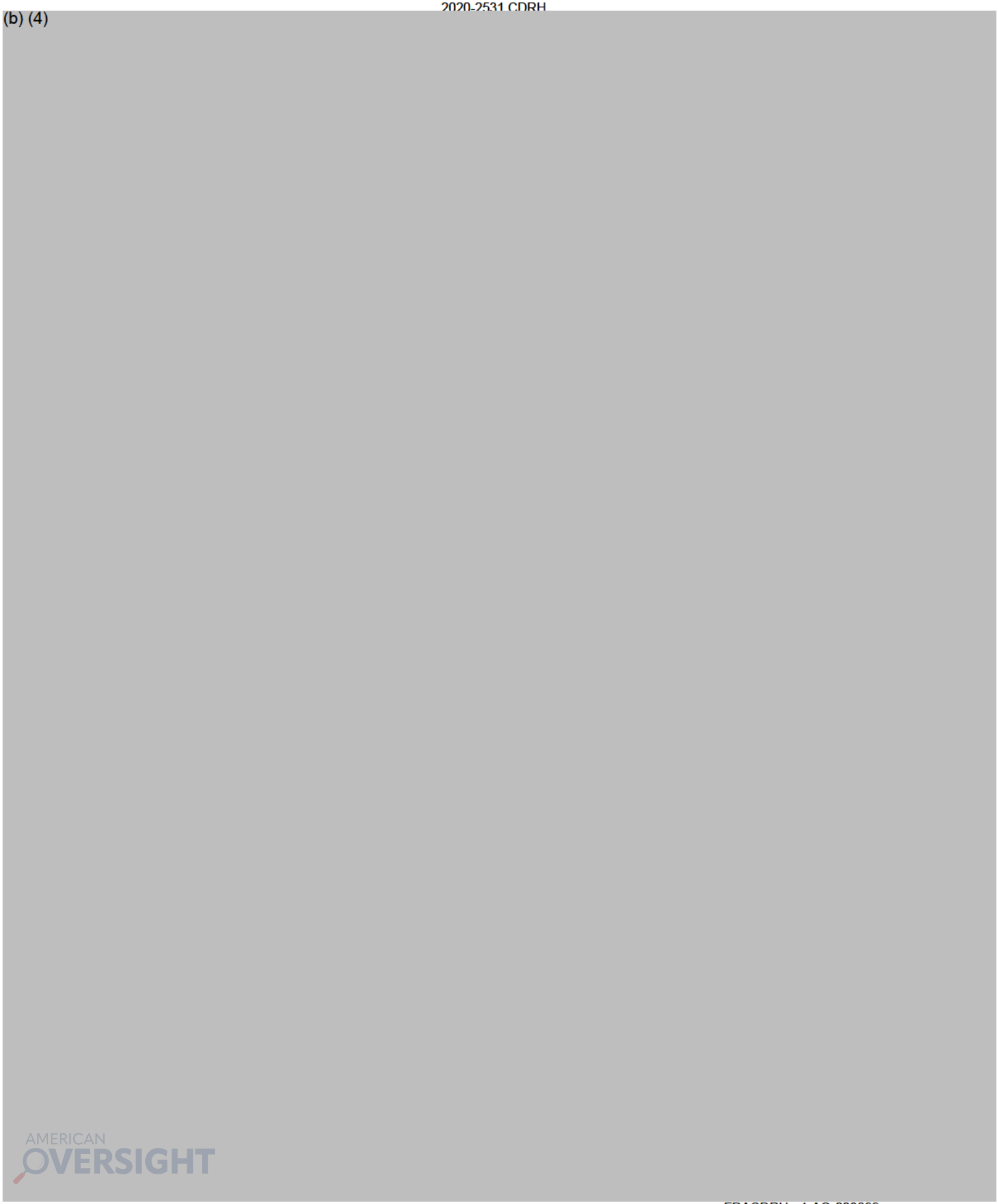
AMERICAN OVERSIGHT

(b) (4)



AMERICAN OVERSIGHT

(b) (4)

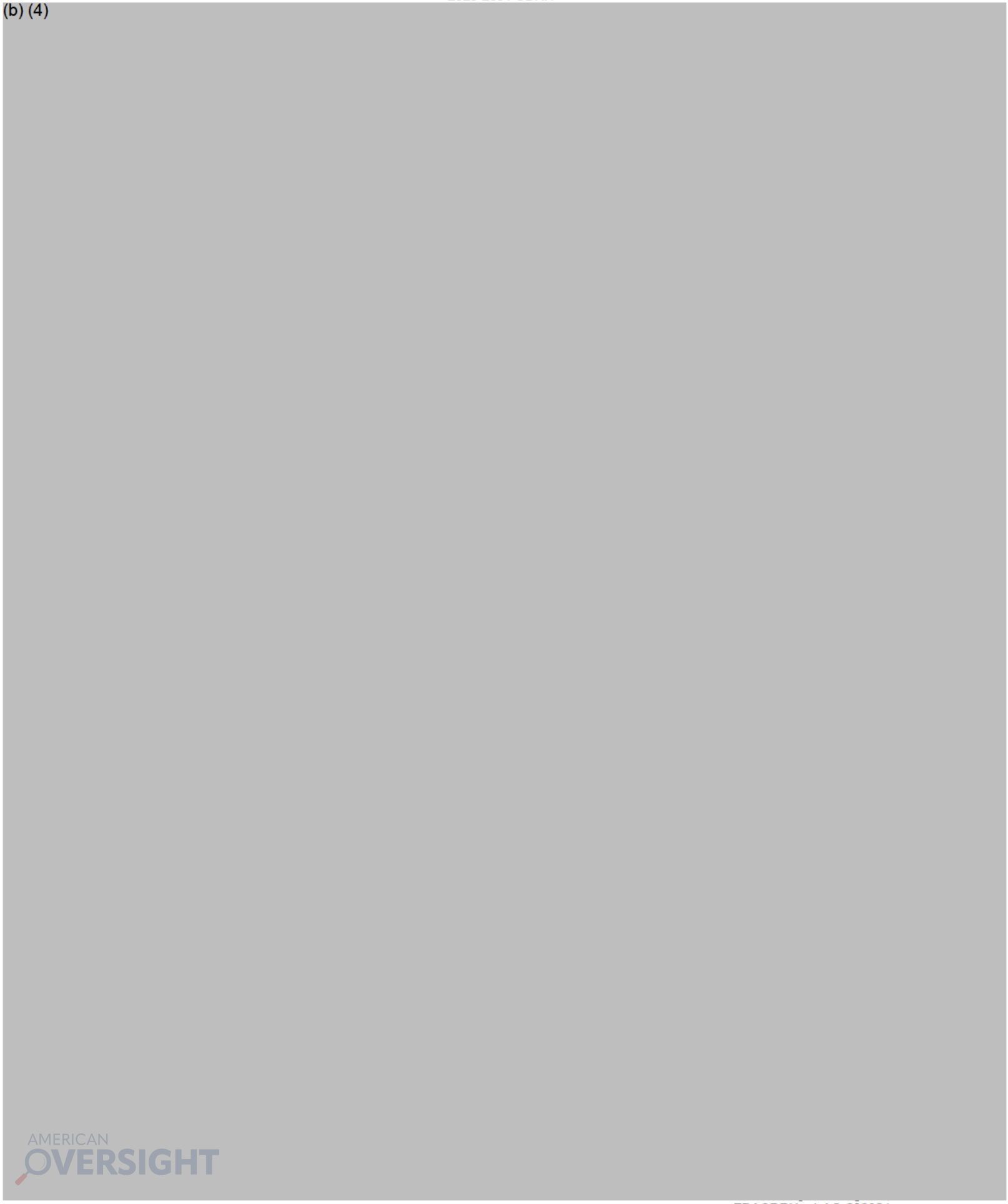


AMERICAN OVERSIGHT

(b) (4)

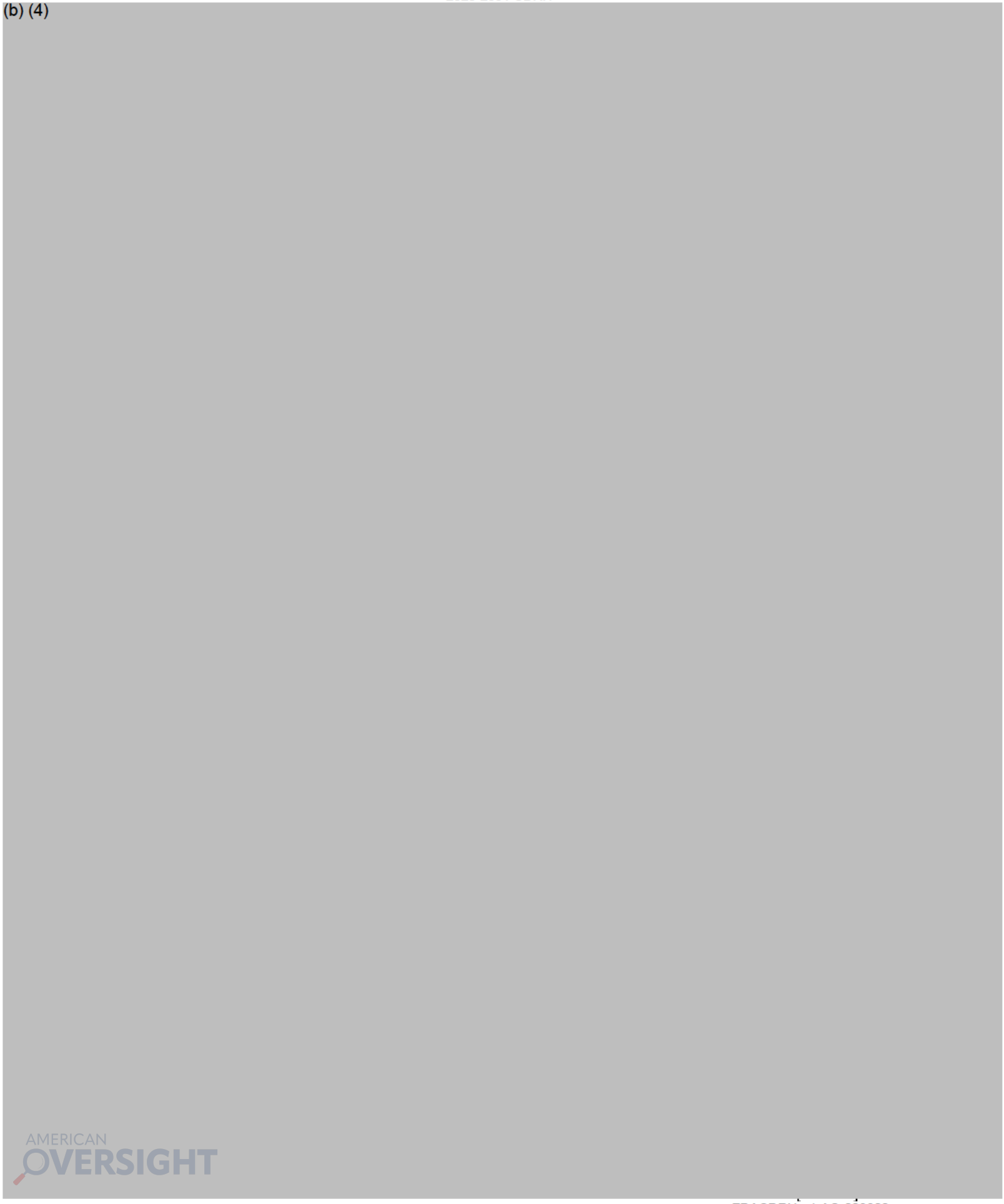


AMERICAN OVERSIGHT



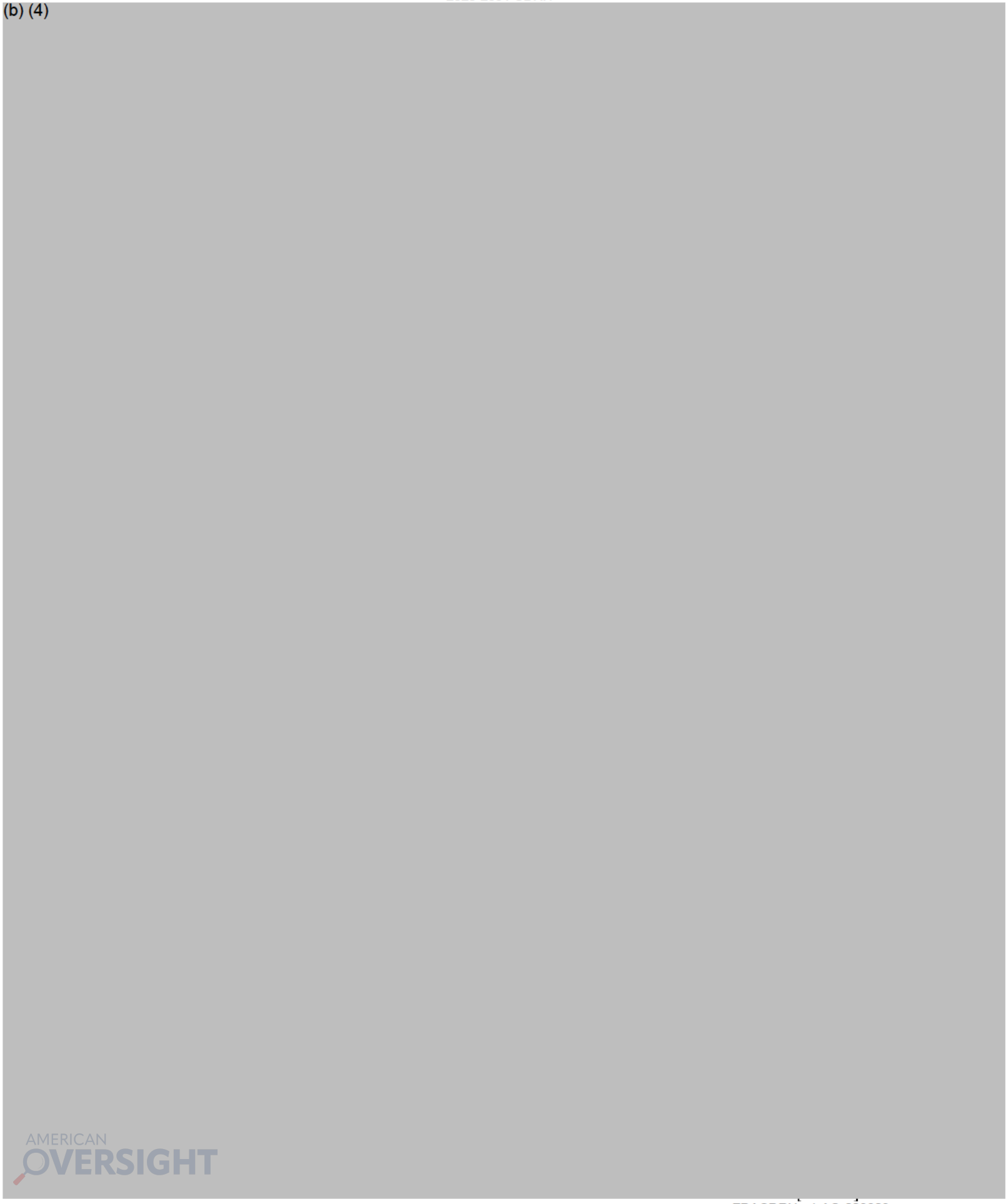

AMERICAN OVERSIGHT

(b) (4)



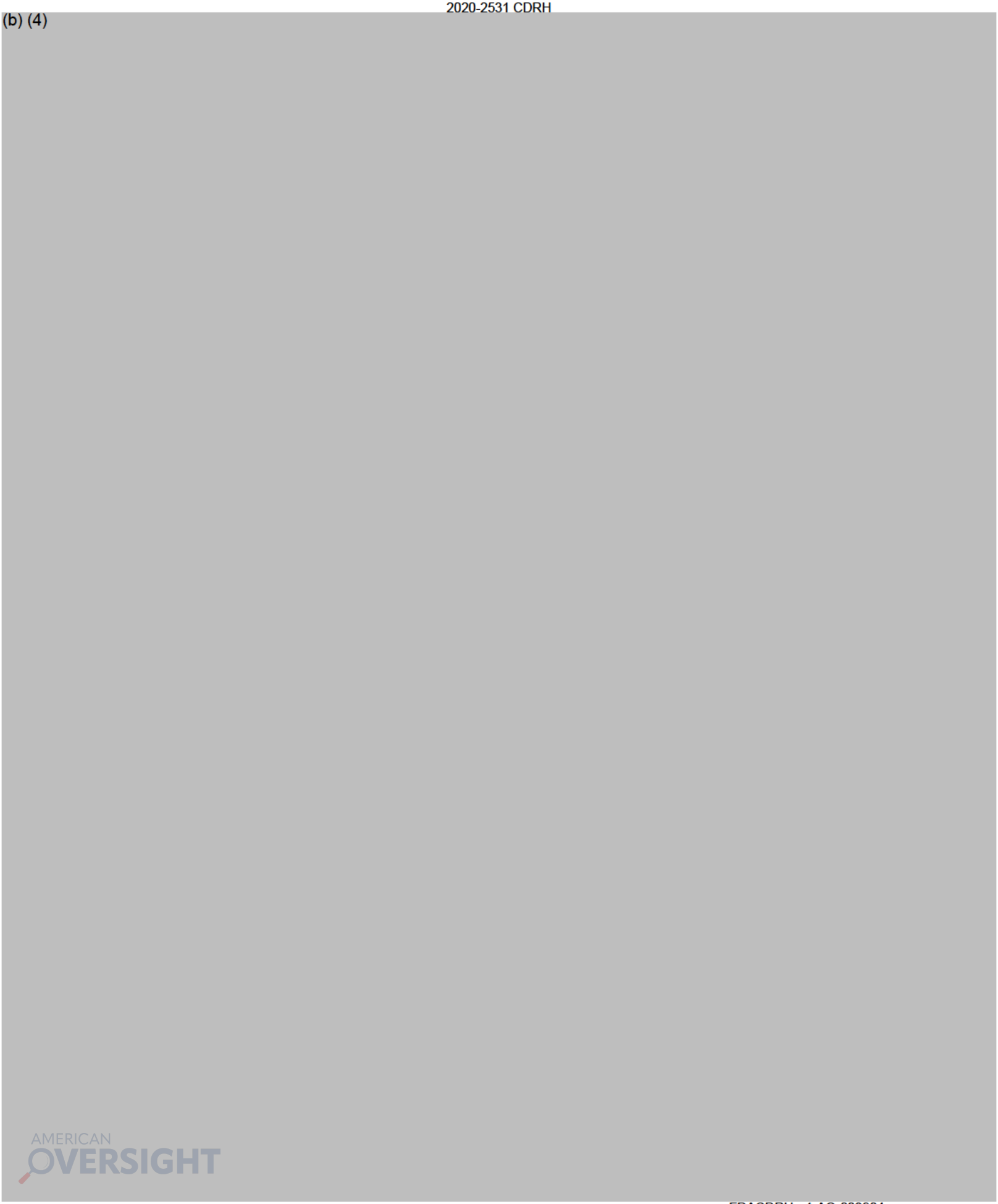
AMERICAN OVERSIGHT

(b) (4)



AMERICAN OVERSIGHT

(b) (4)



AMERICAN OVERSIGHT

(b) (4)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 5:29:46 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Briggs, Joseph (Joseph.Briggs@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Joseph.Briggsbaf]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: EUA200003_Review Memo NewYork SARS-nCoV Real_Time RT-PCR Panel_29FEB2020_Final.doc
**Attachments**: EUA200003_Review Memo NewYork SARS-nCoV Real_Time RT-PCR Panel_29FEB2020_Final.doc

For your records, the document just with the email missing. Uwe

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**From**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Sent**: 3/1/2020 6:50:14 PM
**To**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]

**Subject**: Accepted: COVID-19 EUA support
**Location**: Uwe's office

**Start**: 3/2/2020 9:00:00 AM
**End**: 3/2/2020 9:30:00 AM
**Show Time As**: Busy

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/28/2020 4:01:52 PM
**To**: Ross, Jennifer (Jennifer.Ross@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=RossJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Marcy Busch (Marcy.Busch@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Mair, Michael (Michael.Mair@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Michael.Mair]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

Jennifer, Liz, Claire and Marcy,

I am very sorry but I am sure you were expecting this.
This is highest priority for CDRH, and the Center is expecting to authorized the EUA not later than tomorrow.

The review team has started and will work on this later into the night.

Best,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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---

**From:** Scherf, Uwe
**Sent:** Friday, February 28, 2020 3:30 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Cc:** Ross, Jennifer (Jennifer.Ross@fda.hhs.gov) <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Marcy Busch (Marcy.Busch@fda.hhs.gov) <Marcy.Busch@fda.hhs.gov>
**Subject:** FW: the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

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All,

The NY state submission just came in.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Friday, February 28, 2020 3:21 PM
**To:** oir-policy <CDRH-OIR-POPS@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Subject:** the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

In the attached files, please find the following documents for the EUA submission from Wadsworth for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

1. Cover letter from the Wadsworth Center Director, Dr. Jill Taylor
2. Completed form 3514
3. Wadsworth Center EUA Interactive Review Submission for Molecular-Based test for SARS-CoV-2
4. Associated appendices to the submission:

a. Oligo spec sheets from manufacturer
b. Transcript spec sheet from manufacturer
c. NYSDOH SOP for lot to lot verification testing
d. NYSDOH SOP for the New York State SARS-CoV-2 real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel
e. NYSDOH Info for Patients on New York State SARS-CoV-2 real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel
f. NYSDOH Info for Healthcare Providers on New York State SARS-CoV-2 real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/27/2020 5:30:12 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject**: RE: sars-coV

Just curious, why does UW wants to see the fact sheets? Are they planning to submit the EUA.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 5:09 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: sars-coV

Probably early next week – I am waiting for CDC to finalize as their EPIs are updating.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov




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**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 5:03 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: sars-coV

Hi Kim,

When can I share the draft fact sheets with UW?

Thanks,
Li

**From:** Alex Greninger <agrening@uw.edu>
**Sent:** Thursday, February 27, 2020 4:38 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: sars-coV

would it be possible to obtain the draft fact sheets? thanks!

cheers,
alex

On Feb 27, 2020, at 1:33 PM, Alex Greninger <agrening@uw.edu> wrote:

ok. Happy to take a limitation on that one. thanks again.

cheers,
alex

On Feb 27, 2020, at 1:29 PM, Li, Li (CDRH) <Li.Li2@fda.hhs.gov> wrote:

It is still a recommended in the template.
Based on the in silico data you provided,(b) (4)
(b) (4)
Li

-----Original Message-----
From: agrening@uw.edu <agrening@uw.edu>
Sent: Thursday, February 27, 2020 4:02 PM
To: Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
Subject: sars-coV

AMERICAN OVERSIGHT

Do we still need to do wet lab testing with SARS-CoV?

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 3/1/2020 9:54:02 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: applicant name

Jeff,

Here the number:

- Current testing capacity: (b)(4) pecimens per day at our regular staffing levels (on their LC)
- Could increase this to (b)(4) samples per day with 24 hour testing.
- With our Roche MP96s, they believe they can perform (b)(4) per day; we begin validation now

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 9:35 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** Re: applicant name

Uwe,

That's terrific. Can you/someone on your team please ask them, and subsequent notifiers, how many specimens/patients they can test per week and if that is their maximum capacity or if they can increase their weekly throughput?

AMERICAN OVERSIGHT

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** March 1, 2020 at 9:30:10 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** FW: applicant name
**Importance:** High

Jeff, Tim and Don,

We just got the 1st notification under the accelerated EUA program that UW will start testing patients for SARS-CoV-2 at 8 am tomorrow morning.

We confirmed the receipt of this request in our mailbox and an acknowledgment email went out.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Alex Greninger <agrening@uw.edu>
**Sent:** Sunday, March 1, 2020 9:11 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Keith R. Jerome <kjerome@uw.edu>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Subject:** Re: applicant name

Apologies, Li.

This email serves to notify the FDA that UW Virology is beginning clinical testing for SARS-CoV-2 at 8am tomorrow morning PST.

UW Virology
Keith Jerome
1616 Eastlake Avenue Suite 320
Seattle, WA 98102

AMP OVERSIGHT

contact person: Alex Greninger, agrening@uw.edu, 415-439-3448

Best wishes,
Alex

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/29/2020 8:56:01 AM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Humes, Rosemary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6de8a41cc8d54da69787255ca964affa-HHS-Rosemar]; Faison, Tremel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4945bc9afa3c4d34a274cb286e2f2a09-HHS-Tremel.]; Wallace, Rodney (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2814cd3aa9043f8bf8f8c4490b6b98a-HHS-Rodney.]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**Subject**: RE: LabCorp update

All.
I am on this with UTMB, I will report back,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:46 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** RE: LabCorp update

Dear Federal Colleagues, This is an unacceptable situation that labs and developers who have a test or assay ready to validate cannot obtain the needed and seemingly available material from either BEI or UTMB to finish their validations so they can submit for EUA authorization. I have multiple complaints for developers about both BEI and UTMB.

My cell is (b) (6)

Can we resolve this today?

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Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Krueger, Brian <(b) (6)
**Sent:** Saturday, February 29, 2020 8:37 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** LabCorp update

UTMB did not ship the virus to us this week. The UTMB lab did not receive the countersigned document from UTMB legal. I followed up with UTMB and received no reply. We ordered aliquots of the virus from BEI Friday morning but were told that despite us already being cleared in the system, COVID-19 is a special request and requires approval from NIAID and signatures on a separate form if they approve. We will be ready to knock out the validation in a handful of days once we receive the viral material. We're hoping this all gets resolved early next week but I will keep you posted.

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-This e-mail and any attachments may contain CONFIDENTIAL information, including PROTECTED HEALTH INFORMATION. If you are not the intended recipient, any use or disclosure of this information is STRICTLY PROHIBITED; you are requested to delete this e-mail and any attachments, notify the sender immediately, and notify the LabCorp Privacy Officer at privacyofficer@labcorp.com or call (877) 23-HIPAA / (877) 234-4722

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# ACCELERATED EMERGENCY USE AUTHORIZATION TEMPLATE FOR SARS-COV-2 (covid-19) MOLECULAR TESTING OF RESPIRATORY SPECIMENS IN CLIA CERTIFIED HIGH-COMPLEXITY LABORATORIES

GENERAL INFORMATION ABOUT THIS TEMPLATE

- This template is only for use by CLIA certified high-complexity laboratories with experience developing molecular diagnostics for viral pathogens. Use of the template is applicable only for testing of respiratory specimens, e.g., nasopharyngeal, sputum, and BAL specimens.
- Text highlighted in yellow [Text] should be completed by the laboratory/sponsor. The remaining text should be unchanged. Text in italic bold outlines Food and Drug Administration (FDA) suggestions and clarifications.
- If authorized, the EUA means that this SARS-CoV-2 IVD is temporarily authorized for use until further notice, the public health emergency is terminated or the EUA is revoked by the FDA. Additional recommendations regarding Emergency Use Authorization may be communicated as additional information regarding SARS-CoV-2 emerges.
- This template must be completed and submitted within 15 business days of FDA notification following Interim FDA Guidance available at http://www.fda.gov/xxxx.
- If you need additional information completing this form or wish to consider use an alternative specimen type, please contact the Division of Microbiology devices at (301) 348-1778 or email. XXXX@fda.hhs.gov

## A. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for use of a SARS-CoV-2 molecular diagnostic test to be performed for the in vitro qualitative detection of RNA from the SARS-CoV-2 in respiratory samples from patients as recommended for testing by public health authority guidelines. The test will be performed in CLIA certified high-complexity laboratories. Additional testing and confirmation procedures should be performed in consultation with public health and/or other authorities to whom reporting is required.

Positive results should also be reported in accordance with local, state, and federal regulations.

## B. MEASURAND

Specific nucleic acid sequences from the genome of the SARS-CoV-2 ***[please specify the targeted gene(s) of the pathogen; assays with more than one target are recommended].***

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## C. LABORATORY/SPONSOR

***[Official name, address and contact information of applicant and all locations where specimen testing will be performed***

## D. REGULATORY INFORMATION

***Approval/Clearance Status:***

The SARS-CoV-2 assay test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

## E. PROPOSED INTENDED USE

***1) Intended Use:***

The SARS-CoV-2 assay is a [***specify test technology such as, real-time RT-PCR test***] intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in respiratory specimens from individuals. Testing is limited Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratories with FDA Emergency Use Authorization FDA for performing SARS-CoV-2 testing.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of active infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The assay is intended for use by CLIA certified high-complexity laboratories with experience in developing molecular diagnostics and is authorized under the Food and Drug Administration's Emergency Use Authorization.

## F. DEVICE DESCRIPTION AND TEST PRINCIPLE

***[Example text has been added under each of the sub-headings below for a fluorescence based rRT-PCR test for detection of organism RNA. If a different test principle is used by the test for the detection of a specific analyte please modify the description accordingly to capture the salient points in each of the sub-headings below. Please note the accelerated template is intended for use only with existing, well-established technologies.]***

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1) ***Product Overview/Test Principle:***

The assay is a real-time reverse transcription polymerase chain reaction (rRT -PCR) test. The SARS-CoV-2 primer and probe set(s) is designed to detect RNA from the SARS-CoV-2 in respiratory specimens from patients as recommended for testing by public health authority guidelines.

2) ***Description of Test Steps:***

**Please describe in abbreviated form the steps for performing your assay in sequential order as a numbered list, including extraction methods. This should include the names of the instruments used in your assay, e.g., ABI 7500. A copy of your laboratory procedure would be acceptable and can be appended to this form.**

3) ***Control Material(s) to be Used:***

**Please describe the assay controls to be performed in the laboratory, including the following:**

- **The positive control; ideally the positive control will be used to confirm performance near the test LoD. If a template control is used, please describe in general terms the sequence used.**
- **The extraction control.**
- **The internal control, if present.**

**Your description should also include the frequency that controls will be performed.**

4) ***Assay results and interpretation***

**Please describe the results of your assay procedure, e.g., reactive (positive/detected), non-reactive (negative/non-detected), or Invalid (no result reported)**

## J. PRODUCT MANUFACTURING

Please note that Under the Emergency Use Authorization (EUA) most of the 21 CFR 820 Quality System Regulation (QSR) requirements can be waived for the duration of the EUA. FDA expects that the high-complexity laboratories performing these tests follow comparable practices as much as possible and may consider previous compliance history when determining whether or not to waive certain QSR requirements for a specific product. Please note adverse events, as per 21 CFR Part 803, have to be reported for authorized devices.

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## K. PERFORMANCE EVALUATION

The following validation studies should be performed as during your assay development:

1) ***(Limit of Detection (LoD) (analytical sensitivity):***

***[Laboratories should document the limit of detection (LoD) of their SARS-CoV-2 assay. It is acceptable to spike RNA or inactivated virus into artificial or real clinical matrix (e.g., BAL fluid, sputum, etc.) for LoD determination.***

***It is recommended that laboratories should test a 2-3 fold dilution series of three replicates per concentration, and then confirm the final concentration with 20 replicates. FDA defines LoD as the lowest concentration at which 19/20 replicates are positive. If multiple clinical matrices are intended for clinical testing, laboratories should submit the results from the most challenging clinical matrix to FDA. For example, if testing respiratory specimens (e.g., sputum, BAL, nasopharyngeal (NP) swabs, etc.), only results from sputum need to be reported in the EUA application. If needed, we recommend that you follow the most current version of the CLSI standard, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures (CLSI EP17)]***

**[Please describe in abbreviated form your LoD study, the specific material used (e.g., live viral stocks, in vitro transcripts, etc.), and the LoD (with appropriate units) for your assay]**

2) ***Inclusivity (analytical sensitivity):***

***[Laboratories should document the results of an inclusivity study that demonstrates the strains of SAR-CoV-2 that can be detected by the proposed molecular assay. It is acceptable to conduct an in silico analysis of published SARS-CoV-2 sequences using the assay's primers and probes. FDA anticipates that 100% of published SAR-CoV-2 sequences will be detectable with the selected primers and probes.]***

**[Please describe in abbreviated form your Inclusivity study and confirm that there was 100% detection of all SARS-CoV-2 strains.}**

3) ***Cross-reactivity (analytical specificity)***

***[At a minimum, an in silico analysis of the assay primer and probes compared to common respiratory flora and other viral pathogens is sufficient for initial clinical use. FDA defines in silico cross-reactivity as greater than 80% homology between one of the primers/probes and any sequence present in the targeted microorganism. Laboratories should follow recognized laboratory procedures in the context of the sample types intended for testing for any additional cross-reactivity testing.]***

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**Recommended List of Organisms to be analyzed *in silico* or by Direct Testing***

| Other high priority pathogens from the same genetic family | High priority organisms likely in circulating areas |
|---|---|
| **Human coronavirus 229E** | **Adenovirus (e.g. C1 Ad. 71)** |
| **Human coronavirus OC43** | **Human Metapneumovirus (hMPV)** |
| **Human coronavirus HKU1** | **Parainfluenza virus 1-4** |
| **Human coronavirus NL63** | **Influenza A & B** |
| **SARS-coronavirus** | **Enterovirus (e.g. EV68)** |
| **MERS-coronavirus** | **Respiratory syncytial virus** |
| | **Rhinovirus** |
| | ***Chlamydia pneumoniae*** |
| | ***Haemophilus influenzae*** |
| | ***Legionella pneumophila*** |
| | ***Mycobacterium tuberculosis*** |
| | ***Streptococcus pneumoniae*** |
| | ***Streptococcus pyogenes*** |
| | ***Bordetella pertussis*** |
| | ***Mycoplasma pneumoniae*** |
| | ***Pneumocystis iroveci* (PJP)** |
| | **Pooled human nasal wash – *to represent diverse microbial flora in the human respiratory tract*** |
| | ***Candida albicans*** |
| | ***Pseudomonas aeruginosa*** |
| | ***Staphylococcus epidermis*** |
| | ***Staphylococcus salivarius*** |

* For direct testing, concentrations of $10^6$ CFU/ml or higher for bacteria and $10^5$ pfu/ml or higher for viruses is recommended.].

**[Please describe in abbreviated form your cross-reactivity study and list the microorganisms tested, indicating whether this was performed either in *in silico* or wet testing. Organisms recommended for testing are listed in the table above]**

***4) Clinical Evaluation:***

***[In the absence of known positive samples available for testing, laboratories should confirm the performance of their assay with a series of contrived clinical specimens by testing a minimum of ~~50~~ 30 contrived reactive specimens and ~~50~~ 30 non-reactive specimens. Contrived reactive specimens can be created by spiking RNA or inactivated virus into leftover clinical specimens; the majority of these specimens can be leftover upper respiratory specimens such as NP swabs, sputum, etc. ~~Half~~ Twenty of the contrived clinical specimens should be spiked at a concentration of 1x-2x LoD, with the remainder of specimens spanning the assay testing range. FDA defines the acceptance criteria for the performance as 95% agreement at 1x-2x LoD, and 100% agreement at all other concentrations and for negative specimens.***

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**[Please describe in abbreviated form the procedure and results from clinical performance testing]**

## O. INFORMATION FOR HEALTHCARE PROVIDERS AND PATIENTS:

**Please describe or provide copies of materials intended for use by providers or patients for interpreting results.**

## Q. RECORD KEEPING AND REPORTING INFORMATION TO FDA:

The laboratory will track adverse events and report to FDA under 21 CFR Part 803. A website is available to report on adverse events, and this website is referenced in the Fact Sheet for Health Care providers. The laboratory will maintain will information on the performance of the test, and report to FDA any suspected change in performance of which they become aware. The laboratory will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

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## S. FDA ADMINISTRATIVE INFORMATION:

**This section will be finalized by the FDA Reviewer upon completion of the review process. This will document any interactions of communications with the laboratory. the interactive review of this submission and any conclusions resulting from the interactive review.**

***Product Code:***
[FDA will complete]

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/28/2020 5:21:20 PM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Minimal Criteria for test validation
**Attachments**: EUA Accelerated Template NAT_Novel Coronavirus_2282020.doc

Elizabeth,

Updated EUA template

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 5:13 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

See updates.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 4:49 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

See edits

The minimal criteria acceptable to validate the test to be developed by the target laboratories are listed below. We foresee that it will take 3-4 days for a CLIA-certified, high-complexity laboratory to complete these evaluations.
For item 1. a. below, Genomic RNA manufactured by UTMB, provided to us by NIAID/NIH or BEI is available for testing.

1. Analytical Evaluation

(b) (5)

[redacted]

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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**Jennifer Campbell**
*Administrative Assistant*

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Jennifer.Campbell@fda.hhs.gov

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 4:43 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

Hi Uwe, Jeff and I are concerned that this (b) (5) I am editing this with that in mind, will send an update with edits and then call you.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Stenzel, Timothy
**Sent:** Friday, February 28, 2020 11:22 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

Giving further thought it looks good. Jeff, Can I share with the CDC?

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Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:48 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Minimal Criteria for test validation

Hi Uwe,

This is wonderful. Can we change the near LOD testing to (b) (5) performance would be (b) (5) positive rather that (b) (5) target?

Thanks in advance Uwe! :)

Best,
Tim

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 10:41:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Minimal Criteria for test validation

Jeff and Tim,

The minimal criteria acceptable to validate the test to be developed by the target laboratories are listed below. We foresee that it will take 3-4 days for a CLIA-certified, high-complexity laboratory to complete these evaluations.
For item 1. a. below, Genomic RNA manufactured by UTMB, provided to us by NIAID/NIH or BEI is available for testing.

1. Analytical Evaluation

(b) (5)

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(b) (5)

[redacted]

Let me know if you have any questions.

Uwe

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 3/1/2020 1:54:52 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject:** RE: PEUA200009

Li can you please give me a call at 240-401-0886

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 1:47 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: PEUA200009

Hi all,

Based on a quick review of the accelerated PRE-EUA template, (b) (4), (b) (5)
(b) (4), (b) (5)

(b) (5)

Kim,
Can you please start working on the fact sheets and LOA? (b) (4), (b) (5)
(b) (4), (b) (5) Please advise.

I need to attend to some family business, and will back on-line after 7:00 pm.

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**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, March 01, 2020 1:10 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: PEUA200009

See below. There is apparently an accelerated pre-EUA template from FDA? Where can I find it?
(b) (4), (b) (5) I will review the accelerated template tonight.
Li

---

**From:** Alex Greninger <agrening@uw.edu>
**Sent:** Sunday, March 01, 2020 12:58 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: PEUA200009

Hi Li,

Here's the most updated document I have; it is on the accelerated pre-EUA template (sorry). (b) (4)
(b) (4)

Best wishes,
alex

Alex Greninger MD, PhD, MS, MPhil
Assistant Professor, Department of Laboratory Medicine
Associate Director, Virology Division
University of Washington
Lab: 850 Republican St, S130
Seattle, WA 98109
Clinical Lab: 1616 Eastlake Ave East, Suite 320
Seattle, WA 98102
Phone: 415-439-3448
Fax: 206-616-4340
agrening@uw.edu

On Mar 1, 2020, at 9:07 AM, Li, Li (CDRH) <Li.Li2@fda.hhs.gov> wrote:

Hi Alex,

Just to clarify, we are currently working on a pre-EUA (PEUA200009). After we work out all the issues, you will then submit an official EUA request package. Based on the new FDA guidance on LDTs yesterday, you can offer the UW LDT for patient testing as soon as you complete the validation of the LDT. You should then submit an official EUA request within 15 days of offering the LDT for patient testing.

AMERICAN OVERSIGHT

I will review your updated template (hopefully with validation data) as soon as possible and provide you with feedback as we continue to work on pre-EUA200009. But based on the new FDA guidance on LDTs yesterday, this continued preEUA process should not delay patient testing using the UW test once you determine that all validations are completed.

Thanks,
Li

---

**From:** Alex Greninger <agrening@uw.edu>
**Sent:** Sunday, March 01, 2020 11:54 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** Re:

(b) (4)

cheers,
alex

On Mar 1, 2020, at 8:53 AM, Li, Li (CDRH) <Li.Li2@fda.hhs.gov> wrote:

(b) (4)

Li

---

**From:** Alex Greninger <agrening@uw.edu>
**Sent:** Sunday, March 01, 2020 11:40 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:**

would you prefer next pre-EUA for feedback on the new template or the old template?

alex

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/28/2020 7:50:20 PM
**To:** Wendi L. Kuhnert-Tallman (wdk1@cdc.gov) [wdk1@cdc.gov]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** NYS Wadsworth Center COVID-19 Test

**Importance:** High

Wendi, Dan, Laura,

NYS Wadsworth Center submitted an EUA request to us this afternoon for a test that uses t(b) (4), (b) (5)
(b) (4), (b) (5)

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 3/1/2020 9:48:49 PM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Briggs, Joseph (Joseph.Briggs@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Joseph.Briggsbaf]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]; Mielech, Anna (Anna.Mielech@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]; Conenello, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=730596e0261d4d5389b598b47772cf85-ConenelloG]; Bialas, Kristy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43218ad182d74b3180b50e906723dd84-Kristy.Bial]
**CC**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Notification

All,

UW just notified us that they will start testing tomorrow. Going forward if we have more notifications like this and you are the lead reviewer and in contact with the sponsor, please follow up with the request from Jeff:

How many specimens/patients can they test per week and if that is their maximum capacity or if they can increase their weekly throughput?

Thanks, Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 9:35 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** Re: applicant name

Uwe,

That's terrific. Can you/someone on your team please ask them, and subsequent notifiers, how many specimens/patients they can test per week and if that is their maximum capacity or if they can increase their weekly throughput?

Jeff

---

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

**Date:** March 1, 2020 at 9:30:10 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** FW: applicant name
**Importance:** High

Jeff, Tim and Don,

We just got the 1st notification under the accelerated EUA program that UW will start testing patients for SARS-CoV-2 at 8 am tomorrow morning.

We confirmed the receipt of this request in our mailbox and an acknowledgment email went out.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Alex Greninger <agrening@uw.edu>
**Sent:** Sunday, March 1, 2020 9:11 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Keith R. Jerome <kjerome@uw.edu>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Subject:** Re: applicant name

Apologies, Li.

This email serves to notify the FDA that UW Virology is beginning clinical testing for SARS-CoV-2 at 8am tomorrow morning PST.

UW Virology
Keith Jerome
1616 Eastlake Avenue Suite 320
Seattle, WA 98102

contact person: Alex Greninger, agrening@uw.edu, 415-439-3448

Best wishes,
Alex

AMERICAN OVERSIGHT

(b) (5)



AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 3/1/2020 6:31:42 PM
**To**: Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject**: RE: For Review/Edits - QA re COVID-19 Testing
**Attachments**: EUA COVID-19 Lab Tests - KMQA Set 2 - 3-1-2020.docx

Jennifer,

Sorry, I only had a few thing I could add.

Uwe

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 5:35 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** For Review/Edits - QA re COVID-19 Testing
**Importance:** High

Tim, Uwe, and Kim,

Good evening. Apologies for adding to your long to-do list, though I think this should be pretty straightforward. We are putting together some QA for the calls with the Hill tomorrow, and there are a few attached for which it would be helpful to have OIR review and respond as appropriate. If you are unable to address any of these, just let me know.

Our goal is to send to Jeff and the team this evening before 8 pm if possible, though I understand everyone is crashing on multiple related things.

Please do let me know if anyone has questions.

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

AMERICA'S FDA OVERSIGHT

U.S. FOOD & DRUG ADMINISTRATION

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/27/2020 10:17:25 PM
**To:** Tucker, Angela [(b) (6) @roche.com]
**Subject:** RE: SARS-CoV- 2 tests CE marked

Danke!!!

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Tucker, Angela <(b) (6) @roche.com>
**Sent:** Thursday, February 27, 2020 10:16 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: SARS-CoV- 2 tests CE marked

Analytical studies with contrived samples and a risk analysis justifying the level of V&V, + some formalities like State of the Art, Essential Requirements lists, and Declaration of Conformity...

Angela G. Tucker
Vice President, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588-2722

Phone: +1 925 730-8277
Cell: + 1925 699-5894
Fax: +1 925 225-0207
Email: angela.tucker@roche.com

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On Thu, Feb 27, 2020 at 7:08 PM Scherf, Uwe <Uwe.Scherf@fda.hhs.gov> wrote:

> Angela,
>
> Thanks, very much appreciated.
>
> BTW, you might know what is needed to get CE mark? Only analytical studies with In Virto Transcipts?
>
> Uwe

AMERICAN OVERSIGHT

**From:** Tucker, Angela <(b) (6) @roche.com>
**Sent:** Thursday, February 27, 2020 10:02 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** SARS-CoV- 2 tests CE marked

Dear Uwe,

As follow-up:

From Rita Hoady on my team:

These are all the manufacturers of CE-marked tests:
Frontline Genomics
CO-Diagnostics
Qiagen
Genesig
Novacyt
Primer Design (oligo's only)
(b) (4)

Angela G. Tucker
Vice President, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588-2722

Phone: +1 925 730-8277
Cell: + 1925 699-5894
Fax: +1 925 225-0207
Email: angela.tucker@roche.com

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/25/2020 9:27:53 AM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: 2/54/20 6 AM update

Ellen,

A chat at 9:30 will work, 301-796-5456. Uwe

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 9:20 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/54/20 6 AM update

Hi Uwe,

One question we had is whether (b) (5)
(b) (5)

(b) (5)

OCC and OCET are hoping you can do a quick call with us at 9:30 am.

Thanks,
Ellen

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 7:13 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** 2/54/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/25/20 6 AM update:

**Status of activities on diagnostics:**

- 2/24/20 CDC proposed to change wording the intended use of their EUA from:
  - The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals **who meet CDC criteria for 2019-nCoV testing**
  - To:

AMERICAN OVERSIGHT

(b) (5)

**Also, CDC communicate that they will move forward with changing their assay to a N1+N2 only assay. CDC's intention is to have both changes done with one submission.**

- CDC will provide additional confirmation testing had been conducted by CDC on presumptive positive samples. FDA will rely this additional information for the statistical justification included in the benefit-risk assessment for CDC to exclude using the N3 primer/probeset as part of their assay moving forward.

- A total of 75 IVD Developers have requested and received EUA review template

(b) (4), (b) (5)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/28/2020 7:34:18 AM
**To:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** FW: [External] 2019-nCoV EUA Template

Here it is. Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:15 AM
**To:** Krueger, Brian <(b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: [External] 2019-nCoV EUA Template

Thanks for the update Brian. I am copying Uwe for his immediate awareness. Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Krueger, Brian (b) (6)
**Sent:** Friday, February 28, 2020 6:46 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Subject:** Fwd: [External] 2019-nCoV EUA Template

Additional commentary from the EUA team below.

Get Outlook for Android

---

**From:** Krueger, Brian (b) (6)
**Sent:** Friday, February 28, 2020, 6:38 AM
**To:** Bisht, Himani

AMERICA OVERSIGHT

**Cc:** Sapsford, Kim E
**Subject:** Re: [External] 2019-nCoV EUA Template

Hi Himani,

We are receiving (b)(4) of RNA from UTMB today. (b)(4)
(b)(4)

Sincerely,

-Brian Krueger, PhD

---

**From:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 10:12:58 PM
**To:** Krueger, Brian (b) (6)
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** [External] 2019-nCoV EUA Template

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Dear Brian,

I am providing you our recent feedback regarding two studies; please see below.

(b) (4)

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

I will send remaining FDA comments in the interactive review Template soon.

Note: Please contact FDA if you are interested in obtaining the extracted viral genomic RNA.

Best regards,
Himani

**Himani Bisht, Ph.D.**
*Interdisciplinary Scientist*

Viral Respiratory and HPV Branch
Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3202 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6189| Fax: (301)-847-8512
Himani.Bisht@fda.hhs.gov






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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/27/2020 9:37:44 AM
**To:** Beanan, Maureen J (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0873f9e5a4c34d8eb1ce164b6a19185c-HHS-beananm]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** UTMB extracted nucleic acid - how many vial do we have?

**Importance:** High

Maureen,

How many vials do we have of this material?

# WRCEVA Product Information Sheet (SARS-CoV-2 RNA)

(b)(4)



Material provided by the World Reference Center for Emerging Viruses and Arboviruses (Galveston, TX), NIH R24 AI120942.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456

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uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/24/2020 7:47:17 AM
**To**: Hellyer, Tobin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37e2a25ee6d444e99135475ec426daaa-Tobin.Helly]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sconce, Kimberly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1c7ddcc92284eadab476cd75c0fcf24-KJS]
**Subject**: RE: Dilution calculations for COVID-19 range find and bridging

Tobin,

That makes total sense and was the way (b) (5)
(b) (5)

Uwe

**From:** Hellyer, Tobin <Tobin.Hellyer@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:12 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sconce, Kimberly <Kimberly.Sconce@fda.hhs.gov>
**Subject:** RE: Dilution calculations for COVID-19 range find and bridging

Just a thought, (b) (5)
(b) (5)

Tobin

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 12:07 PM
**To:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Hellyer, Tobin <Tobin.Hellyer@fda.hhs.gov>; Sconce, Kimberly <Kimberly.Sconce@fda.hhs.gov>
**Subject:** RE: Dilution calculations for COVID-19 range find and bridging

Yes, (b) (5)
(b) (5)

Li

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**From:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:45 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Hellyer, Tobin <Tobin.Hellyer@fda.hhs.gov>; Sconce, Kimberly <Kimberly.Sconce@fda.hhs.gov>
**Subject:** RE: Dilution calculations for COVID-19 range find and bridging

Li,
(b) (5)

Also yes the idea is; (b) (5)
(b) (5)

(b) (5)

Kris

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:33 AM
**To:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Hellyer, Tobin <Tobin.Hellyer@fda.hhs.gov>; Sconce, Kimberly <Kimberly.Sconce@fda.hhs.gov>
**Subject:** RE: Dilution calculations for COVID-19 range find and bridging

Thanks Kris. This is great.

(b) (5)

(b) (5)

Best,

Li

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**From:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:35 AM

**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Hellyer, Tobin <Tobin.Hellyer@fda.hhs.gov>; Sconce, Kimberly <Kimberly.Sconce@fda.hhs.gov>
**Subject:** Dilution calculations for COVID-19 range find and bridging

Hi All,
Thanks to Tobin, Kim and Li for the discussion on Friday. Attached is a word doc and a spreadsheet which will hopefully help to design and execute the range finding and bridging studies noted in the COVID-19 bridging study protocol. (b) (5)
spreadsheet. This could be fit in easily if needed.

(b) (5)

The spreadsheet needs review to ensure 100% accuracy, glad to walk anyone through it on Monday.
Kris

p.s. There are at least 2 different philosophies about making a big series like this. Glad to redesign if there is a more preferred strategy.

**Kristian Roth, Ph.D.**
*Branch Chief Bacterial Multiplex and Medical Counter Measures*
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-7024
kristian.roth@fda.hhs.gov




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**CONFIDENTIAL SETTLEMENT COMMUNICATION PROTECTED BY FED. RULE OF EVIDENCE 408**

Vaughn Index Version 2.0
March 10, 2025

***Vaughn Index (V2) for FOIA Request No. 2020-2531***
***American Oversight v. HHS et. al., Case No. 1:20-cv-0947 (D.D.C.)***

| Doc Start | Doc. End | Date of Redacted Doc | Author(s) of Redacted Doc | Document Title | Exemption(s)** | Explanation |
|---|---|---|---|---|---|---|
| 003584 | 003585 | 2/25/2020 | Uwe Scherf, M. Sc., Ph.D. | 2/54/20 6 AM update | (b)(5) | FDA-CVD-SCHERFU-00005561<br>Bates: 003584-003585<br><br>Deliberative Process Privilege: The redacted information in this agency email exchange contains pre-decisional, internal deliberations regarding the EUA review process relating to CDC's 2019-Novel Coronavirus (2019-nCoV) Diagnostic Panel, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003586 | 003593 | 2/2020 | Denise Hinton, FDA's Chief Scientist | Draft Authorization Letter to CDC | (b)(5) | FDA-CVD-SCHERFU-00008058.0001 – attachment to FDA-CVD-SCHERFU-00008058<br>Bates: 003586-003593<br>Deliberative Process Privilege: The redacted draft letter contains pre-decisional, internal deliberations regarding the substance of a letter of authorization for CDC's test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003594 | 003594 | 2/5/2020 | Third-party company | Certificate of Analysis | (b)(4) | FDA-CVD-SCHERFU-000013601.0001<br>Bates: 003594<br>Confidential Commercial Information: The redacted information relates to a third-party company's sales orders of |

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| | | | | | | pelleted oligonucleotide to the New York State Department of Health (NYSDOH). This information would inform a competitor about this company's business operations and would lead to predictable harm. |
| 003595 | 003600 | | New York State Department of Health Wadsworth Center | New York State Department of Health Wadsworth Center Laboratory for Viral Diseases LVC QC Criteria for Lot-to-Lot Verification Testing | (b)(4) | FDA-CVD-SCHERFU-00013601.0002<br>Bates: 003595-003600<br>Confidential Commercial Information: The redacted information is the New York State Department of Health (NYSDOH) Wadsworth Center's standard operating procedure for quality control testing of testing reagents. This information would inform a competitor about the NYSDOH Wadsworth Center's laboratory operations and would lead to predictable harm. |
| 003601 | 003604 | 2/20/2020 | Third-party company | Certificate of Analysis | (b)(4) | FDA-CVD-SCHERFU-00013601.0003<br>Bates: 003601-003604<br>Confidential Commercial Information: The redacted information contains a third-party company's certificate of analysis for certain lots of COVID-19 RNA. This information would inform a competitor about this company's business operations and would lead to predictable harm. |
| 003606 | 003645 | 2/28/2020 | New York State Department of Health | New York State Department of Health Emergency Use Authorization submission for the New York SARS-CoV-2 Real-Time | (b)(4) | FDA-CVD-SCHERFU-00013601.000006<br>Bates: 003606-003645<br>Confidential Commercial Information: The redacted information relates to the NYSDOH's application for Emergency Use Authorization for its COVID-19 test, namely a draft of the NYSDOH EUA Interactive Review template. This information would inform a competitor about the NYSDOH Wadsworth Center's operations and would lead to predictable harm. |

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| | | | | Reverse Transcriptase (RT) PCR Diagnostic Panel | | |
| 003646 | 003646 | 2/28/2020 | Uwe Scherf, M. Sc., Ph.D. | FW: the EUA submission from the Wadsworth Center Laboratory for Viral Diseases for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel | (b)(4) | FDA-CVD-SCHERFU-00013601<br>Bates: 003646<br>Confidential Commercial Information: The redacted information relates to oligonucleotides used by the NYSDOH Wadsworth Center. This information would inform a competitor about the NYSDOH Wadsworth Center's laboratory operations and would lead to predictable harm. |
| 003648 | 003648 | 3/1/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: confirmatory testing | (b)(4) | FDA-CVD-SCHERFU-00013604<br>Bates: 003648<br>Confidential Commercial Information: The redacted information relates to a University of Washington (UW) testing methodology for SARS-CoV-2. This information would inform a competitor about UW's operations and would lead to predictable harm. |
| 003651 | 003659 | 2/2020 | Denise Hinton, FDA's Chief Scientist | Emergency Use Authorization Letter for New York SARS-CoV-2 Real- | (b)(5) | FDA-CVD-SCHERFU-00013613.0002, attachment to FDA-CVD-SCHERFU-00013613<br>Bates: 003651-003659<br>Deliberative Process Privilege: The redacted draft letter contains information pertaining to the Emergency Use |

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| | | | | Time Reverse Transcriptase (RT) PCR Diagnostic Panel | | Authorization of NYSDOH's test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003660 | 003662 | 2/29/2020 | New York State Department of Health | Fact Sheet for Health Care Providers | (b)(4) | FDA-CVD-SCHERFU-00013613.0003<br>Bates: 003660-003662<br>Confidential Commercial Information: The redacted information covers NYSDOH Wadsworth Center's draft fact sheet for healthcare providers regarding the state's test for SARS-CoV-2. This information would inform a competitor about the NYSDOH Wadsworth Center's operations and would lead to predictable harm. |
| 003663 | 003664 | 2/29/2020 | New York State Department of Health | Fact Sheet For Patients | (b)(4) | FDA-CVD-SCHERFU-00013613.0004<br>Bates: 003663-003664<br>Confidential Commercial Information: The redacted information relates to the NYSDOH Wadsworth Center's draft fact sheet for patients regarding the state's test for SARS-CoV-2. This information would inform a competitor about NYSDOH Wadsworth Center's operations and would lead to predictable harm. |
| 003665 | 003681 | 2/29/2020 | FDA | FDA REVIEW MEMORANDUM FOR EMERGENCY USE AUTHORIZATION (EUA) OF THE NEW YORK SARS-CoV-2 REAL- | (b)(4) | FDA-CVD-SCHERFU-00013613.0005<br>Bates: 003665-003681<br>Confidential Commercial Information: The redacted information relates to the NYSDOH Wadsworth Center's application for Emergency Use Authorization for its SARS-CoV-2 test. This information would inform a competitor about NYSDOH's operations and would lead to predictable harm. |

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| | | | | TIME REVERSE TRANSCRIPTASE (RT)-PCR DIAGNOSTIC PANEL | | |
| 003684 | 003688 | 3/1/2020 | Uwe Scherf, M. Sc., Ph.D. | Email exchange | (b)(4), (b)(5), (b)(6) | FDA-CVD-SCHERFU-00013614<br>Bates: 003686-003688<br>Confidential Commercial Information: The redactions cover information pertaining to the sensitivity of the SARS-CoV-2 test developed by a public entity and this entity's application for Emergency Use Authorization for this device. This information would inform a competitor about this entity's operations and would lead to predictable harm.<br><br>Bates: 003685-003686<br>Deliberative Process Privilege: The redacted information contains internal discussions regarding this entity's EUA submission for its SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 003687<br>Personal Privacy Information: The redacted information contains the private phone number of a public entity employee. |
| 003720 | 003720 | 2/27/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: Summary of information from Charles | (b)(5) | FDA-CVD-SCHERFU-00013644<br>Bates: 003720<br>Deliberative Process Privilege: The redacted information contains internal discussions regarding a public entity's EUA |

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| | | | | Chiu; SARS-CoV-2 CRISPR | | submission for its SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003721 | 003721 | 2/27/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: SARS-CoV- 2 tests CE marked | (b)(4), (b)(6) | FDA-CVD-SCHERFU-00013649<br>Bates: 003721<br>Confidential Commercial Information: The redacted information relates to the EUA submission of a company that did not receive authorization for its SARS-CoV-2 test. This information would inform a competitor about the company's operations and would lead to predictable harm.<br><br>Bates: 003721<br>Personal Privacy Information: The redacted information contains the private email address and phone number of a company employee. |
| 003723 | 003724 | 2/29/2020 | Uwe Scherf, M. Sc., Ph.D. | LoD and clinical study | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00013656<br>Bates: 003723-003724<br>Confidential Commercial Information: The redacted information relates to UW's discussions with FDA regarding its process for testing and acquiring data that substantiates the effectiveness of its SARS-CoV-2 test and contains information that pertains to a third-party company's proprietary interests. This information would inform competitors about UW's operations and the third-party company's operations and would lead to predictable harm.<br><br>Bates: 003724<br>Deliberative Process Privilege: The redacted information contains internal agency discussions regarding UW's EUA submission for its SARS-CoV-2 test, the release of which |

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| | | | | | | would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003728 | 003728 | 2/29/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: LabCorp update | (b)(6) | FDA-CVD-SCHERFU-00013663<br>Bates: 003728<br>Personal Privacy Information: The redacted information contains the private email address of a company employee. |
| 003729 | 003730 | 2/28/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: EUA Submission | (b)(4), (b)(6) | FDA-CVD-SCHERFU-00013664<br>Bates: 003730<br>Confidential Commercial Information: The redacted information relates to a company's application for Emergency Use Authorization of its SARS-CoV-2 test. This information would inform competitors about the company's operations and would lead to predictable harm.<br><br>Bates: 003729-003730<br>Personal Privacy Information: The redacted information contains the private phone numbers and email addresses of company employees. |
| 003762 | 003764 | 2/27/2020 | Uwe Scherf, M. Sc., Ph.D. | Draft cover letter for Sponsor 01212020.docx ; EUA Review Template_NAT _Novel Coronavirus 1.19.2020.doc | (b)(4) | FDA-CVD-SCHERFU-00013666<br>Bates: 003762-003763<br>Confidential Commercial Information: The redacted information relates to the NYSDOH Wadsworth Center's evaluation of its SARS-CoV-2 test and the name of a third-party company that provided NYSDOH with certain materials to conduct this testing. This information would inform competitors about NYSDOH's operations and the third-party company's operations and would lead to predictable harm. |
| 003765 | 003766 | 3/1/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: requesting SARS-CoV-2 genetic material | (b)(4), (b)(6) | FDA-CVD-SCHERFU-00013667<br>Bates: 003765-003766 |

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| | | | | | | Confidential Commercial Information: The redacted information relates to ScienCell's request for an aliquot of SARS-CoV-2 genetic material from another entity. This information would inform a competitor about this entity's operations and would lead to predictable harm.<br><br>Bates: 003766<br>Personal Privacy Information: The redacted information covers the name, email address, and phone number of the individual from the third-party entity responsible for approving the provision of SARS-CoV-2 genetic material to ScienCell. |
| 003767 | 003770 | 2/28/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: Two pre-EUA questions....advice please | (b)(4), (b)(5), (b)(6) | FDA-CVD-SCHERFU-00013680<br>Bates: 003767, 003769, 003770<br>Confidential Commercial Information: The redacted information relates to the NYSDOH Wadsworth Center's EUA submission for its SARS-CoV-2 test. The redacted information also covers the names of the manufacturers of the N3 primers that NYSDOH used in the evaluations of its test for SARS-CoV-2. This information would inform competitors about NYSDOH's operations or the operations of these third-party companies and would lead to predictable harm.<br><br>Bates: 003767<br>Deliberative Process Privilege: The redacted information contains internal discussions regarding the NYSDOH Wadsworth Center's EUA submission for its SARS-CoV-2 test and issues around the CDC assay, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| | | | | | | Bates: 003768-003769<br>Personal Privacy Information: The redacted information contains the private email addresses of NYSDOH Wadsworth Center employees. |
| 003771 | 003771 | 2/29/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: EUA200003-Review Memo New York SARS-nCoV Real-Time RT-PCR Panel-29FEB2020-Final.doc | (b)(5) | FDA-CVD-SCHERFU-00013683<br>Bates: 003771<br>Deliberative Process Privilege: The redacted information contains a discussion of the Instructions for Use for New York's SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003783 | 003788 | 2/29/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: IDT Technologies – Draft IFU and Draft EUA Letter | (b)(4), (b)(5), (b)(6) | FDA-CVD-SCHERFU-00013699<br><br>Bates: 003784, 003785<br><br>Confidential Commercial Information: The redacted information relates to draft Instructions for Use for IDT Technologies' SARS-CoV-2 test. This information would inform competitors about IDT Technologies' operations and would lead to predictable harm.<br><br>Bates: 003784-003786<br>Deliberative Process Privilege: The redacted information contains draft language and internal deliberations about the Instructions for Use of IDT Technologies' SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and |

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| | | | | | | informed opinions and recommendations from its subject matter experts.<br><br>Bates: 003785<br>Personal Privacy Information: The redacted information contains the private phone numbers of an FDA employee. |
| 003791 | 003808 | 03/02/2020 | Timothy Stenzel, M.D., Ph.D. | Policy for Diagnostic Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to EUA for Coronavirus Disease-2019 during the Public Health Emergency: Immediately in Effect Guidance | (b)(5) | FDA-CVD-SCHERFU-00013707.0001 – attachment to FDA-CVD-SCHERFU-00013707<br><br>Bates: 003797, 003804, 003805<br><br>Deliberative Process Privilege: The redacted information contains internal deliberations and a draft presentation about testing for SARS-CoV-2 that is performed in clinical settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003809 | 003811 | 03/01/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: EUA COVID-19 Lab Tests – Webinar deck (003) Tim.Uwe.EH.Uwe.pptx | (b)(5) | FDA-CVD-SCHERFU-00013707<br>Bates: 003810<br>Deliberative Process Privilege: The redacted information contains internal deliberations and proposed draft language for a presentation on testing for SARS-CoV-2 in clinical settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and |

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| | | | | | | informed opinions and recommendations from its subject matter experts. |
| 003815 | 003831 | 03/02/2020 | Timothy Stenzel M.D., Ph.D. | Policy for Diagnostic Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to EUA for Coronavirus Disease-2019 during the Public Health Emergency: Immediately in Effect Guidance | (b)(5) | FDA-CVD-SCHERFU-00013710.001, attachment to FDA-CVD-SCHERFU-00013710<br><br>Bates: 003821, 003822, 003828<br><br>Deliberative Process Privilege: The redacted information contains internal deliberations and draft language for a presentation on testing for SARS-CoV-2 in clinical settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003832 | 003834 | 03/01/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: EUA COVID-19 Lab Tests – Webinar deck | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00013710<br>Bates: 003832<br>Confidential Commercial Information: The redacted information relates to draft language in a slide deck that implicates certain companies and their provision of proprietary information to the larger laboratory community. This information would inform competitors about the companies' operations and would lead to predictable harm.<br><br>Bates: 003832<br>Deliberative Process Privilege: The redacted information contains internal deliberations about draft language for a |

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| | | | | | | presentation on testing for SARS-CoV-2 in clinical settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003835 | 003840 | 2/29/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: No update from Co-diagnostic yet | (b)(6) | FDA-CVD-SCHERFU-00013711<br>Bates: 003835-003839<br>Personal Privacy Information: The redacted information contains the private email addresses of CoDiagnostics employees. |
| 003845 | 003847 | 3/1/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: EUA COVID-19 Lab Tests – Webinar deck | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00013728<br>Bates: 003845<br>Confidential Commercial Information: The redacted information relates to proprietary information referenced in draft language of a presentation about testing for SARS-CoV-2 in clinical settings. This information would inform competitors about the operations of companies implicated by this presentation and would lead to predictable harm.<br><br>Bates: 003845<br>Deliberative Process Privilege: The redacted information contains internal deliberations about draft language for a presentation on testing for SARS-CoV-2 in clinical settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003848 | 003851 | 2/29/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: IDT Technologies – Draft IFU and | (b)(4), (b)(5), (b)(6) | FDA-CVD-SCHERFU-00013746<br>Bates: 003848 |

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| | | | | Draft EUA Letter | | Confidential Commercial Information: The redacted information covers certain proprietary information relating to the specifications of IDT Technologies' test for SARS-CoV-2. This information would inform competitors about the IDT Technologies' operations and would lead to predictable harm.<br><br>Bates: 003848, 003850<br>Deliberative Process Privilege: The redacted information contains internal deliberations about the information submitted by IDT Technologies in support of its application for Emergency Use Authorization for its SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 003848<br>Personal Privacy Information: The redacted information contains the private phone numbers of an FDA employee. |
| 003852 | 003855 | 2/28/2020 | Uwe Scherf, M. Sc., Ph.D. | Two Pre-EUA questions…advice please | (b)(4), (b)(6) | FDA-CVD-SCHERFU-00013751<br>Bates: 003853-003855<br>Confidential Commercial Information: The redacted information relates to information about the NYSDOH Wadsworth Center's evaluation of its SARS-CoV-2 test and consultations it had with FDA before applying for Emergency Use Authorization of this test. The redacted information also relates to the names of third-party companies that provided materials to the NYSDOH so that it could evaluate its SARS-CoV-2 test. This information would inform competitors about NYSDOH's operations and these third-party companies' operations and would lead to predictable harm. |

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| | | | | | | Bates: 003853-003854<br>Personal Privacy Information: The redacted information contains the private email addresses of NYSDOH employees. |
| 003856 | 003856 | 2/29/2020 | Uwe Scherf, M. Sc., Ph.D. | SARS-CoV-2 Extracted nucleic acid | (b)(4) | FDA-CVD-SCHERFU-00013758<br>Bates: 003856<br>Confidential Commercial Information: The redacted information relates to the transfer of SARS-CoV-2 nucleic acids from one company to another. This information would inform competitors about these companies' operations and would lead to predictable harm. |
| 003857 | 003860 | 2/29/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: Re: LabCorp update | (b)(6) | FDA-CVD-SCHERFU-00013776<br>Bates: 003857-003859<br>Personal Privacy Information: The redacted information contains the private email address, phone number, and home address of a LabCorp employee, and the private email address of another LabCorp employee. |
| 003861 | 003867 | 3/01/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: requesting SARS-CoV-2 genetic material | (b)(4), (b)(6) | FDA-CVD-SCHERFU-00013778<br>Bates: 003866-003867<br>Confidential Commercial Information: The redacted information relates to the transfer of an aliquot of SARS-CoV-2 nucleic acids from one company to another, as well as identifying information of the companies. This information would inform competitors about these companies' operations and would lead to predictable harm.<br><br>Bates: 003867<br>Personal Privacy Information: The redacted information contains the private phone and fax number of a company employee. |

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| 003868 | 003876 | 2/28/2020 | Uwe Scherf, M. Sc., Ph.D. | FW: RUO Logix Smart 2019-nCoV Kit | (b)(6) | FDA-CVD-SCHERFU-00013783<br>Bates: 003868-003871, 003873-003875<br>Personal Privacy Information: The redacted information contains the private email addresses of CoDiagnostics employees and an access code for a meeting between CoDiagnostics and FDA. |
| 003877 | 003883 | 2/29/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: SARS-CoV-2-CRISPR diagnostic assay—request for quantified COVID-19 RNA for FDA EUA approval | (b)(4), (b)(6) | FDA-CVD-SCHERFU-00013784<br>Bates: 003877, 003879, 003882<br>Confidential Commercial Information: The redacted information relates to a potential application for Emergency Use Authorization for a SARS-CoV-2 CRISPR diagnostic assay. The redacted information also relates to the number of vials of SARS-CoV-2 nucleic acids that University of Texas Medical Branch (UTMB) can provide to researchers at the University of California at San Francisco. This information would inform competitors about the UMTB's and UCSF's operations and would lead to predictable harm.<br><br>Bates: 003877-003883<br>Personal Privacy Information: The redacted information covers a number of private email addresses, phone numbers, and fax numbers of employees from the federal government, universities, and private entities. |
| 003884 | 003888 | 3/01/2020 | Uwe Scherf, M. Sc., Ph.D. | FW: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issued an | (b)(4) | FDA-CVD-SCHERFU-00013786<br>Bates: 003884<br>Confidential Commercial Information: The redacted information relates to the NYSDOH Wadsworth Center's testing capacity for SARS-CoV-2. The release of this information would inform competitors about NYSDOH's operations and would lead to predictable harm. |

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| | | | | Emergency Use Authorization | | |
| 003889 | 003905 | 2/29/2020 | FDA | FDA Review Memorandum for the New York SARS-CoV-2-r-RT-PCR Panel EUA | (b)(4) | FDA-CVD-SCHERFU-00013791.001, attachment of FDA-CVD-SCHERFU-00013791<br>Bates: 003889-003905<br>Confidential Commercial Information: The redacted information relates to the NYSDOH Wadsworth Center's and the New York City Department of Health and Mental Hygiene Public Health Laboratories' application for Emergency Use Authorization for their RNA-based test for SARS-CoV-2. The release of this information would inform competitors about these entities' operations and would lead to predictable harm. |
| 003911 | 003913 | 2/27/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: sars-coV | (b)(4) | FDA-CVD-SCHERFU-00013800<br>Bates: 003912<br>Confidential Commercial Information: The redacted information relates to a conversation between FDA and the University of Washington with regard to the University's development of a test for SARS-CoV-2. This information would inform competitors about the University of Washington's operations and would lead to predictable harm. |
| 003914 | 003916 | 3/1/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: applicant name | (b)(4) | FDA-CVD-SCHERFU-00013804<br>Bates: 003914<br>Confidential Commercial Information: The redacted information relates to the University of Washington's clinical testing of its test for SARS-CoV-2 and contains information about their expected testing capacity. This information would inform competitors about the University of Washington's operations and would lead to predictable harm. |
| 003917 | 003918 | 2/29/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: LabCorp update | (b)(6) | FDA-CVD-SCHERFU-00013818<br>Bates: 003917-003918 |

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| | | | | | | Personal Privacy Information: The redacted information contains the private cell phone number of an FDA employee and the private email address of a third-party company employee. |
| 003926 | 003930 | 2/28/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: Minimal Criteria for test validation | (b)(5) | FDA-CVD-SCHERFU-00013823<br>Bates: 003927-003930<br>Deliberative Process Privilege: The redacted information relates to an internal discussion between FDA employees about the minimum criteria that must be met for a SARS-CoV-2 test to be validated, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003931 | 003933 | 3/01/2020 | Uwe Scherf, M. Sc., Ph.D. | Re: PEUA200009 | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00013827<br>Bates: 003931-003931Confidential Commercial Information: The redacted information relates to the University of Washington's Pre-Emergency Use Authorization application for its SARS-CoV-2 test, including questions asked and updates provided by university personnel. This information would inform competitors about the University of Washington's operations and would lead to predictable harm.<br><br>Bates: 003931-003932<br>Deliberative Process Privilege: The redacted information relates to the University of Washington's Pre-Emergency Use Authorization application for its SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 003934 | 003934 | 2/28/2020 | Uwe Scherf, M. Sc., Ph.D. | New York State Department of Health Wadsworth Center COVID-19 Test | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00013830<br>Bates: 003934<br>Confidential Commercial Information: The redacted information relates to the NYSDOH Wadsworth Center's application for Emergency Use Authorization of its SARS-CoV-2 test. This information would inform competitors about NYSDOH's operations and would lead to predictable harm.<br><br>Bates: 003934<br>Deliberative Process Privilege: The redacted information relates to discussions between FDA and CDC personnel about the NYSDOH Wadsworth Center's EUA submission, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003937 | 003937 | | FDA | EUA COVID-19 Lab Test – KMQA Set 2 3-1-2020 | (b)(5) | FDA-CVD-SCHERFU-00013851.0001 attachment of FDA-CVD-SCHERFU-00013851.0001<br>Bates: 003937<br>Deliberative Process Privilege: The redacted information relates to a draft document containing potential answers to questions about the efficacy of tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003940 | 003941 | 2/27/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: SARS-CoV-2 tests CE marked | (b)(4), (b)(6) | FDA-CVD-SCHERFU-00013875<br>Bates: 003940<br>Confidential Commercial Information: The redacted information relates to an unapproved EUA submission. This |

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| | | | | | | information would inform competitors about the company's operations and would lead to predictable harm.<br><br>Bates: 003940-003941<br>Personal Privacy Information: The redacted information contains the private email address of a company employee. |
| 003942 | 003943 | 2/25/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: 2/54/AM update | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00013880<br>Bates: 003943<br>Confidential Commercial Information: The redacted information relates to an unapproved EUA submission. This information would inform competitors about the company's operations and would lead to predictable harm.<br><br>Bates: 003942-003943<br>Deliberative Process Privilege: The redacted information relates to FDA's internal discussions about the CDC 2019 Novel Coronavirus (2019-nCoV) Real Time Reverse Transcriptase (RT)-PCR Diagnostic Panel, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003944 | 003946 | 2/28/2020 | Uwe Scherf, M. Sc., Ph.D. | FW: [External] 2019-nCoV EUA Template | (b)(4), (b)(6) | FDA-CVD-SCHERFU-00013881<br>Bates: 003945-003946<br>Confidential Commercial Information: The redacted information relates to LabCorp's testing of its own SARS-CoV-2 test and statements regarding the timing of its application for Emergency Use Authorization for this test. The redacted information also relates to LabCorp's receipt of viral RNA from the University of Texas Medical Branch (UTMB). This information would inform a competitor about |

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| | | | | | | LabCorp's operations and UTMB's operations and would lead to predictable harm.<br><br>Bates: 003944-003945<br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee and the private email address of a LabCorp employee. |
| 003947 | 003948 | 2/27/2020 | Uwe Scherf, M. Sc., Ph.D. | UTMB extracted nucleic acid – how many vials do we have | (b)(4) | FDA-CVD-SCHERFU-00013883<br>Bates:003947<br>Confidential Commercial Information: The redacted information relates to University of Texas Medical Branch's (UTMB) product information for SARS-CoV-2 RNA. This information would inform a competitor about UTMB's operations and would lead to predictable harm. |
| 003949 | 003951 | 2/27/2020 | Uwe Scherf, M. Sc., Ph.D. | RE: Dilution calculations for COVID-19 range find and bridging | (b)(5) | FDA-CVD-SCHERFU-00013888<br>Bates: 003949-003951<br>Deliberative Process Privilege: The redacted information relates to internal discussions regarding the proper calculations for dilutions and the preparation of solutions needed to test for the presence of SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

* Page prefix is FDACDRH-p1-
** Exemption codes refer to the sections of the Freedom of Information statue 5 U.S.C. § 552(b).

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 9:09:55 AM
**To**: Fulmer, Sonja [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6136c44586e4a1ca8ce73d55803cfe5-Sonja.Fulme]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Foy, Jonette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a71f13265e4c6db631bad25f224ce6-JRF]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Mednick, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba9faf32217141efaf6904d00b795eb2-David.Medni]
**CC**: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: For OMB Review: Diagnostics (FDA Guidance)

Let's go with SARS-CoV-2 virus. Uwe, can you confirm?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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**From:** Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:08 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

I'll let Jeff/Elizabeth respond re: the correct terminology for the virus. Just also wanted to ask you to correct the font in the final paragraph to remove the blue/underline for the text ", and take other appropriate actions such as"?

Sonja
Office – 240.402.5979

*Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received at this link.*

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:02 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Okay, I'll make that change. (b) (5) Thanks.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:59 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Spoke with Tim on the public health agencies questions. Let's revise as report to "appropriate Federal, State, or local public health agencies".

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:50 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja

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<Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

All,

Here is the passback from EOP. I will look now as well. If this is a simple clean-up, I can do it and recirculate.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:31 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

We need an hour to prep the guidance and EUA template.

Also, once we post it takes between 15-30 minutes for the documents to appear online.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:26 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Great. How much time do you need to post the guidance and the updated EUA template?

Jeff

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:23 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

CDRH Comms is online now and on standby for the final guidance.

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:18 AM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Adding Alicia.

Our web folks need about an hour from the time they receive the materials to post to get them up on the website.

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:15 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

If guidance is online, we can get press release out to reporters asap.

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:14 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** FW: For OMB Review: Diagnostics (FDA Guidance)

Jeff, Elizabeth, Keagan, Stephanie –

HHS asking whether we will post before 10 am. I'm not familiar with our rollout plans (press release, etc), can you let me know if this is doable?

Thanks,
Lauren

---

**From:** Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
**Sent:** Saturday, February 29, 2020 8:00 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Re: For OMB Review: Diagnostics (FDA Guidance)

AMERICAN OVERSIGHT

Good morning,

The Secretary is having a 10am meeting and will share our progress.

I hope we can post before 10 am. Is someone standing by to post?

Thank you

On Feb 29, 2020, at 7:36 AM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

Fyi

Begin forwarded message:

**From:** "Hirsch, Quinn N. EOP/OMB" (b) (6)
**Date:** February 29, 2020 at 7:03:13 AM EST
**To:** "Malliou, Ekaterini (OS/IOS)" <Ekaterini.Malliou@hhs.gov>
**Subject: Re: For OMB Review: Diagnostics (FDA Guidance)**

Received. Will circulate and ask for ASAP sign off, no later than 8:30 am

Sent from my iPhone, please excuse brevity and typos

On Feb 28, 2020, at 10:46 PM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

Hi Quinn,

The FDA guidance is attached. We look forward to your concur or comments (redline/bubble comments, please).

Thank you

<IIE nCoV guidance_Passback 2-28-20 1030pm_CLEAN.docx>

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/29/2020 8:33:23 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** RE: If possible to review by 9pm

2 cents - For the 2nd question, (b) (5)

(b) (5)

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:14 PM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: If possible to review by 9pm

I edited the last bullet in the first question, which I highlighted. I don't want folks to think we have a bunch of EUAs in house that we've been sitting on.

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:36 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** If possible to review by 9pm

AMERICAN OVERSIGHT

HHS just asked us to provide some TPs to FDA, CDC, ASPR for VP/Secretary to use tomorrow in TV interviews. I've pulled out the relevant FDA Qs. TPs look ok?

(b) (5)



**Stephanie Caccomo**
*Press Officer*

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: 240.762.8873
stephanie.caccomo@fda.hhs.gov






AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/28/2020 2:13:29 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Questions

Call me or let me know what is decided about RUO kits. Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 2:13 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Questions

Can you stop by?

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 2:01 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Questions

AMERICAN OVERSIGHT

I'm reviewing the guidance now. It says:

(b) (5)

[redacted]

I can take it out…

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:53 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: Questions

Ok, no then. I will defer to the notes….

Best,
***Tim***

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:52 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Questions

(b) (5)

[redacted]

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>

AMERICAN OVERSIGHT

**Sent:** Friday, February 28, 2020 1:49 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Questions

(b) (5)

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:44 PM
**To:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: Questions

Hi Rosemary,

I defer to Jeff. Do you have a list of companies that have RUO assays for 2019 nCoV today on their shelves that can ship?

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Friday, February 28, 2020 12:21 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Questions

AMERICAN OVERSIGHT

Hi Tim,

I didn't get a chance to put together email for Uwe after our call last night. I am OOO today, but Rodney Wallace, my boss, was called to Sec Azar's office this morning about the new proposed LDT pathway. He was given this document, and told to call some companies to see what they needed.

I just spoke with Uwe, and he indicated that the requirements for commercial developers haven't changed, this is just for clinical labs.

(b) (5)

Other questions best for phone.

I am available until 12:45, and after 2:15. (b) (6)

Thanks,

Rosemary

<< File: Notes for RosemaryRodney 228.pdf >>

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/28/2020 4:39:44 PM
**To**: Mark J Rieder [mrieder@uw.edu]
**CC**: Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Jay Shendure [shendure@uw.edu]; Helen Y Chu [helenchu@uw.edu]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: IDT lot numbers

Hi Mark,

Dan and I just spoke. Please stay tuned. We will be providing more information soon.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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**From:** Mark J Rieder <mrieder@uw.edu>
**Sent:** Friday, February 28, 2020 4:33 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jay Shendure <shendure@uw.edu>; Helen Y Chu <helenchu@uw.edu>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** Re: IDT lot numbers

Hi Tim -

I am expecting additional follow up on some of the questions raised on the call today.
Feel free to call me on my cell if you need to get a hold of me.

Thanks
Mark

AMERICAN OVERSIGHT

On Fri, Feb 28, 2020 at 1:05 PM Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov> wrote:

Steve can confirm but I believe the lot we have is (b) (4) which is different though the performance may be similar.

Best,

*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Friday, February 28, 2020 3:59 PM
**To:** Jay Shendure <shendure@uw.edu>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Mark Rieder <mrieder@uw.edu>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Helen Y Chu <helenchu@uw.edu>
**Subject:** FW: IDT lot numbers

Thanks Jay! I have pushed this with the photos to Tim Stenzel from FDA who was on our call. Tim, this is the same lot that we have here.

Thanks, wendi

**Wendi Kuhnert-Tallman**
**Office - 404-639-3103**
**Mobile – 678-576-2121**

**From:** Jay Shendure <shendure@uw.edu>
**Sent:** Friday, February 28, 2020 1:26 PM
**To:** Mark Rieder <mrieder@uw.edu>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Helen Y Chu

AMERICAN OVERSIGHT

<helenchu@uw.edu>
**Subject:** IDT lot numbers

Hi Wendi, Mark, Helen --

I did not see on the invite the contact info for the person who was asking for the IDT lot numbers, but they are below/attached.

Wendi, do you have their contact information and can you forward on (or Helen, if you happen to have it?)

Jay

---

Jay Shendure, MD, PhD
Investigator, Howard Hughes Medical Institute
Director, Allen Discovery Center for Lineage Tracing
Director, Brotman Baty Institute for Precision Medicine
Professor, Genome Sciences, University of Washington
shendure@uw.edu | 206.685.8543

---

---------- Forwarded message ---------
From: **petedhan** <petedhan@uw.edu>
Date: Fri, Feb 28, 2020 at 10:17 AM
Subject: Re: Lot numbers
To: Jay A. Shendure <shendure@uw.edu>, lstarita <lstarita@uw.edu>

---

**From:** petedhan
**Sent:** Friday, February 28, 2020 10:16 AM
**To:** Jay A. Shendure <shendure@uw.edu>; lstarita <lstarita@uw.edu>
**Subject:** Lot numbers

Taq Path lots (b) (4) [redacted]

2019 nCoV Kit (b) (4) [redacted]

2019-nCoV_N positive control (b) (4) [redacted]

AMERICAN OVERSIGHT

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 10:18:47 PM
**To**: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

Hi Denise,

Absolutely, I have cleared my calendar for all but Coronavirus. We actually bonded quite quickly and were able to make great progress together!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:16 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

I'll touch base with you on Monday. I'd love to hear about your experience.

Thank you for working alongside them – teamwork at its finest!

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:15 PM
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Subject:** RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

Hi Denise,

AMERICAN OVERSIGHT

Thanks for asking! Yes, I arrived back home early this morning and have been working all day on Coronavirus. A little tired but hanging in there!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:12 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

How are you – have you returned from Atlanta?

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Caliguiri, Laura (OS) <Laura.Caliguiri@hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

Absolutely fantastic work everyone! Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

AMERICAN OVERSIGHT

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**

Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:48 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Caliguiri, Laura (OS) <Laura.Caliguiri@hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel

All,

The signed Emergency Authorization Letter for New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel package has just been send to Wadsworth Center.

Dr. Kristen St. George has confirmed the receipt of the letter.

Thanks you all for your incredible work getting this done today.

Kind regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Saturday, February 29, 2020 9:42 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Dear Dr. Scherf,

This is confirmation of receipt of the letter, notifying Emergency Use Authorization of the New York State SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel.

Our sincere thanks. It has been an absolute pleasure working with you and your team.

With kind regards, Kirsten St. George

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
(b) (6)
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george




AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/27/2020 10:52:05 AM
**To:** Behrends, Claire (b) (6) @idtdna.com]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]
**CC:** Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Rager, Stacy (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9981c603ae364ec38dbd5a6cb260caf1-HHS-vmk4-cd]; Terrill, Roman [rterrill@idtdna.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: IDT Kit CoA, Lot number, inventory, etc

Thank you Claire, Yes, that is the lot we received. Since the new lot of (b) (4) kits is from the same mix formulation event we may not have to do function QC on it.

CDC, Do we want to sequester these (b) (4) kits?

Thanks!

Best,
Tim

---

**From:** Behrends, Claire <(b) (6) @idtdna.com>
**Date:** February 27, 2020 at 10:43:25 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Rager, Stacy (CDC) <vmk4@cdc.gov>, Terrill, Roman <rterrill@idtdna.com>
**Subject:** RE: IDT Kit CoA, Lot number, inventory, etc

Hi Tim,

I believe your order was kit lot (b) (4) (but please confirm). I've attached the COA above for your review.

I've put a hold on the existing inventory ((b) (4) kits) of the same kit lot you tested for 2019-nCoV Kit, (b) (4) rxn product.

Later today, we will have another (b) (4) units of the 2019-nCoV Kit, (b) (4) rxn kits from the same mix formulation event that I can dedicate to your team if you see fit. These will have different aliquot and kit lot numbers due to batch numbers in our ERP systems, but were from the same bulk formulation event.

We also have more builds coming behind the one described above but will be from a new mix formulation (all still from the same original synthesis.)

Thanks,

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**Claire Behrends**
Product Manager, qPCR

Integrated DNA Technologies, Inc.
o: (b) (6) | m: (b) (6)

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 8:19 AM
**To:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Rager, Stacy (CDC) <vmk4@cdc.gov>; Behrends, Claire <(b) (6)@idtdna.com>; Terrill, Roman <rterrill@idtdna.com>
**Subject:** IDT Kit CoA, Lot number, inventory, etc

Hi Claire and Roman,

Can we get the CoA for the lot you sent? Copy all on this email?

I am still trying to get the lot number.

Can you give us the current inventory of the (b) (4) reaction kits. Hopefully they are all sequestered. Stay tuned for our QC results and next steps.

We greatly appreciate your help!

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Thursday, February 27, 2020 8:10 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>

**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Subject:** RE: Revisiting use of existing CDC kits at PHL labs for N1 + N2 only

Hi Tim,
These are over in the QC lab. We can get the information this morning.
One note, the CoA for these kits was posted on the IDT website, but now has been pulled along with the product from the IDT website. It would be useful to have IDT provide the CoA for the kit lot that was pulled from their website.
Thanks
Steve

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 9:12:17 AM
**To**: Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: For OMB Review: Diagnostics (FDA Guidance)

Is this what you needed? Your email came late.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:11 AM
**To:** Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Uwe confirms “SARS-CoV-2 virus” is the name

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**

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Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:10 AM
**To:** Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Let's go with SARS-CoV-2 virus. Uwe, can you confirm?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:08 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>;

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Mednick, David <David.Mednick@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

I'll let Jeff/Elizabeth respond re: the correct terminology for the virus. Just also wanted to ask you to correct the font in the final paragraph to remove the blue/underline for the text "(b) (5)

Sonja
Office – 240.402.5979

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---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:02 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Okay, I'll make that change.(b) (5) Thanks.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:59 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Spoke with Tim on the public health agencies questions. Let's revise as report to "appropriate Federal, State, or local public health agencies".

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:50 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

AMERICAN OVERSIGHT

All,

Here is the passback from EOP. I will look now as well. If this is a simple clean-up, I can do it and recirculate.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:31 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

We need an hour to prep the guidance and EUA template.

Also, once we post it takes between 15-30 minutes for the documents to appear online.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:26 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Great. How much time do you need to post the guidance and the updated EUA template?

Jeff

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:23 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

CDRH Comms is online now and on standby for the final guidance.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:18 AM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy

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<Timothy.Stenzel@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Adding Alicia.

Our web folks need about an hour from the time they receive the materials to post to get them up on the website.

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:15 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

If guidance is online, we can get press release out to reporters asap.

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:14 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** FW: For OMB Review: Diagnostics (FDA Guidance)

Jeff, Elizabeth, Keagan, Stephanie –

HHS asking whether we will post before 10 am. I'm not familiar with our rollout plans (press release, etc), can you let me know if this is doable?

Thanks,
Lauren

---

**From:** Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
**Sent:** Saturday, February 29, 2020 8:00 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Re: For OMB Review: Diagnostics (FDA Guidance)

Good morning,

The Secretary is having a 10am meeting and will share our progress.

I hope we can post before 10 am. Is someone standing by to post?

Thank you

AMERICAN OVERSIGHT

On Feb 29, 2020, at 7:36 AM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

Fyi

Begin forwarded message:

**From:** "Hirsch, Quinn N. EOP/OMB" (b) (6)
**Date:** February 29, 2020 at 7:03:13 AM EST
**To:** "Malliou, Ekaterini (OS/IOS)" <Ekaterini.Malliou@hhs.gov>
**Subject: Re: For OMB Review: Diagnostics (FDA Guidance)**

Received. Will circulate and ask for ASAP sign off, no later than 8:30 am

Sent from my iPhone, please excuse brevity and typos

On Feb 28, 2020, at 10:46 PM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

Hi Quinn,

The FDA guidance is attached. We look forward to your concur or comments (redline/bubble comments, please).

Thank you

<IIE nCoV guidance_Passback 2-28-20 1030pm_CLEAN.docx>

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/28/2020 1:53:29 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Questions

Ok, no then. I will defer to the notes….

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:52 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Questions

(b) (5)

[redacted]

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:49 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Questions

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(b) (5)

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:44 PM
**To:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: Questions

Hi Rosemary,

I defer to Jeff. Do you have a list of companies that have RUO assays for 2019 nCoV today on their shelves that can ship?

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Friday, February 28, 2020 12:21 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Questions

Hi Tim,
I didn't get a chance to put together email for Uwe after our call last night. I am OOO today, but Rodney Wallace, my boss, was called to Sec Azar's office this morning about the new proposed LDT pathway. He was given this document, and told to call some companies to see what they needed.
I just spoke with Uwe, and he indicated that the requirements for commercial developers haven't changed, this is just for clinical labs.

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(b) (5)

Other questions best for phone.
I am available until 12:45, and after 2:15. (b) (6)
Thanks,
Rosemary

<< File: Notes for RosemaryRodney 228.pdf >>

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 10:42:29 AM
**To**: Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: For OMB Review: Diagnostics (FDA Guidance)

Hi Jeff,

Can I let APHL and the Seattle lab now about this link?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:23 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** Re: For OMB Review: Diagnostics (FDA Guidance)

Agreed! Thank you all!!

Sent from my iPhone

On Feb 29, 2020, at 9:59 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

AMERICAN OVERSIGHT

I don't think I have ever seen a guidance and PR developed, cleared and made publicly available this quickly. Very, very impressive. Congratulations to all of you on one heck of a job.

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:52 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Guidance live, pushing out PR now

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia-prior

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:13 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Changes made (including Sonja's good catch). Clean version attached for posting.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:11 AM
**To:** Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Uwe confirms "SARS-CoV-2 virus" is the name

Best,
*Tim*

AMERICAN OVERSIGHT

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*

*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:10 AM
**To:** Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Let's go with SARS-CoV-2 virus. Uwe, can you confirm?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:08 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia

AMERICAN OVERSIGHT

<Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

I'll let Jeff/Elizabeth respond re: the correct terminology for the virus. Just also wanted to ask you to correct the font in the final paragraph to remove the blue/underline for the text "(b) (5)

Sonja
Office – 240.402.5979

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---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:02 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Okay, I'll make that change (b) (5) Thanks.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:59 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Spoke with Tim on the public health agencies questions. Let's revise as report to "appropriate Federal, State, or local public health agencies".

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:50 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

AMERICAN OVERSIGHT

All,

Here is the passback from EOP. I will look now as well. If this is a simple clean-up, I can do it and recirculate.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:31 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

We need an hour to prep the guidance and EUA template.

Also, once we post it takes between 15-30 minutes for the documents to appear online.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:26 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Great. How much time do you need to post the guidance and the updated EUA template?

Jeff

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:23 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

CDRH Comms is online now and on standby for the final guidance.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:18 AM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner,

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Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Adding Alicia.

Our web folks need about an hour from the time they receive the materials to post to get them up on the website.

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:15 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

If guidance is online, we can get press release out to reporters asap.

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:14 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** FW: For OMB Review: Diagnostics (FDA Guidance)

Jeff, Elizabeth, Keagan, Stephanie –

HHS asking whether we will post before 10 am. I'm not familiar with our rollout plans (press release, etc), can you let me know if this is doable?

Thanks,
Lauren

---

**From:** Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
**Sent:** Saturday, February 29, 2020 8:00 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Re: For OMB Review: Diagnostics (FDA Guidance)

Good morning,

The Secretary is having a 10am meeting and will share our progress.

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I hope we can post before 10 am. Is someone standing by to post?

Thank you

On Feb 29, 2020, at 7:36 AM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

Fyi

Begin forwarded message:

**From:** "Hirsch, Quinn N. EOP/OMB" (b) (6)
**Date:** February 29, 2020 at 7:03:13 AM EST
**To:** "Malliou, Ekaterini (OS/IOS)" <Ekaterini.Malliou@hhs.gov>
**Subject: Re: For OMB Review: Diagnostics (FDA Guidance)**

Received. Will circulate and ask for ASAP sign off, no later than 8:30 am

Sent from my iPhone, please excuse brevity and typos

On Feb 28, 2020, at 10:46 PM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

Hi Quinn,

The FDA guidance is attached. We look forward to your concur or comments (redline/bubble comments, please).

Thank you

<IIE nCoV guidance_Passback 2-28-20 1030pm_CLEAN.docx>

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/29/2020 6:57:57 AM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Fwd: SEATTLE Flu Study Lab Result

**Importance:** High

Hi Jeff, Can you call me to discuss this situation? Thanks! Best, Tim

---

**From:** Cowgill, Karen <n-kcowgill@kingcounty.gov>
**Date:** February 28, 2020 at 4:46:43 PM EST
**To:** Mark J Rieder <mrieder@uw.edu>, Helen Y Chu <helenchu@uw.edu>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Langley, Gayle E (CDC) <fez7@cdc.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Duchin, Jeff <Jeff.Duchin@kingcounty.gov>, Kay, Meagan <Meagan.Kay@kingcounty.gov>
**Cc:** Robin A Prentice <robins4@uw.edu>, Janet Englund (b) (6) @seattlechildrens.org) (b) (6) @seattlechildrens.org>, Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>, Jay A. Shendure <shendure@uw.edu>, Trevor Bedford (b) (6) >, lstarita <lstarita@uw.edu>
**Subject:** RE: SEATTLE Flu Study Lab Result
**Importance:** High

Hi Tim, et al. at CDC and Mark, et al. at SFS – Jeff Duchin (Chief Health Officer at Public Health Seattle-King County) asked me to follow up with you about the outcome of our discussion earlier today (9 PT/12 ET) about Seattle Flu Study testing for SARS-CoV-2.

At the end of the call, Tim said he would get back to Mark within the hour, but we haven't heard anything on our end.

Could someone please send a summary of where things stand and specifically
- what the current guidance is about SFS continued testing of samples for nCoV (retrospective and prospective)
- if testing continues, what is the flow of information to public health / re-contacting patients with results
- any other relevant info (e.g., was the lot of the kit SFS used to confirm their initial positive the same lot that CDC had QC'd?)

Thank you,

Karen Cowgill, PhD, MSc *(she/her)*
COVID-19 Response Epidemiologist
Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Affiliate Assistant Professor in Global Health, University of Washington
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (b) (6) Fax: (206) 296-4803
E-mail: n-kcowgill@kingcounty.gov

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**From:** Mark J Rieder <mrieder@uw.edu>
**Sent:** Thursday, February 27, 2020 10:57 PM

**To:** Helen Y Chu <helenchu@uw.edu>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Robin A Prentice <robins4@uw.edu>; Janet Englund (b) (6) @seattlechildrens.org) (b) (6) @seattlechildrens.org>; Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>; Jay A. Shendure <shendure@uw.edu>; Trevor Bedford (b) (6) ; lstarita <lstarita@uw.edu>
**Subject:** Re: SEATTLE Flu Study Lab Result

[EXTERNAL Email Notice! ] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

Here is the Zoom link for the call in tomorrow (Friday, 2/28 @ 9 am PT)
Mark Rieder is inviting you to a scheduled Zoom meeting.

Topic: CDC Call
Time: Feb 28, 2020 09:00 AM Pacific Time (US and Canada)

Join Zoom Meeting
https://washington.zoom.us/j(b) (6) .

Meeting ID (b) (6)

One tap mobile
+(b) (6) # US (San Jose)
+(b) (6) # US (New York)

Dial by your location
+(b) (6) (San Jose)
+(b) (6) New York)
Meeting ID: (b) (6)

On Thu, Feb 27, 2020 at 10:50 PM Helen Y Chu <helenchu@uw.edu> wrote:

> Let's all plan to be on a 9:00 am call tomorrow to discuss this. Robin, can you set up a zoom call and include whoever else should join from the SFS team.
> Thank you.
>
> Get Outlook for iOS
>
> ---
>
> **From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
> **Sent:** Thursday, February 27, 2020 8:19 PM
> **To:** Duchin, Jeff (CDC kingcounty.gov)
> **Cc:** Helen Y Chu; Janet Englund (b) (6) @seattlechildrens.org); Lindquist, Scott SL (CDC doh.wa.gov); Cowgill, Karen
> **Subject:** Re: SEATTLE Flu Study Lab Result
>
> Thanks much Jeff for connecting us. Happy to make the time any time - 7:30 your time is fine but I will wait to see the calendar invite to confirm.
>
> Thanks!

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Get Outlook for iOS

---

**From:** Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
**Sent:** Thursday, February 27, 2020 11:17:20 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Cc:** Helen Y Chu <helenchu@uw.edu>; Janet Englund (b) (6) @seattlechildrens.org) <(b) (6) @seattlechildrens.org>; Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>
**Subject:** SEATTLE Flu Study Lab Result

Wendy,

Thanks for helping us navigate with FDA colleagues what we can say/do in response to a potential positive test result from the SFS research assay. Helen Chu and Jan Englund are the SFS researchers that can provide the details of the test method and other relevant information. I'm also copying Scott Lindquist, the WA State DOH communicable disease epidemiologist and Karen Cowgill who works on surveillance with us. It probably would be good to have a call early tomorrow Pacific time (7:30) but Helen and Jan should schedule the time with you.

Very much appreciate your help.

Jeff

Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (b) (6) ; Fax: (206) 296-4803
E-mail: jeff.duchin@kingcounty.gov

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/28/2020 1:50:55 PM
**To:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Questions

Deliberative/Predicisional

(b) (5)

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:49 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Questions

(b) (5)

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:44 PM
**To:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: Questions

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Hi Rosemary,

I defer to Jeff. Do you have a list of companies that have RUO assays for 2019 nCoV today on their shelves that can ship?

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

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**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Friday, February 28, 2020 12:21 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Questions

Hi Tim,
I didn't get a chance to put together email for Uwe after our call last night. I am OOO today, but Rodney Wallace, my boss, was called to Sec Azar's office this morning about the new proposed LDT pathway. He was given this document, and told to call some companies to see what they needed.
I just spoke with Uwe, and he indicated that the requirements for commercial developers haven't changed, this is just for clinical labs.

(b) (5)

Other questions best for phone.
I am available until 12:45, and after 2:15. (b) (6)
Thanks,
Rosemary

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<< File: Notes for RosemaryRodney 228.pdf >>

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/27/2020 6:17:50 PM
**To**: Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) [zey9@cdc.gov]
**CC**: Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Smith, Lia H (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cda5acfaea1403d98eeed026beb76bd-HHS-loh5-cd]; Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Product equivalence template
**Attachments**: DRAFT Letter to PHLs - Acceptable Materials.docx

Thanks Laura! We will likely need to add the lot number to the equivalence letter. Can't think of anything else at the moment.

I hope you don't mind that I have copied Jeff and Uwe.

Jeff and Uwe, This letter is being drafted to send to PHLs that have already bought the same lot of IDT RUO kits that is currently being QC'd here at the CDC. If it passes QC we want to send this letter to APHL and their labs to let them know they can immediately begin using this kit lot from IDT.

It may also I guess be used when we have IDT send kits to the labs we specify.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Thursday, February 27, 2020 5:51 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

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**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>
**Subject:** Product equivalence template

Dr. Stenzel,

Per Wendi's request, I am sharing a draft template that may be used to communicate product equivalency. We would appreciate your review.

Regards,
Laura Rose
CDC EOC Novel Coronavirus Lab Task Force

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

February 27, 2020

**Additional Acceptable Materials**
**CDC 2019 Novel Coronavirus (nCoV) Real-Time RT-PCR Diagnostic Panel (EUA200001)**

Dear Public Health Partner,

CDC has identified, in consultation with FDA, products that are equivalent to and may be used in place of certain materials required for performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Please see the table below:

| CDC Product | Equivalent Product |
|---|---|
| CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel<br>Cat# 2019-nCoVEUA-01<br>(Box 1: Primers and Probes) | [Insert name, manufacturer and catalog#] |
| Component 1: 2019-nCoV_N1 (Part #RV202001) | [Insert component name and part #] |
| Component 2: 2019-nCoV_N2 (Part #RV202002) | |
| Component 3: RP (Part #RV202004) | |

Product equivalency was determined through functional testing of the materials at CDC.

If you have any questions regarding this communication, please contact:

CDC EOC Laboratory Task Force
eocevent177@cdc.gov

Sincerely,

Centers for Disease Control and Prevention

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/26/2020 1:25:39 PM
**To:** Russell Herbert [(b) (6) :@LGCGroup.com]; Darren Cook [(b) (6) .@LGCGroup.com]
**CC:** Rager, Stacy (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9981c603ae364ec38dbd5a6cb260caf1-HHS-vmk4-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: LGC

Thanks you Russell for this update! I also heard that (b) (4) has a Coronavirus RUO kit order in with you that is being prepared and has not yet been delivered. Do you know that status of that order? Also the number of kits and reactions per kit?

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Russell Herbert (b) (6) @LGCGroup.com>
**Sent:** Wednesday, February 26, 2020 1:03 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Darren Cook (b) (6) @LGCGroup.com>
**Cc:** Rager, Stacy (CDC) <vmk4@cdc.gov>
**Subject:** RE: LGC

Tim

I am sure you are likely aware of this – but we do have a current contract with the LRN group of the CDC.
75D30119A04957

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The Coronavirus is listed as one of the assays on this contract.

As part of the submission we added the following to accommodate an outbreak event.

(b) (4)



I look forward to hearing from you

Regards

Russell

Russell Herbert | Director Global Sales | Biosearch Technologies
Strategic Accounts | Healthcare & Diagnostic Market
Cell: (b) (6) @LGCGroup.com

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 7:09 AM
**To:** Darren Cook (b) (6) :@LGCGroup.com>
**Cc:** Russell Herbert (b) (6) :@LGCGroup.com>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Subject:** RE: LGC

Hi Darren,

Thanks for the fast TAT! I will check with my FDA and CDC colleagues and get back to you on RUO kit production as soon as possible.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

AMERICAN OVERSIGHT

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Darren Cook (b) (6) @LGCGroup.com>
**Sent:** Tuesday, February 25, 2020 10:02 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Russell Herbert (b) (6) @LGCGroup.com>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Subject:** RE: LGC

Tim,

It was a pleasure to connect with you via phone earlier this evening. I just reached my home and during my journey I was able to connect with our operations team out in California.

(b) (4)

Please do let us know if you'd like to have us initiate the production of RUO kits at the (b) (4) scale and we'll get the team to jump on it immediately.

Thanks again for your time on the phone. I'll be in touch once I get connected with Roman.

Kind regards, Darren

Darren Cook | VP Global Sales | Genomics |
LGC | 3600 Minnesota St. Alexandria, MN 56308 |
Tel: (b) (6) | Mob: (b) (6) (b) (6) |
(b) (6) @lgcgroup.com |
www.lgcgroup.com |
www.biosearchtech.com |

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**From:** Ruth Miller (b) (6) @LGCGroup.com>
**Sent:** Tuesday, February 25, 2020 6:51 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Cc:** Russell Herbert (b) (6) :@LGCGroup.com>; Darren Cook (b) (6) .@LGCGroup.com>; Brian Kim (b) (6) @LGCGroup.com>
**Subject:** RE: LGC

Hi Dr. Stenzel,

Thank you very much for letting me know. I am very relieved to hear this! I hope that you have a wonderful evening.

Kind regards,
Ruth

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:49 PM
**To:** Ruth Miller (b) (6) @LGCGroup.com>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Cc:** Russell Herbert (b) (6) :@LGCGroup.com>; Darren Cook (b) (6) .@LGCGroup.com>; Brian Kim (b) (6) @LGCGroup.com>
**Subject:** RE: LGC

Hi Ruth,

Thanks for your help. I was able to connect by phone with Darren Cook and so we are good. He is going to take things from here.

☺

Best,
***Tim***

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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**From:** Ruth Miller (b) (6) @LGCGroup.com>
**Sent:** Tuesday, February 25, 2020 7:01 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rager, Stacy (CDC) <vmk4@cdc.gov>

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**Cc:** Russell Herbert [(b) (6)]:@LGCGroup.com>; Darren Cook <[(b) (6)].@LGCGroup.com>; Brian Kim [(b) (6)]@LGCGroup.com>
**Subject:** RE: LGC

Hello Dr. Stenzel,

It was very nice to make your acquaintance. I am still working on this request and appreciate that you have copied the other people involved.

Kind regards,
Ruth

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:28 PM
**To:** Ruth Miller [(b) (6)]r@LGCGroup.com>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Cc:** Russell Herbert [(b) (6)]:@LGCGroup.com>; Darren Cook [(b) (6)].@LGCGroup.com>; Brian Kim [(b) (6)]@LGCGroup.com>
**Subject:** RE: LGC

Thank you Ruth,

I am so glad we connected with you. I have copied people who were at the meeting today or originally scheduled for the meeting at the CDC today.

Thanks! ☺

Best,
***Tim***

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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---

**From:** Ruth Miller [(b) (6)]r@LGCGroup.com>
**Sent:** Tuesday, February 25, 2020 6:18 PM
**To:** Rager, Stacy (CDC) <vmk4@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: LGC

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Hello Stacy and Tim,

Thank you for sending this email. I am doing my very best to get you in touch with the correct individual.

Kind regards,
Ruth

---

**From:** Rager, Stacy (CDC/DDID/NCEZID/DPEI) <vmk4@cdc.gov>
**Sent:** Tuesday, February 25, 2020 3:12 PM
**To:** Ruth Miller (b) (6) @LGCGroup.com>
**Cc:** Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** LGC
**Importance:** High

EXTERNAL EMAIL

Today we met with Russell Herbert and Darren Cook and it was mentioned that a temporary licensing might be able to be granted to IDT to help manufacture kits for the nCoV response. The FDA and CDC are working on this and we urgently need to discuss with the appropriate people at LGC to try and make this happen.

You may respond anytime day or night to Tim at (b) (6)

Thank you so much for your help with this!!

**Stacy Rager, CQA, CBA**
Quality Manager, Laboratory Preparedness and Response Branch
Division of Preparedness and Emerging Infections, NCEZID, CDC
404-639-4197
srager@cdc.gov
Telework: Thursday

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AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/28/2020 9:44:04 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Hi Jeff,

Can we talk about this sooner than later today? I will be in the morning briefing here 10-11 am. Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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---

**From:** Stenzel, Timothy
**Sent:** Thursday, February 27, 2020 12:40 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Yes

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 27, 2020 at 10:54:07 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Tim,

CDC will have someone participate. Can you participate by phone if I'm Atlanta or in person if back in town? Keagan just pinged me.

AMERICAN OVERSIGHT

Jeff

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 27, 2020 at 7:52:00 AM EST
**To:** Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Please see the request from Julie Khani at the beginning of this email trail. Is this something you and Dan might consider doing together by videoconference, if you are still in Atlanta next week? If you are here I'd have you go in person but you should stay at CDC as long as is necessary (and as long as you are willing).

Jeff

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 7:19 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

(b) (5) [redacted]

Sent from my iPhone

On Feb 26, 2020, at 7:18 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thoughts? (b) (5) [redacted]

Sent from my iPhone

Begin forwarded message:

**From:** Julie Khani <jkhani@acla.com>
**Date:** February 26, 2020 at 7:16:24 PM EST
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
**Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing**

It's a hotel ballroom. I could look into videoconferencing?

Also, just FYI, I reached out to Danielle Steele on this as well, re both FDA and CDC participation.

Sent from my iPhone

On Feb 26, 2020, at 5:41 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Not sure we could get anyone to do it in person. Could the FDA person participate by phone?

---

**From:** Julie Khani <jkhani@acla.com>
**Sent:** Wednesday, February 26, 2020 2:52 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

AMERICAN OVERSIGHT

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available here.

I am reaching out because in addition to Commissioner Hahn's remarks, I think the ACLA meeting would provide an excellent opportunity for the FDA to address the diagnostics community about the Coronavirus. I've extended the same invitation to the CDC. There will be approximately 200 people in attendance at the meeting, including CEOs and senior leadership from companies such as LabCorp, Quest, Mayo Clinic Laboratories, Hologic, and Siemens. ACLA and several member companies have a weekly call with the CDC, and the FDA has participated on some of the calls. We have shared information with the CDC about lab capacity and other information, in the event that public health labs are unable to handle testing needs, and surge capacity is necessary.

While these calls have been helpful, numerous questions remain about the availability of the CDC assay to commercial labs, the FDA EUA process, and other issues. I'd be happy to modify the agenda to allow time for a representative from the FDA, CDC, or both, to provide an update an answer questions.

I know the situation is changing quickly, and I can only imagine how busy it is at the FDA. But, as a lot of the key players in the diagnostics community will be together at our meeting next week, I wanted to extend the opportunity.

My office and mobile numbers are below if you have questions or if you would like to discuss.

Thanks.

Julie

**Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) \ (b) (6) m)**

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/28/2020 1:44:02 PM
**To**: Humes, Rosemary (OS/ASPR/BARDA) [Rosemary.Humes@hhs.gov]
**CC**: Wallace, Rodney (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2814cd3aa9043f8bf8f8c4490b6b98a-HHS-Rodney.]; Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Elizabeth J Hillebrenner (Elizabeth.Hillebrenner@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Questions

Hi Rosemary,

I defer to Jeff. Do you have a list of companies that have RUO assays for 2019 nCoV today on their shelves that can ship?

Thanks!

Best,
***Tim***

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Friday, February 28, 2020 12:21 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Questions

Hi Tim,
I didn't get a chance to put together email for Uwe after our call last night. I am OOO today, but Rodney Wallace, my boss, was called to Sec Azar's office this morning about the new proposed LDT pathway. He was given this document, and told to call some companies to see what they needed.

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I just spoke with Uwe, and he indicated that the requirements for commercial developers haven't changed, this is just for clinical labs.

(b) (5)

Other questions best for phone.
I am available until 12:45, and after 2:15. (b) (6)
Thanks,
Rosemary

<< File: Notes for RosemaryRodney 228.pdf >>

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/29/2020 12:43:29 AM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) [wdk1@cdc.gov]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: SEATTLE Flu Study Lab Result

Just got home. Call my cell as early as you want in the morning and we can discuss. Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Friday, February 28, 2020 9:35 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: SEATTLE Flu Study Lab Result
**Importance:** High

Tim, when you have time and can fill me in on where this stands I would appreciate it. (b) (5) [redacted]

Thanks and have a great weekend.

**Wendi Kuhnert-Tallman**
**phone - 404-639-3103**

---

**From:** Cowgill, Karen <n-kcowgill@kingcounty.gov>
**Sent:** Friday, February 28, 2020 4:46 PM
**To:** Mark J Rieder <mrieder@uw.edu>; Helen Y Chu <helenchu@uw.edu>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Duchin, Jeff (CDC kingcounty.gov) <jeff.duchin@kingcounty.gov>; Kay, Meagan K. (CDC kingcounty.gov) <meagan.kay@kingcounty.gov>
**Cc:** Robin A Prentice <robins4@uw.edu>; Janet Englund (b) (6) @seattlechildrens.org) <janet.englund@seattlechildrens.org>; Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>; Jay A. Shendure <shendure@uw.edu>; Trevor Bedford (b) (6) >; Istarita <lstarita@uw.edu>

AMERICAN OVERSIGHT

**Subject:** RE: SEATTLE Flu Study Lab Result
**Importance:** High

Hi Tim, et al. at CDC and Mark, et al. at SFS – Jeff Duchin (Chief Health Officer at Public Health Seattle-King County) asked me to follow up with you about the outcome of our discussion earlier today (9 PT/12 ET) about Seattle Flu Study testing for SARS-CoV-2.

At the end of the call, Tim said he would get back to Mark within the hour, but we haven't heard anything on our end.

Could someone please send a summary of where things stand and specifically
- what the current guidance is about SFS continued testing of samples for nCoV (retrospective and prospective)
- if testing continues, what is the flow of information to public health / re-contacting patients with results
- any other relevant info (e.g., was the lot of the kit SFS used to confirm their initial positive the same lot that CDC had QC'd?)

Thank you,

Karen Cowgill, PhD, MSc *(she/her)*
COVID-19 Response Epidemiologist
Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Affiliate Assistant Professor in Global Health, University of Washington
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (b) (6); Fax: (206) 296-4803
E-mail: n-kcowgill@kingcounty.gov

---

**From:** Mark J Rieder <mrieder@uw.edu>
**Sent:** Thursday, February 27, 2020 10:57 PM
**To:** Helen Y Chu <helenchu@uw.edu>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Robin A Prentice <robins4@uw.edu>; Janet Englund (b) (6) @seattlechildrens.org) (b) (6) @seattlechildrens.org>; Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>; Jay A. Shendure <shendure@uw.edu>; Trevor Bedford (b) (6) Istarita <lstarita@uw.edu>
**Subject:** Re: SEATTLE Flu Study Lab Result

[EXTERNAL Email Notice! ] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

Here is the Zoom link for the call in tomorrow (Friday, 2/28 @ 9 am PT)
Mark Rieder is inviting you to a scheduled Zoom meeting.

Topic: CDC Call
Time: Feb 28, 2020 09:00 AM Pacific Time (US and Canada)

Join Zoom Meeting
https://washington.zoom.us/j/(b) (6).

Meeting ID: (b) (6)

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One tap mobile
(b) (6) US (San Jose)
US (New York)

Dial by your location
(b) (6) (San Jose)
(b) (6) (New York)
Meeting ID: (b) (6)

On Thu, Feb 27, 2020 at 10:50 PM Helen Y Chu <helenchu@uw.edu> wrote:

Let's all plan to be on a 9:00 am call tomorrow to discuss this. Robin, can you set up a zoom call and include whoever else should join from the SFS team.
Thank you.

Get Outlook for iOS

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Thursday, February 27, 2020 8:19 PM
**To:** Duchin, Jeff (CDC kingcounty.gov)
**Cc:** Helen Y Chu; Janet Englund ((b) (6) @seattlechildrens.org); Lindquist, Scott SL (CDC doh.wa.gov); Cowgill, Karen
**Subject:** Re: SEATTLE Flu Study Lab Result

Thanks much Jeff for connecting us. Happy to make the time any time - 7:30 your time is fine but I will wait to see the calendar invite to confirm.

Thanks!

Get Outlook for iOS

---

**From:** Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
**Sent:** Thursday, February 27, 2020 11:17:20 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Cc:** Helen Y Chu <helenchu@uw.edu>; Janet Englund (b) (6) @seattlechildrens.org) (b) (6) @seattlechildrens.org>; Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>
**Subject:** SEATTLE Flu Study Lab Result

Wendy,

Thanks for helping us navigate with FDA colleagues what we can say/do in response to a potential positive test result from the SFS research assay. Helen Chu and Jan Englund are the SFS researchers that can provide the details of the test method and other relevant information. I'm also copying Scott Lindquist, the WA State DOH communicable disease epidemiologist and Karen Cowgill who works on surveillance with us. It probably would be good to have a call early tomorrow Pacific time (7:30) but Helen and Jan should schedule the time with you.

Very much appreciate your help.

AMERICAN OVERSIGHT

Jeff

_____ Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (b) (6) ; Fax: (206) 296-4803
E-mail: jeff.duchin@kingcounty.gov

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/29/2020 7:45:30 PM
**To:** Krueger, Brian [(b) (6) @LabCorp.com]; Humes, Rosemary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6de8a41cc8d54da69787255ca964affa-HHS-Rosemar]; Eisenberg, Marcia [Eisenbm@LabCorp.com]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Burns, Ayla [(b) (6) @LabCorp.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: RE: RE: RE: LabCorp update

That's what I need. Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Krueger, Brian <(b) (6) @LabCorp.com>
**Sent:** Saturday, February 29, 2020 7:40 PM
**To:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Eisenberg, Marcia <Eisenbm@LabCorp.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Burns, Ayla <(b) (6) @LabCorp.com>
**Subject:** RE: RE: RE: LabCorp update

Sorry, Tim, you asked for weekly, not daily :) (b) (4) samples per week at the (b) (4) site, but as I said, we have a number of other large national labs that utilize the same instrumentation so we can support very high volumes of testing if needed.

-Brian

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**From:** Krueger, Brian <(b) (6) @LabCorp.com>
**Sent:** Saturday, February 29, 2020 6:36:07 PM
**To:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Eisenberg, Marcia <Eisenbm@LabCorp.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Burns, Ayla <(b) (6) @LabCorp.com>
**Subject:** Re: [External] RE: RE: RE: LabCorp update

(b) (4)/samples per day but we can scale to much higher volumes relatively quickly with instrument purchases or transferring to other large national labs within our Network.

-Brian

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 6:31:25 PM
**To:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Eisenberg, Marcia <Eisenbm@LabCorp.com>; Krueger, Brian <(b) (6) @LabCorp.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Burns, Ayla <(b) (6) @LabCorp.com>
**Subject:** [External] RE: RE: RE: LabCorp update

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Hi Marcia and Brian, Got a question for you. Given that once you have completed validation and notified the FDA you can begin testing and then submit your package within 15 days. What will your weekly testing capacity be?

It is short notice but can you get me this information in about 1 hour – by 8:30 pm?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
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**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Saturday, February 29, 2020 3:55 PM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>; Krueger, Brian (b) (6) @LabCorp.com>

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**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Burns, Ayla (b) (6) @LabCorp.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: RE: RE: LabCorp update

Hi Marcia,
Thanks for the info. I'll pass along to BEI now.
Rosemary

---

On: 29 February 2020 15:53,
"Eisenberg, Marcia" <Eisenbm@LabCorp.com> wrote:

Here is the address

LabCorp
ATTN: Ayla Burns, R&D 6500
1447 York Court
Burlington, NC 27215

On Feb 29, 2020, at 3:51 PM, Eisenberg, Marcia <Eisenbm@labcorp.com> wrote:

Hi Dr. Scherf
I talked to Ayla
Of course you can ship to the lab if the home address is unacceptable. We are working through the weekend and the lab itself never closes. If the courier has Ayla's cell we can meet them wherever they try to deliver. The Burlington NC lab is huge with multiple entrances.

On Feb 29, 2020, at 3:28 PM, Krueger, Brian (b) (6) @labcorp.com> wrote:

Hi Dr. Scherf,

Ayla's cell is below:
(b) (6)

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**Sent:** Saturday, February 29, 2020 2:12:31 PM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Burns, Ayla <(b) (6) @LabCorp.com>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: [External] RE: RE: LabCorp update

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Hi Dr. Scherf,

I'm sorry I missed your call. We have a team at the lab working tomorrow to prepare samples in anticipation of receipt of this virus.

Avla Burns
(b) (6)

Phone: (b) (6)

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 1:41:25 PM
**To:** Krueger, Brian (b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
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Where would it need to be shipped to.

I copied Rosemary Humes, she ahs close contact to (b) (4) and has facilitated the process.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/27/2020 12:34:35 PM
**To:** Humes, Rosemary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6de8a41cc8d54da69787255ca964affa-HHS-Rosemar]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Re: (b) (4)

Do you have a contact for (b) (4) that we can talk with today in case we want to use their kits in our response?

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Date:** February 27, 2020 at 12:13:33 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: Qiagen

Sent this to Uwe this morning.

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Thursday, February 27, 2020 8:06 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Qiagen

Hi Uwe,
FYSA- As discussed , we are being asked about U.S. status everytime a company makes a press announcement about the availability of their test outside the US. This one from Qiagen raised a bunch of questions last night.

FEB 26 2020

# QIAGEN announces worldwide shipments of QIAstat-Dx test kits for SARS-CoV-2

**• QIAstat-Dx Respiratory 2019-nCoV Panel rapidly differentiates novel coronavirus from 21 other pathogens implicated in serious respiratory syndromes**

**• Panel being tested at four hospitals in China after initial evaluation on clinical samples by a leading Paris hospital**

**• Adds to QIAGEN's portfolio of molecular testing solutions to aid in global public health emergency**

**Hilden, Germany, and Germantown, Maryland, February 26, 2020** – QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced it has shipped its newly developed QIAstat-Dx Respiratory Panel 2019-nCoV test kit to four hospitals in China for evaluation. The new kit detects the novel coronavirus SARS-CoV-2 and adds rapid Sample to Insight syndromic

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testing to QIAGEN's portfolio of molecular testing solutions in the public health emergency. QIAGEN is also in the process of shipping QIAstat-Dx testing kits to public health institutions in other regions, including Europe, South-East Asia, and the Middle East.

Since January QIAGEN has been providing instruments and consumables to support detection of the virus in China and other markets. Official protocols for SARS-CoV-2 detection include QIAGEN extraction kits, reagents and instruments for real-time polymerase chain reaction (RT-PCR) workflows. Customers also are deploying QIAsymphony modular instruments and NeuMoDx integrated PCR systems to automate higher-throughput processing of their laboratory-developed tests for SARS-CoV-2.

"Our dedicated task force has moved very fast to develop and make available the QIAstat-Dx respiratory panel with SARS-CoV-2 detection. We are partnering closely with authorities and customers around the world to bring rapid, accurate diagnosis to the fight against this deadly infectious disease," said Thierry Bernard, Interim CEO of QIAGEN and Senior Vice President, Head of the Molecular Diagnostics Business Area. "As we have in past health crises such as SARS and the swine flu, QIAGEN is working hard to deliver better, faster testing solutions for hospitals and public health institutions to aid in the effort to monitor and bring the outbreak under control. Our employees' extraordinary response embodies QIAGEN's core mission to make improvements in life possible."

The QIAstat-Dx system was introduced in Europe in 2018 as a CE-product and cleared by the Food and Drug Administration (FDA) in the United States in mid-2019. It enables fast, cost-effective and easy-to-use syndromic testing with novel Sample to Insight workflows. The system streamlines molecular testing from end to end. A technician simply loads a clinical sample (such as a swab) into a single-use QIAstat-Dx cartridge and places it in the analyzer. QIAGEN chemistries for sample processing and analysis are built in, and the QIAstat-Dx instrument delivers results in about one hour.

**New QIAstat-Dx testing solution for SARS-CoV-2**

The QIAstat-Dx Respiratory 2019-nCoV Panel is a new version of the existing QIAstat-Dx Respiratory Panel for differential analysis of 21 viral and bacterial pathogens in respiratory syndromes. Once the SARS-CoV-2 genome was sequenced in January, QIAGEN developed two highly sensitive assays to detect SARS-CoV-2 targeting Orb1ab and the E gene. The addition of these targets provides parallel tools for combined detection of the novel coronavirus with increased sensitivity.

The expanded QIAstat-Dx panel is currently being evaluated at the Bichat-Claude Bernard Hospital in Paris. "After more than a year of experience using the existing QIAstat-Dx Respiratory Panel to evaluate patients coming into our Emergency Department with respiratory syndromes, we are evaluating the new panel with SARS-CoV-2 against RT-PCR testing using WHO recommended protocols. The QIAstat-Dx solution can provide results in about one hour, with high sensitivity and specificity and minimal hands-on time for hospital or laboratory personnel," said Dr. Benoit Visseaux, Associate Professor of Virology at Bichat-Claude Bernard Hospital in Paris.

Amid the rapidly evolving response to the coronavirus outbreak, the regulatory status of the QIAstat-Dx Respiratory Panel will vary by location. QIAGEN will apply for emergency authorization for marketing of the new panel from the U.S., the Korean KCDC/MFDS, and FDA and China's National Medical Products Administration (NMPA); the panel will be available with CE-IVD marking in Europe and other markets.

**Multiple other QIAGEN testing solutions for SARS-CoV-2**

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QIAGEN has moved quickly on several fronts to provide molecular testing solutions to researchers working to counter the international threat from the SARS-CoV-2 virus. Building on its strong position and experience in molecular testing for infectious diseases, QIAGEN is providing a variety of solutions:

- Enabling laboratory-developed tests (LDTs) – extraction kits, PCR enzymes and instruments, supporting in-house testing by laboratories and public health institutions. CDC guidelines for RT-PCR testing list QIAGEN's EZ1 DSP Virus kits, which run on EZ1 Advanced workstations, and QIAamp DSP Viral RNA Mini kits, which can be automated on QIAcube instruments. Chinese authorities and the Berlin Charitè protocol also include QIAGEN consumables.
- Mid- and high-throughput automation – QIAsymphony modular systems for sample preparation and PCR analysis, as well as NeuMoDx 96 and 288 systems for fully integrated PCR analysis, enabling customers to implement higher-throughput solutions for laboratory-developed RT-PCR tests. QIAGEN recently started placing NeuMoDx systems in China, for use in with LDTs in SARS-CoV-2 testing.
- Additional real-time PCR tests – two new RT-PCR tests for detection of SARS-CoV-2 have been developed at QIAGEN sites in China and the United States and will be available for Research Use Only. The company is investigating potential emergency use options for the automated PCR-based test solutions.

Further information can be also found here

**About QIAGEN**

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in Molecular Diagnostics (human healthcare) and Life Sciences (academia, pharma R&D and industrial applications, primarily forensics). As of December 31, 2019, QIAGEN employed approximately 5,100 people in over 35 locations worldwide. Further information can be found athttp://www.qiagen.com.

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**Subject:** RE: RE: RE: LabCorp update

**Importance:** High

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It is short notice but can you get me this information in about 1 hour – by 8:30 pm?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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Hi Marcia,
Thanks for the info. I'll pass along to (b) (4) now.
Rosemary

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**Subject:** Re: [External] RE: RE: LabCorp update

Hi Dr. Scherf,

I'm sorry I missed your call. We have a team at the lab working tomorrow to prepare samples in anticipation of receipt of this virus.

Ayla Burns
(b) (6)

Phone: (b) (6)

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/27/2020 2:24:32 PM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Smith, Lia H (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cda5acfaea1403d98eeed026beb76bd-HHS-loh5-cd]; Pallansch, Mark (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2941652b4c784575b079ef1164b4f089-HHS-map1-cd]
**CC**: Gerber, Susan I (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75e9a3507e84f3db20707eeccd86d44-HHS-bhx1-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Rager, Stacy (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9981c603ae364ec38dbd5a6cb260caf1-HHS-vmk4-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Must haves this morning
**Attachments**: QC Testing of CDC 2019- nCoV rRT-PCR Primers Probes DRAFT.pdf

This is great! Unless I hear otherwise by 2:35 pm Eastern, I am sending this to APHL for distribution to PHLs.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Thursday, February 27, 2020 2:21 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom,

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Stephen (CDC) <sql5@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>; Pallansch, Mark (CDC) <map1@cdc.gov>
**Cc:** Gerber, Susan I (CDC) <bhx1@cdc.gov>
**Subject:** RE: Must haves this morning

Found it!

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 2:05 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Haynes, Lia (CDC/DDPHSIS/CPR/OD) <loh5@cdc.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>
**Cc:** Gerber, Susan I. (CDC/DDID/NCIRD/DVD) <bhx1@cdc.gov>
**Subject:** RE: Must haves this morning

Understood, Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Thursday, February 27, 2020 1:51 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>; Pallansch, Mark (CDC) <map1@cdc.gov>
**Cc:** Gerber, Susan I (CDC) <bhx1@cdc.gov>
**Subject:** RE: Must haves this morning

Steve is in the lab trying to rework kits, and Janna is setting up plates for IDT QC – I will see if I can find it.

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Thursday, February 27, 2020 1:44 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Haynes, Lia (CDC/DDPHSIS/CPR/OD) <loh5@cdc.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>
**Cc:** Gerber, Susan I. (CDC/DDID/NCIRD/DVD) <bhx1@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD)

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<wdk1@cdc.gov>
**Subject:** RE: Must haves this morning

Steve, I just spoke with Tim and he urgently needs for you to provide the enhanced QC procedure requested below. He needs to share this with APHL as FDA has granted permission for the PHLs to order the IDT kits, follow this enhanced QC process and then use the kits to perform routine testing. What he needs is a summary of how your lab performed the QC that you presented to us this morning. If you do not have a procedure then we would like to see, at a minimum, the document that you showed us this morning with the data removed. This is needed urgently within the next hour if possible.

Thanks, wendi

**Wendi Kuhnert-Tallman**
**Office - 404-639-3103**
**Mobile – 678-576-2121**

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Thursday, February 27, 2020 9:11 AM
**To:** Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Haynes, Lia (CDC/DDPHSIS/CPR/OD) <loh5@cdc.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Carroll, Darin (CDC/DDID/NCEZID/OD) <zuz4@cdc.gov>; Karem, Kevin (CDC/DDPHSIS/CGH/OD) <kdk6@cdc.gov>
**Cc:** Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Gerber, Susan I. (CDC/DDID/NCIRD/DVD) <bhx1@cdc.gov>
**Subject:** RE: Must haves this morning

Updates provided below:

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 7:18 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Haynes, Lia (CDC/DDPHSIS/CPR/OD) <loh5@cdc.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Carroll, Darin (CDC/DDID/NCEZID/OD) <zuz4@cdc.gov>; Karem, Kevin (CDC/DDPHSIS/CGH/OD) <kdk6@cdc.gov>
**Cc:** Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** Must haves this morning

Hi All,

Good morning. I feel like we are making good progress.

It is important I get the following this morning:

(b) (4), (b) (5)



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(b) (4), (b) (5)

[redacted]

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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Office of Product Evaluation and Quality

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**From:** Stenzel, Timothy
**Sent:** Wednesday, February 26, 2020 12:41 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>; Pallansch, Mark (CDC) <map1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Karem, Kevin L (CDC) <kdk6@cdc.gov>
**Cc:** Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Revisiting use of (b) (5) [redacted]

Great news Steve.

(b) (4) [redacted] Let's assume that will come through.

I am NOT asking for rush QC, best to follow good practices. For planning purposes, how long will QC for each take and when will results be available?

Thanks!

Best,
*Tim*

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**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Office of Product Evaluation and Quality

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---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Wednesday, February 26, 2020 12:18 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>; Pallansch, Mark (CDC) <map1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Karem, Kevin L (CDC) <kdk6@cdc.gov>
**Cc:** Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Revisiting use of (b) (5)

UPDATE:
CDC primers/probes for N1, N2 and RP were received from IDT today. Undergoing QC testing now. RP were mislabeled as N4. Other labels for RP provided by IDT for relabeling also do not meet spec provided. QA review commencing and relabeling of RP tubes will proceed.

IDT Primer/probe kits received at room temp. All reagents provided as wet. Package insert attached referring users to the CDC website for RUO protocol however oligo concentrations to not agree with CDC protocol. Looks like references to kit have been removed from IDT website so specs are not clear. Are these ZEN probes as I was last informed? We can share our ZEN qualified that was performed as per FDA guidance.

Please let us know what the current plan is.
Thanks.
Steve

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Wednesday, February 26, 2020 7:52 AM
**To:** Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Haynes, Lia (CDC/DDPHSIS/CPR/OD) <loh5@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Carroll, Darin (CDC/DDID/NCEZID/OD) <zuz4@cdc.gov>; Karem, Kevin (CDC/DDPHSIS/CGH/OD) <kdk6@cdc.gov>
**Cc:** Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Revisiting use of (b) (5)

Hi Tim,

(b) (5) We can discuss further if necessary.

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Thanks,
Julie

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 7:46 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Haynes, Lia (CDC/DDPHSIS/CPR/OD) <loh5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Carroll, Darin (CDC/DDID/NCEZID/OD) <zuz4@cdc.gov>
**Cc:** Thomas, Jennifer (Jennie) (CDC/DDID/NCEZID/DPEI) <fsu8@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** Revisiting use of (b) (5) [redacted]

Hi,

Giving you all a head up. Can we revisit this tomorrow morning?

Dan and I tonight discussed the possibility (b) (5) [redacted]

Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Jennifer.Campbell@fda.hhs.gov

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(b) (5) Draft

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(b) (5) Draft

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(b) (5) Draft

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(b) (5) Draft

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(b) (5) Draft

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(b) (5) Draft

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/26/2020 1:49:04 PM
**To:** Russell Herbert [(b) (6) :@LGCGroup.com]; Darren Cook [(b) (6) :@LGCGroup.com]
**CC:** Rager, Stacy (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9981c603ae364ec38dbd5a6cb260caf1-HHS-vmk4-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: LGC

Hi Russell,

(b) (4)

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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**From:** Russell Herbert <(b) (6) :@LGCGroup.com>
**Sent:** Wednesday, February 26, 2020 1:46 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Darren Cook (b) (6) .@LGCGroup.com>
**Cc:** Rager, Stacy (CDC) <vmk4@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** RE: LGC

(b) (4)

Russell Herbert | Director Global Sales | Biosearch Technologies
Strategic Accounts | Healthcare & Diagnostic Market

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Cell: (b) (6) @LGCGroup.com

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 11:26 AM
**To:** Russell Herbert (b) (6) @LGCGroup.com>; Darren Cook <(b) (6) @LGCGroup.com>
**Cc:** Rager, Stacy (CDC) <vmk4@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** RE: LGC

Thanks you Russell for this update! I also heard that (b) (4) has a Coronavirus RUO kit order in with you that is being prepared and has not yet been delivered. Do you know that status of that order? Also the number of kits and reactions per kit?

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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**Jennifer Campbell**
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**From:** Russell Herbert <(b) (6) :@LGCGroup.com>
**Sent:** Wednesday, February 26, 2020 1:03 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Darren Cook <(b) (6) @LGCGroup.com>
**Cc:** Rager, Stacy (CDC) <vmk4@cdc.gov>
**Subject:** RE: LGC

Tim

I am sure you are likely aware of this – but we do have a current contract with the LRN group of the CDC. 75D30119A04957

The Coronavirus is listed as one of the assays on this contract.

As part of the submission we added the following to accommodate an outbreak event.

(b) (4)

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(b) (4)



I look forward to hearing from you

Regards

Russell

Russell Herbert | Director Global Sales | Biosearch Technologies
Strategic Accounts | Healthcare & Diagnostic Market
Cell: (b) (6) @LGCGroup.com

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 7:09 AM
**To:** Darren Cook (b) (6) .@LGCGroup.com>
**Cc:** Russell Herbert (b) (6) :@LGCGroup.com>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Subject:** RE: LGC

Hi Darren,

Thanks for the fast TAT! I will check with my FDA and CDC colleagues and get back to you on (b) (4) production as soon as possible.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Darren Cook <(b) (6) @LGCGroup.com>
**Sent:** Tuesday, February 25, 2020 10:02 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Russell Herbert <(b) (6) :@LGCGroup.com>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Subject:** RE: LGC

Tim,

It was a pleasure to connect with you via phone earlier this evening. I just reached my home and during my journey I was able to connect with our operations team out in California.

(b) (4)

Please do let us know if you'd like to have us initiate the production of RUO kits at the (b) (4) scale and we'll get the team to jump on it immediately.

Thanks again for your time on the phone. I'll be in touch once I get connected with Roman.

Kind regards, Darren

Darren Cook | VP Global Sales | Genomics |
LGC | 3600 Minnesota St. Alexandria, MN 56308 |
Tel: +(b) (6) | Mob: (b) (6) (b) (6) |
(b) (6) @lgcgroup.com |
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www.biosearchtech.com |

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---

**From:** Ruth Miller (b) (6) r@LGCGroup.com>
**Sent:** Tuesday, February 25, 2020 6:51 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rager, Stacy (CDC) <vmk4@cdc.gov>

AMERICAN OVERSIGHT

**Cc:** Russell Herbert (b) (6) @LGCGroup.com>; Darren Cook (b) (6) @LGCGroup.com>; Brian Kim (b) (6) @LGCGroup.com>
**Subject:** RE: LGC

Hi Dr. Stenzel,

Thank you very much for letting me know. I am very relieved to hear this! I hope that you have a wonderful evening.

Kind regards,
Ruth

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:49 PM
**To:** Ruth Miller <(b) (6) @LGCGroup.com>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Cc:** Russell Herbert <(b) (6) @LGCGroup.com>; Darren Cook (b) (6) @LGCGroup.com>; Brian Kim (b) (6) @LGCGroup.com>
**Subject:** RE: LGC

Hi Ruth,

Thanks for your help. I was able to connect by phone with Darren Cook and so we are good. He is going to take things from here.

☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Ruth Miller <(b) (6) @LGCGroup.com>
**Sent:** Tuesday, February 25, 2020 7:01 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Cc:** Russell Herbert (b) (6) @LGCGroup.com>; Darren Cook (b) (6) @LGCGroup.com>; Brian Kim (b) (6) @LGCGroup.com>
**Subject:** RE: LGC

AM OVERSIGHT

Hello Dr. Stenzel,

It was very nice to make your acquaintance. I am still working on this request and appreciate that you have copied the other people involved.

Kind regards,
Ruth

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:28 PM
**To:** Ruth Miller <(b) (6) @LGCGroup.com>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Cc:** Russell Herbert (b) (6) @LGCGroup.com>; Darren Cook (b) (6) @LGCGroup.com>; Brian Kim <(b) (6) @LGCGroup.com>
**Subject:** RE: LGC

Thank you Ruth,

I am so glad we connected with you. I have copied people who were at the meeting today or originally scheduled for the meeting at the CDC today.

Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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---

**From:** Ruth Miller <(b) (6) r@LGCGroup.com>
**Sent:** Tuesday, February 25, 2020 6:18 PM
**To:** Rager, Stacy (CDC) <vmk4@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: LGC

Hello Stacy and Tim,

Thank you for sending this email. I am doing my very best to get you in touch with the correct individual.

Kind regards,
Ruth

AMERICAN OVERSIGHT

**From:** Rager, Stacy (CDC/DDID/NCEZID/DPEI) <vmk4@cdc.gov>
**Sent:** Tuesday, February 25, 2020 3:12 PM
**To:** Ruth Miller (b) (6) @LGCGroup.com>
**Cc:** Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** LGC
**Importance:** High

EXTERNAL EMAIL

Today we met with Russell Herbert and Darren Cook and it was mentioned that a temporary licensing might be able to be granted to IDT to help manufacture kits for the nCoV response. The FDA and CDC are working on this and we urgently need to discuss with the appropriate people at LGC to try and make this happen.

You may respond anytime day or night to Tim at (b) (6)

Thank you so much for your help with this!!

**Stacy Rager, CQA, CBA**
Quality Manager, Laboratory Preparedness and Response Branch
Division of Preparedness and Emerging Infections, NCEZID, CDC
404-639-4197
srager@cdc.gov
Telework: Thursday

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AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 8:34:08 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Fwd: APHL Letter for FDA
**Attachments**: enforcement discretion request for COVID-19 for PHLs final.pdf

FYI

---

**From:** Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>
**Date:** February 24, 2020 at 8:20:42 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Fwd: APHL Letter for FDA

FYI

---

**From:** Becker, Scott | APHL <Scott.Becker@aphl.org>
**Sent:** Monday, February 24, 2020 11:22 AM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD); Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS)
**Subject:** APHL Letter for FDA

Dear Wendi and Ren:

I am writing to let you know that the APHL Board of Directors approved sending a letter urging the FDA Commissioner to consider enforcement discretion to allow governmental public health laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). In the letter we state that to the extent possible, public health laboratories could work together to:

- Utilize a standard protocol or use a limited set of protocols
- Purchase reagents including primers and probes from a common source
- Utilize a standard validation panel
- Recommend a minimum standard validation approach
- Enable confirmation at another PHL while cases remain sporadic. It is also possible to consider the use of LRN advanced labs to serve as a confirmatory lab if resources are available to do so.

We recognize that not all PHL's will develop and implement an LDT. If PHL's decided against the use of an LDT for whatever reason, they could: 1) wait for the availability of the new CDC replacement kit, 2) coordinate with a PHL that has developed an LDT (this is not uncommon for PHLs to work together), or 3) use a commercially available assay once approved by FDA under an EUA.

We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request.

We will let you know the outcome of our communication with FDA, which is attached. The letter was sent to the FDA Commissioner, copy to his chief of staff; Dr. Redfield, copy to Dr. Jernigan.

Sincerely,

Scott Becker

AMERICAN OVERSIGHT

---
Scott Becker MS
Executive Director
Association of Public Health Laboratories
Silver Spring MD
240.485.2747
---

**Scott J. Becker** (he/him)
Chief Executive Officer
**P** +1 240.485.2747 | **M** +1 301.526.5704
scott.becker@aphl.org | @scottjbecker

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8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
www.aphl.org | APHL Blog
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ID Lab Con 2020 | APHL 2020 Why Attend? (video)

AMERICAN OVERSIGHT

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

February 24, 2020

Stephen M. Hahn, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn,

On behalf of our nation's state and local public health laboratories (PHLs), we are writing to urge you to consider enforcement discretion to allow this select group of governmental laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request.

While we appreciate the many efforts underway at CDC to provide a diagnostic assay to our member labs under the Emergency Use Authorization (EUA), this has proven challenging and we find ourselves in a situation that requires a quicker local response. We are now many weeks into the response with still no diagnostic or surveillance test available outside of CDC for the vast majority of our member laboratories. While we understand that the EUA process is open to PHLs, we believe a more expeditious route is needed at this time.

To the extent possible, public health laboratories could work together to:

- Utilize a standard protocol or use a limited set of protocols
- Purchase reagents including primers and probes from a common source
- Utilize a standard validation panel
- Recommend a minimum standard validation approach
- Enable confirmation at another PHL while cases remain sporadic. It is also possible to consider the use of LRN advanced labs to serve as a confirmatory lab if resources are available to do so.

We recognize that not all PHL's will develop and implement an LDT. If PHL's decided against the use of an LDT for whatever reason, they could: 1) wait for the availability of the new CDC replacement kit, 2) coordinate with a PHL that has developed an LDT (this is not uncommon for PHLs to work together), or 3) use a commercially available assay once approved by FDA under an EUA.

We look forward to discussing this request with you and your staff as soon as possible. If you have questions, please contact Scott Becker at 301-526-5704 or via email at scott.becker@aphl.org.

Sincerely,

Grace Kubin

Scott J. Becker

Grace Kubin, Ph.D.
Director, Laboratory Services Section
Texas Department of State Health Services

Scott J. Becker, MS
Chief Executive Officer
Association of Public Health Laboratories

cc: Robert Redfield, MD, Director, Centers for Disease Control and Prevention

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/18/2020 12:21:13 PM
**To:** Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: CDC Coronavirus assay question.

Hi Jeff and Uwe,

It looks like the ask (b) (5) [redacted]

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 12:19 PM
**To:** Salerno, Reynolds M (CDC) <yyw2@cdc.gov>; Iademarco, Michael (CDC) <mai9@cdc.gov>
**Cc:** Clark, David W (CDC) <dqc5@cdc.gov>; Sen, Oishee (CDC) <qam3@cdc.gov>; Chaitram, Jasmine M (CDC) <zoa6@cdc.gov>
**Subject:** RE: CDC Coronavirus assay question.

Thanks Ren,

So it sounds like (b) (5) [redacted]. Thanks for the update and if we can (b) (5) [redacted], let us know.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

AMENDED
ORIGINAL

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>
**Sent:** Tuesday, February 18, 2020 11:16 AM
**To:** Iademarco, Michael (CDC) <mai9@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Clark, David W (CDC) <dqc5@cdc.gov>; Sen, Oishee (CDC) <qam3@cdc.gov>; Chaitram, Jasmine M (CDC) <zoa6@cdc.gov>
**Subject:** RE: CDC Coronavirus assay question.

Hi Tim,

My division has responsibility for CDC's relationship with the non-public health laboratory sector. (b) (5) [redacted]

Thanks,
Ren

---

**From:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Sent:** Tuesday, February 18, 2020 10:53 AM
**To:** Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>; Clark, David W. (CDC/DDPHSS/CSELS/OD) <dqc5@cdc.gov>; Sen, Oishee (CDC/DDPHSS/CSELS/OD) <qam3@cdc.gov>
**Subject:** RE: CDC Coronavirus assay question.

Very interesting, Tim. Ren help guide you to the answer, which could include Wendi. (b) (5) [redacted]

In a "response" (where we activate the EOC for an emergency), we (CDC) must go through the EOC for all questions and answers, and not to programs. You cannot be expected to figure that out.

Ren, with Mr. Clark's help, can navigate the question from FDA, CSELS, to the response. Ren's division of laboratory system is the CDC focal point for all clinical laboratories at CDC.

Dr. Wendi Kuhnert is the senior laboratory advisor to the Deputy Director for Infectious Diseases, which overseas the three infectious disease centers. More importantly in this instance, Wendi is one of three deputy incident managers in the response. Lab Task Force is covered under her.

AMERICAN OVERSIGHT

Also do note that FDA has a liaison to the response, I think. Mr. Clark will let you know who that is (if you don't know), and take a reinforcing approach through the FDA liaison, who at a minimum should be kept in the loop.

Looking forward to see you later this week.

Best, Michael

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 9:56 AM
**To:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Subject:** CDC Coronavirus assay question.

Hi Michael,

I have a question for the CDC and don't know who to ask and am hoping you can help.

(b) (5)

[redacted]

We are getting EUA developers who are saying they will be using the CDC primers and probes in their assays and wanted to check on this as well.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
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AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 9:08:12 PM
**To:** Huynh, Chuong Q (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c549fa2b588241a3bbde4b060f28d694-HHS-Chuong.]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Re: COVID-19 Diagnostics Validation materials (update Feb 24, 2020)

Sorry Chuong. Spell check error.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 24, 2020 at 9:06:49 PM EST
**To:** Huynh, Chuong Q (OS) <Chuong.Huynh@hhs.gov>
**Subject:** Re: COVID-19 Diagnostics Validation materials (update Feb 24, 2020)

Hi Chung, Roche just updated me that they have received live virus from (b) (4). Labcorp just told me that they hadn't yet received their (b) (4) live virus order. I am hoping that since Roche got theirs, labcorp will get theirs very soon. And just heard from Uwe that UTMB is ready to ship extracted RNA. Best, Tim

---

**From:** Huynh, Chuong (OS/ASPR/BARDA) <Chuong.Huynh@hhs.gov>
**Date:** February 24, 2020 at 3:23:49 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Carroll, Darin S (CDC) <zuz4@cdc.gov>, Smith, Lia H (CDC) <loh5@cdc.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Subject:** COVID-19 Diagnostics Validation materials (update Feb 24, 2020)

Hi,

- **Diagnostics validation materials:**

(b) (5)

AMERICAN OVERSIGHT

Chuong Huynh
Currently assigned to COVID-19 response - ASPR/BARDA liaison to CDC-Atlanta
HHS/OS/ASPR/BARDA/IEID
Mobile: (b) (6)
Email: Chuong.Huynh@hhs.gov
https://www.medicalcountermeasures.gov/

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 4:12:31 PM
**To:** Huynh, Chuong (OS/ASPR/BARDA) [Chuong.Huynh@hhs.gov]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: COVID-19 Diagnostics Validation materials (update Feb 24, 2020)

Thank you Chuong for the update.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Huynh, Chuong (OS/ASPR/BARDA) <Chuong.Huynh@hhs.gov>
**Sent:** Monday, February 24, 2020 3:22 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Subject:** COVID-19 Diagnostics Validation materials (update Feb 24, 2020)

Hi,

- **Diagnostics validation materials:**

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

Chuong Huynh
Currently assigned to COVID-19 response - ASPR/BARDA liaison to CDC-Atlanta
HHS/OS/ASPR/BARDA/IEID
Mobile: (b) (6)
Email: Chuong.Huynh@hhs.gov
https://www.medicalcountermeasures.gov/

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/18/2020 10:01:39 AM
**To:** Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC:** Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: BY noon tomorrow

Hi Jeff,

Please see Rosemary's note below about (b) (5)

(b) (5)

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 8:47 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Re: BY noon tomorrow

Hi Tim,
Thanks for the response. (b) (5)

(b) (5)

AMERICAN OVERSIGHT

Look forward to feedback from you and Uwe on talking points and landscapes.
Rosemary

---

On: 17 February 2020 17:57,
"Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov> wrote:

Hi Rosemary, Here it is.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 17, 2020 at 1:05:25 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Thank you.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 17, 2020 at 12:40:22 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Uwe, My POC thoughts below. Copying Jeff for his awareness.

(b) (5)



Dear Rosemary,

Here are my thoughts.

(b) (5)



AMERICAN OVERSIGHT

(b) (5)

[redacted]

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 17, 2020 at 9:59:06 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: BY noon tomorrow

Tim,

I need your help on this request, since I will not find time to provide feedback to Rosemary.

I am working with CDC on their change in cut-off proposal.

Thanks,
Uwe

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 8:36 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** BY noon tomorrow

Uwe and Wendi,
We have been asked to put together a one-pager and landscape on POC diagnostics discussing time (development and manufacturing(b) (5) costs and issues with developing a hand held diagnostic/tests.

(b) (5)

[redacted]

Need today -

1. throw some thoughts for what we can put in the one-pager into an email – will get a joint draft ready ASAP.
   a. Uwe, please address regulatory issues, (b) (5)
2. provide some ideas on what we can do to reality set this expectation.

Thanks very much,

AMERICAN OVERSIGHT

Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
Cell: (b) (6)

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/18/2020 12:19:14 PM
**To**: Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) [yyw2@cdc.gov]; Iademarco, Michael (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60a2bbf679974a56950bbb13b73d2549-HHS-mai9-cd]
**CC**: Clark, David W (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a61a4e3fd8dc4ba78aa44dd2181415b1-HHS-dqc5-cd]; Sen, Oishee (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50f36c7e65c34f21ad6c81277ec8f8df-HHS-qam3-cd]; Chaitram, Jasmine M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f23099b19f4dfab6048ca7c6bd202c-HHS-zoa6-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: CDC Coronavirus assay question.

Thanks Ren,

So it sounds like (b) (5) [redacted]. Thanks for the update and if we can help with (b) (5) [redacted] let us know.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>
**Sent:** Tuesday, February 18, 2020 11:16 AM
**To:** Iademarco, Michael (CDC) <mai9@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Clark, David W (CDC) <dqc5@cdc.gov>; Sen, Oishee (CDC) <qam3@cdc.gov>; Chaitram, Jasmine M (CDC) <zoa6@cdc.gov>
**Subject:** RE: CDC Coronavirus assay question.

Hi Tim,

AMERICAN OVERSIGHT

My division has responsibility for CDC's relationship with the non-public health laboratory sector. (b) (5)

Thanks,
Ren

**From:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Sent:** Tuesday, February 18, 2020 10:53 AM
**To:** Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>; Clark, David W. (CDC/DDPHSS/CSELS/OD) <dqc5@cdc.gov>; Sen, Oishee (CDC/DDPHSS/CSELS/OD) <qam3@cdc.gov>
**Subject:** RE: CDC Coronavirus assay question.

Very interesting, Tim. Ren help guide you to the answer, which could include Wendi (b) (5)

In a "response" (where we activate the EOC for an emergency), we (CDC) must go through the EOC for all questions and answers, and not to programs. You cannot be expected to figure that out.

Ren, with Mr. Clark's help, can navigate the question from FDA, CSELS, to the response. Ren's division of laboratory system is the CDC focal point for all clinical laboratories at CDC.

Dr. Wendi Kuhnert is the senior laboratory advisor to the Deputy Director for Infectious Diseases, which overseas the three infectious disease centers. More importantly in this instance, Wendi is one of three deputy incident managers in the response. Lab Task Force is covered under her.

Also do note that FDA has a liaison to the response, I think. Mr. Clark will let you know who that is (if you don't know), and take a reinforcing approach through the FDA liaison, who at a minimum should be kept in the loop.

Looking forward to see you later this week.

Best, Michael

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 9:56 AM
**To:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Subject:** CDC Coronavirus assay question.

Hi Michael,

I have a question for the CDC and don't know who to ask and am hoping you can help.

(b) (5)

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Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 8:33:38 PM
**To**: Salerno, Reynolds M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=049f0ba7591d4296a05476b62825fc16-HHS-yyw2-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Re: APHL Letter for FDA

Thanks Ren. Appreciate it.

---

**From:** Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>
**Date:** February 24, 2020 at 8:20:42 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Fwd: APHL Letter for FDA

FYI

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**From:** Becker, Scott | APHL <Scott.Becker@aphl.org>
**Sent:** Monday, February 24, 2020 11:22 AM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD); Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS)
**Subject:** APHL Letter for FDA

Dear Wendi and Ren:

I am writing to let you know that the APHL Board of Directors approved sending a letter urging the FDA Commissioner to consider enforcement discretion to allow governmental public health laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). In the letter we state that to the extent possible, public health laboratories could work together to:

- Utilize a standard protocol or use a limited set of protocols
- Purchase reagents including primers and probes from a common source
- Utilize a standard validation panel
- Recommend a minimum standard validation approach
- Enable confirmation at another PHL while cases remain sporadic. It is also possible to consider the use of LRN advanced labs to serve as a confirmatory lab if resources are available to do so.

We recognize that not all PHL's will develop and implement an LDT. If PHL's decided against the use of an LDT for whatever reason, they could: 1) wait for the availability of the new CDC replacement kit, 2) coordinate with a PHL that has developed an LDT (this is not uncommon for PHLs to work together), or 3) use a commercially available assay once approved by FDA under an EUA.

We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request.

We will let you know the outcome of our communication with FDA, which is attached. The letter was sent to the FDA Commissioner, copy to his chief of staff; Dr. Redfield, copy to Dr. Jernigan.

Sincerely,

Scott Becker

AMERICAN OVERSIGHT

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Scott Becker MS
Executive Director
Association of Public Health Laboratories
Silver Spring MD
240.485.2747
---

**Scott J. Becker** (he/him)
Chief Executive Officer
**P** +1 240.485.2747 | **M** +1 301.526.5704
scott.becker@aphl.org | @scottjbecker

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www.aphl.org | APHL Blog
Facebook | Twitter | LinkedIn | Instagram

ID Lab Con 2020 | APHL 2020 Why Attend? (video)

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/22/2020 8:07:12 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Fwd: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Jeff,

The CDC now reports (b) (5) labs besides the CDC lab have been successful with verification.

Best,
Tim

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Date:** February 22, 2020 at 8:01:42 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
Our request for response from labs that were able to successfully verify the test went out yesterday afternoon. As of now, a total of twelve labs have responded that they were successful with verification. This includes the seven labs previously identified. We will keep you updated on the status of responses.
I hope this is useful.
Thank you
Steve

Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30329
Phone: 404-639-1587

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 5:17:02 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH)

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<Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Steve and Julie,

Do you have any updates on the labs that successfully validated your assay and are ready to run clinical samples? Did any lab respond?

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 11:22 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
Notifications that CDC received from public health laboratories regarding the reactivity of the N1 and N3 assay as well as those that notified CDC of successful verification are below:

36 labs notified CDC of issues with N3 assay
6 labs notified CDC of issues with N1 assay (these labs are included in those that also saw issues with N3)
7 labs reported that they successfully verified the test in their laboratories

We are reaching out to labs today to notify CDC if they have successfully verified the test and will update if this number changes.

Thank you very much.
Steve

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Friday, February 21, 2020 10:59 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
I just wanted to follow up with you to let you know that we are now working to compile the numbers we have and will get these to you shortly. Also, we will be sending a request to all labs that have received the reagents to please notify CDC if they successfully verified the test in their lab, so the number of verified labs may change from the numbers we initially report to you.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use
**Importance:** High

Julie & Steve,

As requested earlier, please clarify the number of labs that have successfully verified the CDC test panel for use asap. You communicated earlier that ~110 labs received your test and that (b) (5) HL informed you that they could not verify the test.

The question is in the context of a statement by APHL today that only 3 out of 100 public health labs have verified the CDC test for use. Can you confirm that?
"Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.'

See article below:

The article also states, according to CDC, that CDC will distribute a second test and will need it approved by the FDA first.

- Please clarify what that means: Are we talking about the new lot that is being manufactured or the change in cut-off?

Thanks,
Uwe

**Problems with CDC coronavirus test delay expanded US screening**

By David Lim

02/20/2020 05:03 PM EST

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

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The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

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**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

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Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

(b) (5)



Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

There are laboratories that have not had any problems and are testing. We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

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On a second note, could you please clarify one issue for me: (b) (5) [redacted] is that correct?

Thank you for your feedback.

Uwe

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 9:06:49 PM
**To:** Huynh, Chuong Q (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c549fa2b588241a3bbde4b060f28d694-HHS-Chuong.]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Re: COVID-19 Diagnostics Validation materials (update Feb 24, 2020)

Hi Chung, Roche just updated me that they have received live virus from (b) (4). Labcorp just told me that they hadn't yet received their (b) (4) live virus order. I am hoping that since Roche got theirs, labcorp will get theirs very soon. And just heard from Uwe that UTMB is ready to ship extracted RNA. Best, Tim

---

**From:** Huynh, Chuong (OS/ASPR/BARDA) <Chuong.Huynh@hhs.gov>
**Date:** February 24, 2020 at 3:23:49 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Carroll, Darin S (CDC) <zuz4@cdc.gov>, Smith, Lia H (CDC) <loh5@cdc.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Subject:** COVID-19 Diagnostics Validation materials (update Feb 24, 2020)

Hi,

- **Diagnostics validation materials:**

(b) (5)

Chuong Huynh
Currently assigned to COVID-19 response - ASPR/BARDA liaison to CDC-Atlanta
HHS/OS/ASPR/BARDA/IEID
Mobile: (b) (6)
Email: Chuong.Huynh@hhs.gov
https://www.medicalcountermeasures.gov/

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/22/2020 8:05:37 PM
**To:** Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Re: Cut-off change - Number of public health labs that verified CDC panel for use

Thanks Steve! It is helpful. Best, Tim

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Date:** February 22, 2020 at 8:01:42 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
Our request for response from labs that were able to successfully verify the test went out yesterday afternoon. As of now, a total of twelve labs have responded that they were successful with verification. This includes the seven labs previously identified. We will keep you updated on the status of responses.
I hope this is useful.
Thank you
Steve

Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30329
Phone: 404-639-1587

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 5:17:02 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Steve and Julie,

Do you have any updates on the labs that successfully validated your assay and are ready to run clinical samples? Did any lab respond?

Thanks,
Uwe

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 11:22 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
Notifications that CDC received from public health laboratories regarding the reactivity of the N1 and N3 assay as well as those that notified CDC of successful verification are below:

36 labs notified CDC of issues with N3 assay
6 labs notified CDC of issues with N1 assay (these labs are included in those that also saw issues with N3)
7 labs reported that they successfully verified the test in their laboratories

We are reaching out to labs today to notify CDC if they have successfully verified the test and will update if this number changes.

Thank you very much.
Steve

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Friday, February 21, 2020 10:59 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
I just wanted to follow up with you to let you know that we are now working to compile the numbers we have and will get these to you shortly. Also, we will be sending a request to all labs that have received the reagents to please notify

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CDC if they successfully verified the test in their lab, so the number of verified labs may change from the numbers we initially report to you.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use
**Importance:** High

Julie & Steve,

As requested earlier, please clarify the number of labs that have successfully verified the CDC test panel for use asap. You communicated earlier that ~110 labs received your test and that (b) (5) HL informed you that they could not verify the test.

The question is in the context of a statement by APHL today that only 3 out of 100 public health labs have verified the CDC test for use. Can you confirm that?
"Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.'

See article below:

The article also states, according to CDC, that CDC will distribute a second test and will need it approved by the FDA first.

- Please clarify what that means: Are we talking about the new lot that is being manufactured or the change in cut-off?

Thanks,
Uwe

**Problems with CDC coronavirus test delay expanded US screening**

By David Lim

02/20/2020 05:03 PM EST

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to

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use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

---

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

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HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

(b) (5)



Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

There are laboratories that have not had any problems and are testing. We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

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Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding that public health and the state labs that didn't have any problems with their verification are proceeding with testing, is that correct?

Thank you for your feedback.

Uwe

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/17/2020 10:52:58 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: BY noon tomorrow

Ok, thanks Uwe

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 17, 2020 at 10:22:06 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: BY noon tomorrow

Tim,

Attached my edits for the talking points. (b) (5) .

Best,
Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:50 PM
**To:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Re: BY noon tomorrow

Hi Rosemary, That is news about the CDC assay. Thanks! Best, Tim

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Date:** February 17, 2020 at 8:47:31 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Re: BY noon tomorrow

Hi Tim,
Thanks for the response. (b) (5)
(b) (5)

Look forward to feedback from you and Uwe on talking points and landscapes.
Rosemary

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On: 17 February 2020 17:57,
"Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov> wrote:

Hi Rosemary, Here it is.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 17, 2020 at 1:05:25 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Thank you.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 17, 2020 at 12:40:22 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Uwe, My POC thoughts below. Copying Jeff for his awareness.

(b) (5)

Dear Rosemary,

Here are my thoughts.

(b) (5)

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(b) (5)

[redacted]

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 17, 2020 at 9:59:06 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: BY noon tomorrow

Tim,

I need your help on this request, since I will not find time to provide feedback to Rosemary.

I am working with CDC on their change in cut-off proposal.

Thanks,
Uwe

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 8:36 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** BY noon tomorrow

Uwe and Wendi,
We have been asked to put together a one-pager and landscape on POC diagnostics discussing time (development and manufacturing (b) (5) costs and issues with developing a hand held diagnostic/tests.

(b) (5)

[redacted]

Need today -
1. throw some thoughts for what we can put in the one-pager into an email – will get a joint draft ready ASAP.
a. Uwe, please address regulatory issues, (b) (5)
2. provide some ideas on what we can do to reality set this expectation.

Thanks very much,
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA

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202-205-8238
Cell: (b) (6)

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/25/2020 1:56:54 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: CDC

Deliberative/Predecisional

Sounds like the (b) (5) [redacted] ?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 1:51 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: CDC

CDC wants to go with only a 2-primer test and only with the new production lots of N1 and N2. Details below.

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Tuesday, February 25, 2020 1:47 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E

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<Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC

Good morning Kim,

Steve, Julie and I spoke with response and scientific leadership and all have decided that (b) (5) [redacted]

[redacted]

[redacted]

We hope this helps clarify our preferred approach. Please let us know if you have any additional questions.

Warm regards,
Laura Rose

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Busch, Marcy (FDA/OC) <Marcy.Busch@fda.hhs.gov>; Ross, Jennifer (FDA/OC) <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC

Dear all,

Summary of questions that will help inform the test EUA approach

Should we set up a call for later today as a follow-up

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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-----Original Appointment-----
**From:** Sapsford, Kim E
**Sent:** Tuesday, February 25, 2020 10:42 AM
**To:** Sapsford, Kim E; Villanueva, Julie M (CDC); Wendi L Kuhnert-Tallman (CDC) (wdk1@cdc.gov); Flannery, Ellen; Uwe Scherf (Uwe.Scherf@fda.hhs.gov); Stenzel, Timothy; Rose, Laura E (CDC); Lindstrom, Stephen (CDC)
**Cc:** Busch, Marcy; Ross, Jennifer (Jennifer.Ross@fda.hhs.gov)
**Subject:** CDC
**When:** Tuesday, February 25, 2020 11:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
**Where:** WebEx

Call to discuss

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

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Meeting password: (b) (6)

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/18/2020 9:50:45 AM
**To:** Humes, Rosemary (OS/ASPR/BARDA) [Rosemary.Humes@hhs.gov]
**CC:** Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: BY noon tomorrow
**Attachments:** Diagnostics for Coronavirus Timeline Projection v3.docx

Thanks Uwe, I just reviewed and looks good.

Hi Rosemary, I am seeking support from Jeff Shuren and will forward this to him. Looking at other documents next.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 10:22 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: BY noon tomorrow

Tim,

Attached my edits for the talking points. (b) (5) [redacted]

Best,
Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:50 PM
**To:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>

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**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Re: BY noon tomorrow

Hi Rosemary, That is news about the CDC assay. Thanks! Best, Tim

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Date:** February 17, 2020 at 8:47:31 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Re: BY noon tomorrow

Hi Tim,
Thanks for the response. (b) (5)
[redacted]
Look forward to feedback from you and Uwe on talking points and landscapes.
Rosemary

---

On: 17 February 2020 17:57,
"Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov> wrote:

Hi Rosemary, Here it is.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 17, 2020 at 1:05:25 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Thank you.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 17, 2020 at 12:40:22 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Uwe, My POC thoughts below. Copying Jeff for his awareness.

(b) (5)
[redacted]

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(b) (5)

[redacted]

Dear Rosemary,

Here are my thoughts.

(b) (5)

[redacted]

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 17, 2020 at 9:59:06 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: BY noon tomorrow

Tim,

I need your help on this request, since I will not find time to provide feedback to Rosemary.

I am working with CDC on their change in cut-off proposal.

Thanks,
Uwe

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**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 8:36 AM

**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** BY noon tomorrow

Uwe and Wendi,
We have been asked to put together a one-pager and landscape on POC diagnostics discussing time (development and manufacturing (b) (5) ), costs and issues with developing a hand held diagnostic/tests.
(b) (5)

Need today -

1. throw some thoughts for what we can put in the one-pager into an email – will get a joint draft ready ASAP.

a. Uwe, please address regulatory issues (b) (5) .

2. provide some ideas on what we can do to reality set this expectation.

Thanks very much,
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
Cell (b) (6)

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/19/2020 5:28:58 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Fantastic. Send on to the CDC then. Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 5:28 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Tim,

The added changes clarify the issue. Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 5:21 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

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**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Hi Uwe,

Are you okay with the following changes?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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Jennifer.Campbell@fda.hhs.gov

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 5:17 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Our thinking was that (b) (5) [redacted]

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 5:10 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission
**Importance:** High

I thought (b) (5) [redacted]

(b) (5) [redacted]

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 5:04 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Hi Uwe,

Your edits look good to me. Bringing others in for their information on the status and that we expect to receive the new package in the next day or two and we are focused on turning it around as soon as possible, even beginning work on the current draft that we have.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**

Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:01 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Tim,

Laura send me the summary of the conversation we had today. Please see added comments from the team. Anything else that you heard/want to add for clarification.

Thanks, Uwe

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Wednesday, February 19, 2020 2:32 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Good afternoon Uwe,

Thank you again for taking the time to meet with us today to discuss the regulatory considerations for community transmission surveillance. I wanted to share my understanding of the outcome of the meeting to ensure CDC and FDA are on the same page.

(b) (5)



(b) (5)

[redacted]

Please let me know if I have misunderstood our conversation or if I have missed a key point.

Many thanks,
Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

OLSS Office of Laboratory Science and Safety

*Strengthening the culture of laboratory science and safety at CDC*

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/19/2020 5:28:27 PM
**To**: Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

Hi Marcy,

Sure. I am on the phone with Uwe. As your schedules may be more challenging than Uwe's and his team, if you could schedule it that would be fine. You can copy me but I don't think I am needed on the call.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 5:07 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

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Ok thanks, that would be great. (b) (5)

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:52 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

Yes, the CDC says they will submit a new EUA referencing the data in their first EUA in a day or two.

Marcy, it may be beneficial for you to come up to speed with our help to understand the current draft now (b) (5)
(b) (5)

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
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**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:43 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

Uwe clarified for me that (b) (5)

**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:41 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

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**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

(b) (5)

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:26 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

**CDC announced they are doing this –**

CDC Will Implement Novel Coronavirus Surveillance in Select Public Health Labs

Feb 19, 2020

Madeleine Johnson

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[redacted]

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 11:07 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

Ellan & Marcy,

We just got the updated information from CDC regarding their Sentinel Surveillance to Detect 2019-nCoV.

The human subject considerations now state:

(b) (4), (b) (5)

[redacted]

Uwe

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/21/2020 4:18:02 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Cut-off change - lot release testing criteria

Ok, I am heading to 5425 now

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Office of Product Evaluation and Quality

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 4:04 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: Cut-off change - lot release testing criteria

Tim, this just arrived. (b) (5) [redacted]. Let's discuss before you leave today. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 3:37 PM

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**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hello Uwe,
We would like to share with you our bulk QC data summary for oligo sets N1, N2 and RP for your review. We continue to manufacture N3 and will forward as soon as that data is reviewed.
Please be aware there are two tab in the excel file.
Please let us know if you have questions.
Do you and your colleagues have a time tomorrow that you would like to arrange a call to discuss?
Thank you very much.
Steve

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
For clarification the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel consists of two separate boxes. Box #1 contains the primers and probes as described below:

(b) (5)

Also as requested, please find attached the QC testing process of primer/probe reagents at bulk and post-fill analysis.

We hope this helps to clarify the data presented and addresses your request.
Thank you very much.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch

AMERICAN OVERSIGHT

Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 10:07 AM
**To:** 'Scherf, Uwe' <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
(b) (5) I hope this addresses your question.
We will send a meeting invitation shortly for 1pm if that time is still OK for your team.
Thank you very much.
Steve

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing the (b) (5)

Thanks,
Uwe

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

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Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

(b) (5) [redacted]

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Steve,

Thank you for the update, when will you send us (b) (5) [redacted]

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

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(b) (5)

[redacted]

Please let us know if you have any additional questions.
Thank you very much!
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5)

(b) (5)

[redacted]

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(b) (5)

[redacted]

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

Since the deployment of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel to domestic public health laboratories, CDC has received a reports regarding sporadic aberrant reactivity resulting in false positive results with Ct values in the high 30s. This reactivity is more often reported with the N3 assay component of the test, and to a lesser extent with the N1 assay.

This reactivity has not been observed at CDC throughout the validation testing as presented in the EUA submission, nor has it been observed with any testing of hundreds of clinical specimens from PUI cases. (b) (5)

(b) (5)

[redacted]

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(b) (5) [redacted]

If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts (b) (5) [redacted]

(b) (5) [redacted]

Thanks,
Uwe

---

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>

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**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

(b) (5)



Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

There are laboratories that have not had any problems and are testing. We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>

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**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) [redacted] is that correct?

Thank you for your feedback.

Uwe

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/20/2020 8:05:06 PM
**To**: Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) [sql5@cdc.gov]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi, I just spoke with Steve.

Wendi or Dan, I am wondering if either of you could give me call? You can reach me on my FDA cell at (b) (6)

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Thursday, February 20, 2020 7:21 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>;

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Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: Cut-off change - Number of public health labs that verified CDC panel for use

Thank you Uwe and sorry for the unfortunate press. We will get the information we have to you tomorrow. We will only have the numbers that have notified us of their successful verification. We will also request APHL to have phls that have verified the assay to notify cdc at the mailbox.
Thank you and sorry again for this complication.
Steve

Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30329
Phone: 404-639-1587

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:16:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Julie & Steve,

As requested earlier, please clarify the number of labs that have successfully verified the CDC test panel for use asap. You communicated earlier that ~110 labs received your test and that (b) (5) HL informed you that they could not verify the test.

The question is in the context of a statement by APHL today that only 3 out of 100 public health labs have verified the CDC test for use. Can you confirm that?
"Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.'

See article below:

The article also states, according to CDC, that CDC will distribute a second test and will need it approved by the FDA first.

- Please clarify what that means: Are we talking about the new lot that is being manufactured or the change in cut-off?

Thanks,
Uwe

AMERICAN OVERSIGHT

**Problems with CDC coronavirus test delay expanded US screening**

By David Lim

02/20/2020 05:03 PM EST

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

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*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

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**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

(b) (5)



Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

There are laboratories that have not had any problems and are testing. We will need to work to find more detailed information for you.

AMERICAN OVERSIGHT

Thanks,

Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/22/2020 2:41:21 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**CC:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Iademarco, Michael (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60a2bbf679974a56950bbb13b73d2549-HHS-mai9-cd]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Follow Up

Thanks Wendi!

They booked me on an earlier flight and I just landed in Atlanta.

We have reviewed (b) (5) [redacted]. Uwe will be reaching out shortly to set up a telecon to discuss our review and next steps.

(b) (5) [redacted]

Do you have anyone in house at the CDC who is working on (b) (5) [redacted]? If so, can you connect us?

Thanks in advance!

Best, Tim

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Date:** February 21, 2020 at 8:10:27 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Iademarco, Michael (CDC) <mai9@cdc.gov>
**Subject:** RE: Follow Up

Thanks Tim for reaching out and suggesting the visit. We would love to have you come join us in the EOC on Monday. I agree that this will be a great opportunity for enhanced communication and coordination as we push forward with this important EUA. (b) (5) [redacted]

Lets touch base on timing for meeting you on Monday for campus access.

Thanks, wendi

Wendi Kuhnert-Tallman
phone - 404-639-3103

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 7:26 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Cc:** Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Subject:** Follow Up

Hi Wendi,

Thanks to you and Steve for the late evening calls yesterday. It was very helpful to understand the current situation and ways to move forward. And we were excited to hear the good news this afternoon on the clean QC testing outcomes for the new lots of N1 and N2.

It has been suggested that having me visit the CDC as soon as possible, over the weekend even if work is being done over the weekend, would help the communication and coordination during this emergency including all the activities with getting new lots out to the PHL labs and the follow on EUAs and supplements, etc. I have booked my flight and hotel for Sunday afternoon. I can arrive tomorrow if there is work being done at CDC over the weekend. Is there anything I need to do aside from show up?

I am looking for ways to help. I don't want to interfere in any way. I am hoping I can simply join response meetings to be a resource and FDA contact.

Many thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/18/2020 11:08:38 AM
**To**: Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: CDC Coronavirus assay question.

Latest…

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Sent:** Tuesday, February 18, 2020 10:53 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Salerno, Reynolds M (CDC) <yyw2@cdc.gov>; Clark, David W (CDC) <dqc5@cdc.gov>; Sen, Oishee (CDC) <qam3@cdc.gov>
**Subject:** RE: CDC Coronavirus assay question.

Very interesting, Tim. Ren help guide you to the answer, which could include Wendi (b) (5) [redacted]

In a "response" (where we activate the EOC for an emergency), we (CDC) must go through the EOC for all questions and answers, and not to programs. You cannot be expected to figure that out.

Ren, with Mr. Clark's help, can navigate the question from FDA, CSELS, to the response. Ren's division of laboratory system is the CDC focal point for all clinical laboratories at CDC.

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Dr. Wendi Kuhnert is the senior laboratory advisor to the Deputy Director for Infectious Diseases, which overseas the three infectious disease centers. More importantly in this instance, Wendi is one of three deputy incident managers in the response. Lab Task Force is covered under her.

Also do note that FDA has a liaison to the response, I think. Mr. Clark will let you know who that is (if you don't know), and take a reinforcing approach through the FDA liaison, who at a minimum should be kept in the loop.

Looking forward to see you later this week.

Best, Michael

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 9:56 AM
**To:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Subject:** CDC Coronavirus assay question.

Hi Michael,

I have a question for the CDC and don't know who to ask and am hoping you can help.

(b) (5)

[redacted]

We are getting EUA developers who are saying they will be using the CDC primers and probes in their assays and wanted to check on this as well.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/20/2020 7:40:58 PM
**To:** Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC:** Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Jeff,

We got a response but not helpful. I am going to call Stephen now.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Thursday, February 20, 2020 7:21 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: Cut-off change - Number of public health labs that verified CDC panel for use

Thank you Uwe and sorry for the unfortunate press. We will get the information we have to you tomorrow. We will only have the numbers that have notified us of their successful verification. We will also request APHL to have phls that have verified the assay to notify cdc at the mailbox.
Thank you and sorry again for this complication.
Steve

AMERICAN OVERSIGHT

Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30329
Phone: 404-639-1587

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:16:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Julie & Steve,

As requested earlier, please clarify the number of labs that have successfully verified the CDC test panel for use asap. You communicated earlier that ~110 labs received your test and that (b) (5) APHL informed you that they could not verify the test.

The question is in the context of a statement by APHL today that only 3 out of 100 public health labs have verified the CDC test for use. Can you confirm that?
"Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.'

See article below:

The article also states, according to CDC, that CDC will distribute a second test and will need it approved by the FDA first.

- Please clarify what that means: Are we talking about the new lot that is being manufactured or the change in cut-off?

Thanks,
Uwe

**Problems with CDC coronavirus test delay expanded US screening**

By David Lim

02/20/2020 05:03 PM EST

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to

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use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

---

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

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HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

(b) (5)



Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

There are laboratories that have not had any problems and are testing. We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

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Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) [redacted] is that correct?

Thank you for your feedback.

Uwe

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/18/2020 6:38:35 PM
**To:** Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC:** Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: "Final" Dx development POC talking points and landscapes
**Attachments:** 2019-nCoV Diagnostics Landscape-POC 2-18-20.pptx; Diagnostics for Coronavirus Timeline Projection v4 clean.docx

Hi Jeff,

Just keeping you up to date.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Tuesday, February 18, 2020 5:35 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Beanan, Maureen J (NIH) (b) (6); Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Marston, Hilary D (NIH) (b) (6); Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Eder, Paul (OS) <Paul.Eder@hhs.gov>; Lee, John S (OS) <John.Lee@hhs.gov>; Huynh, Chuong Q (OS) <Chuong.Huynh@hhs.gov>
**Subject:** "Final" Dx development POC talking points and landscapes

Dear Dx WG members,
1. Thanks to all for the quick turn around on the landscape and talking points. Attached are the versions that went up to BARDA OD at noon. (b) (5)

AMERICAN OVERSIGHT

(b) (5)

[redacted]

Again, sincere appreciation for all your help. If there are topics that you feel the WG should address, please let me know.
Thanks,
Rosemary

---

**From:** Humes, Rosemary (OS/ASPR/BARDA)
**Sent:** Monday, February 17, 2020 7:29 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Carroll, Darin (CDC/DDID/NCEZID/OD) <zuz4@cdc.gov>; Beanan, Maureen (NIH/NIAID) [E(b) (6) >; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; 'Opdyke, Jason A CIV USARMY (USA' <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] (b) (6) >; 'Schoske, Richard CIV DTRA J9 (USA)' <richard.schoske.civ@mail.mil>
**Cc:** 'Stenzel, Timothy' <Timothy.Stenzel@fda.hhs.gov>; Eder, Paul (HHS/ASPR) (CTR) (Paul.Eder@hhs.gov) <Paul.Eder@hhs.gov>; Lee, John (OS/ASPR/BARDA) <John.Lee@hhs.gov>; Huynh, Chuong (OS/ASPR/BARDA) <Chuong.Huynh@hhs.gov>
**Subject:** For review by 11am Tuesday: Dx development POC talking points and landscapes

Diagnostics WG members,
Following up from earlier email. Thanks to all who were avaible to discuss/provide feedback today.
1. Slide deck: Need to deliver "POC" slide deck by noon Tuesday, please send comments by 11am. Continuing to try to address pressure for POC diagnostics. Trying once again to take approach of what we CAN do, what we believe is best approach. Please take a look, let me know if there is anything that is wrong, or missing. Especially slide 3 – any companies we should add? Slide 5 – are overall timelines reasonable – think big picture/best case.
2. Talking points – if all agree with these, we can jointly use, rework for individual agency messages but provide overall consensus message up to leadership. All suggestions for better ways to communicate are welcome. (b) (5)

[redacted]

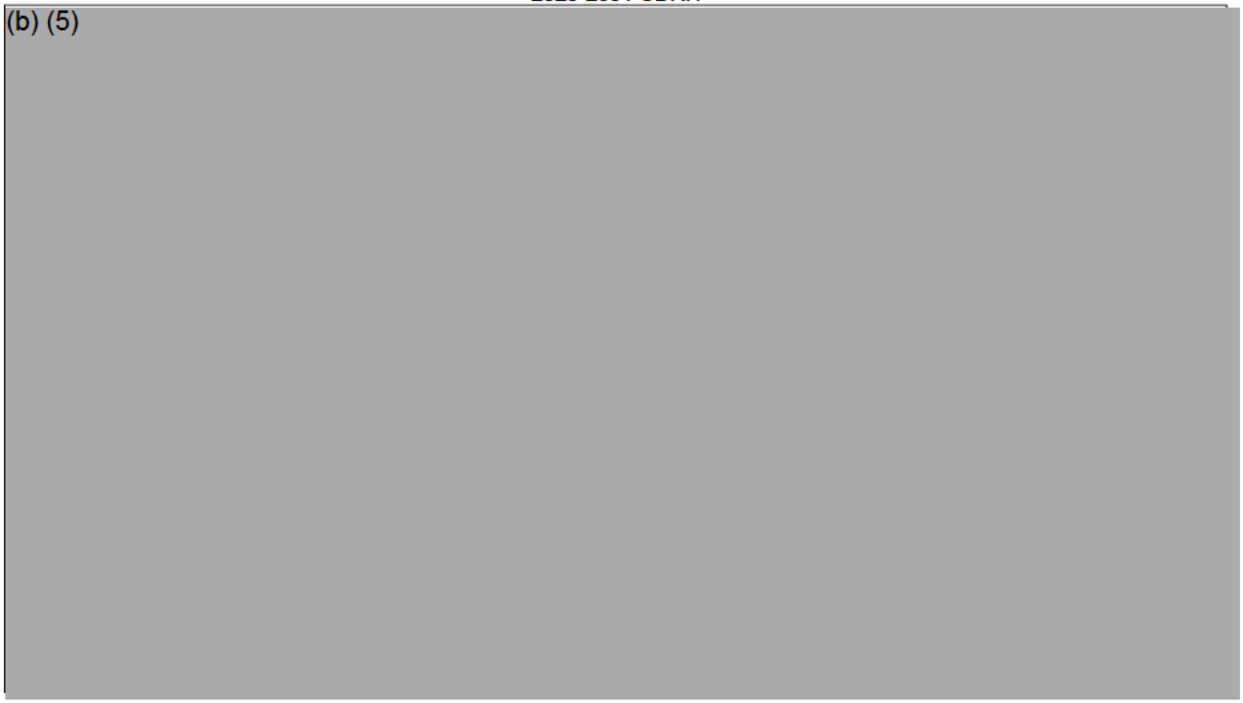
Again, many thanks for all the support.
Rosemary

AMERICAN OVERSIGHT

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
Cell (b) (6)

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(b) (5)



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(b) (5)



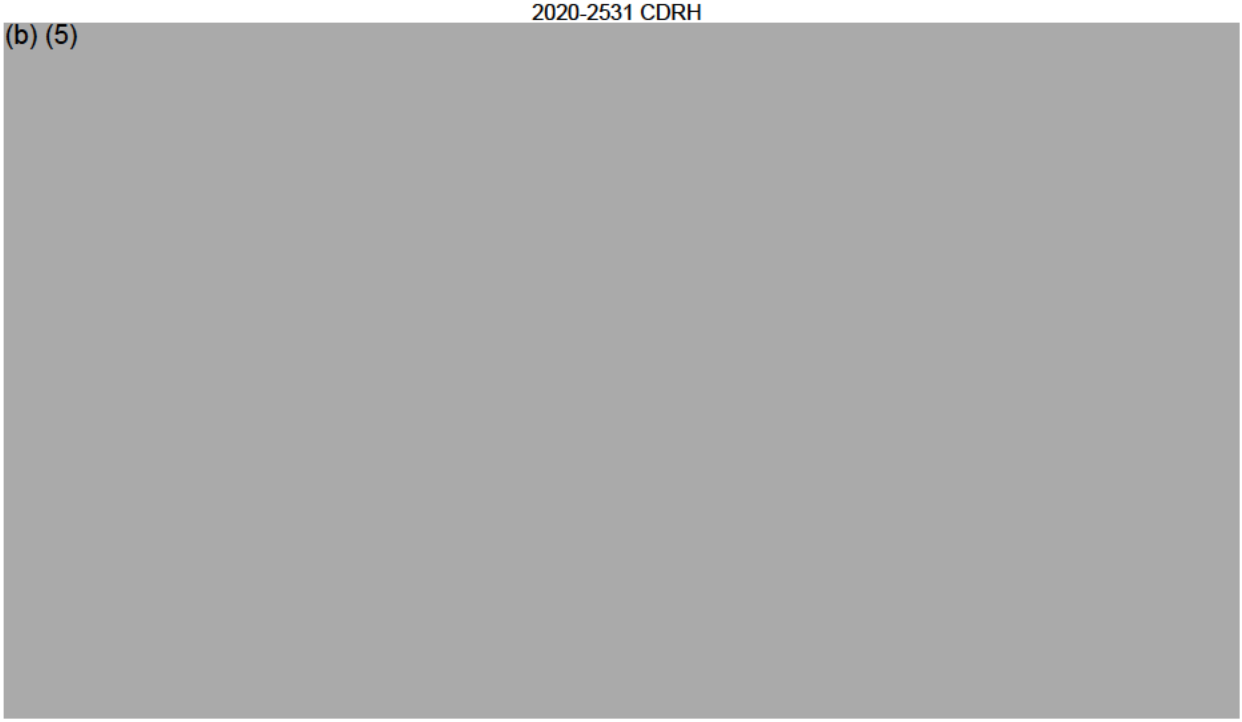
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(b) (5)



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(b) (5)



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(b) (5)



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(b) (5)



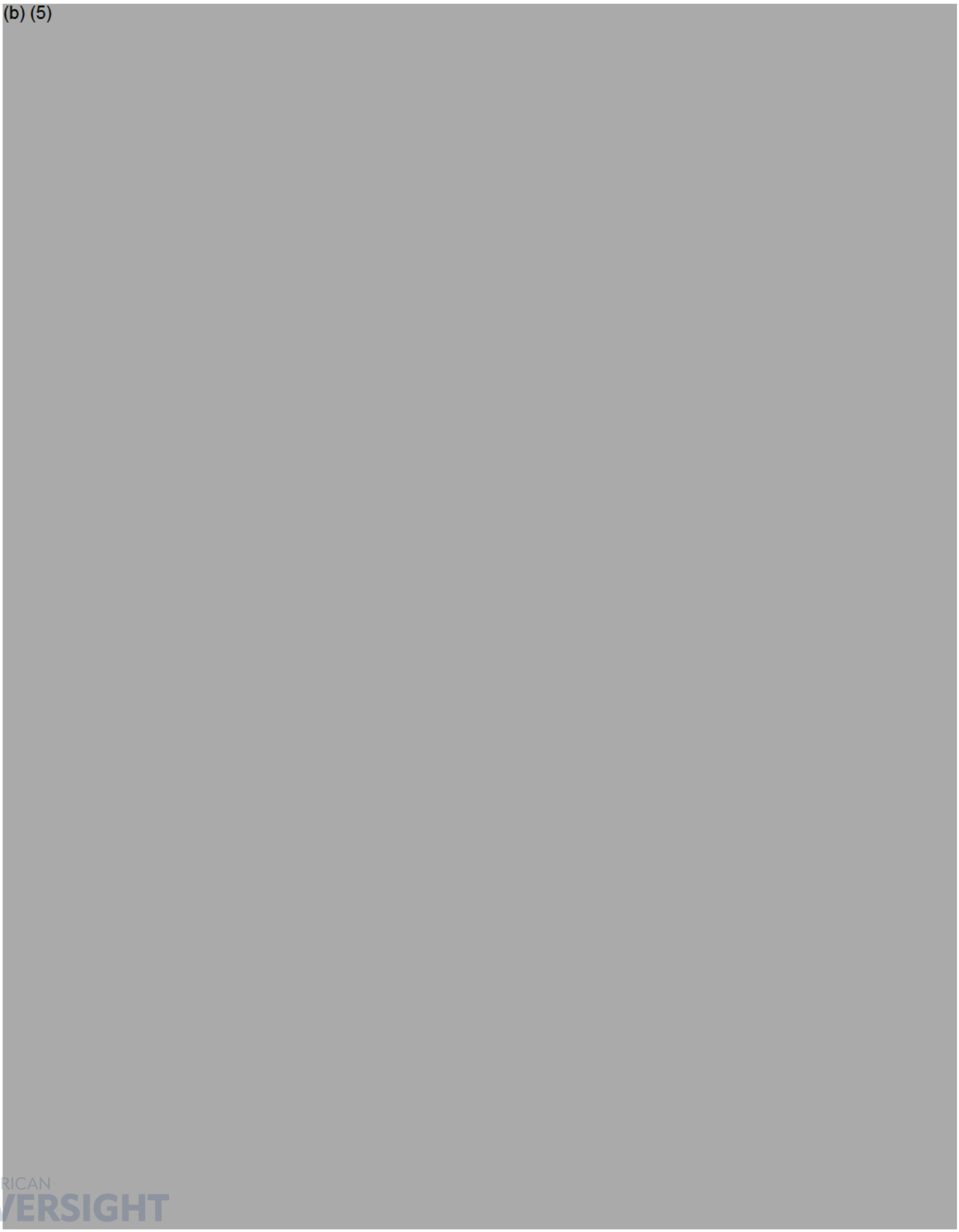
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(b) (5)



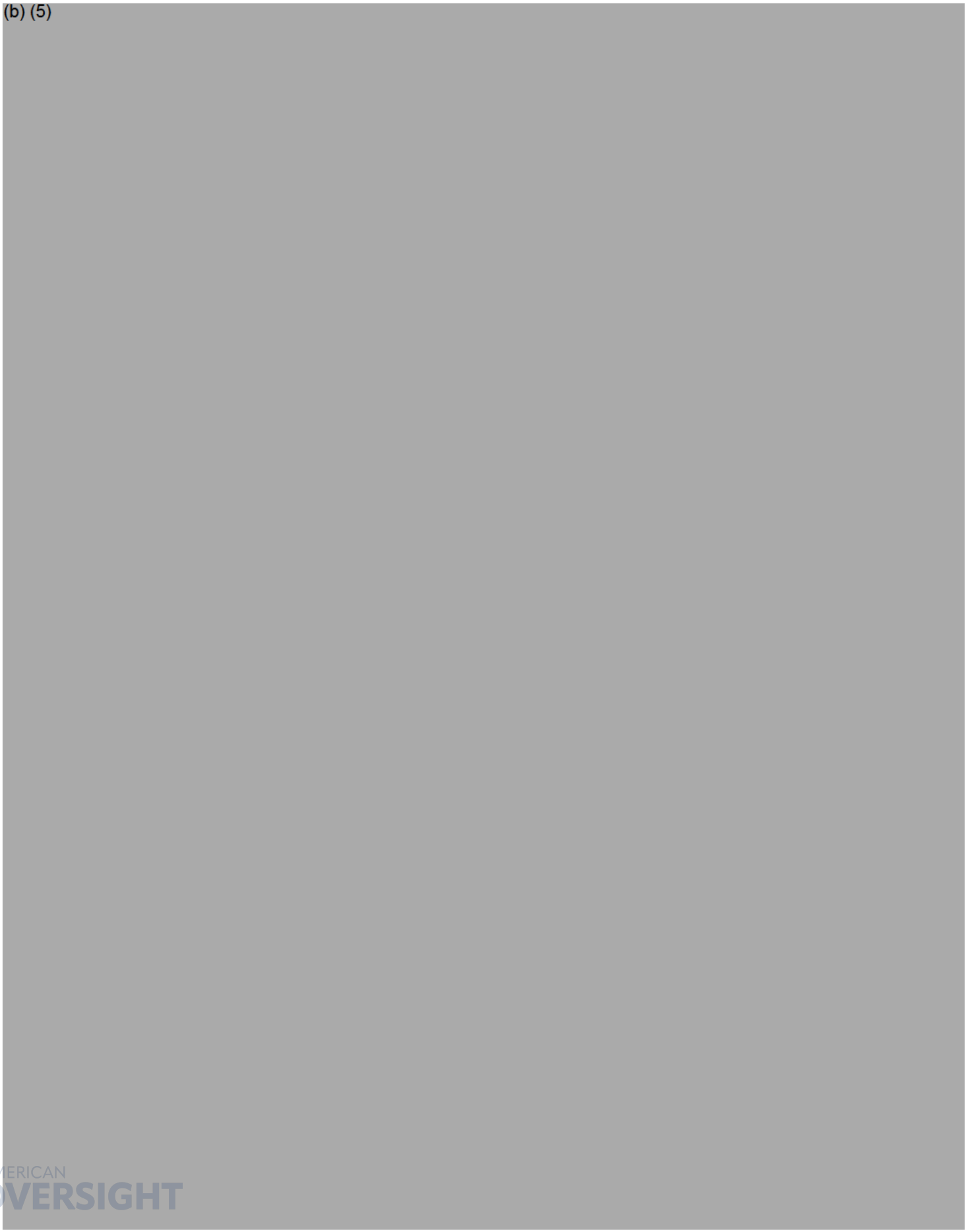
AMERICAN OVERSIGHT

(b) (5)



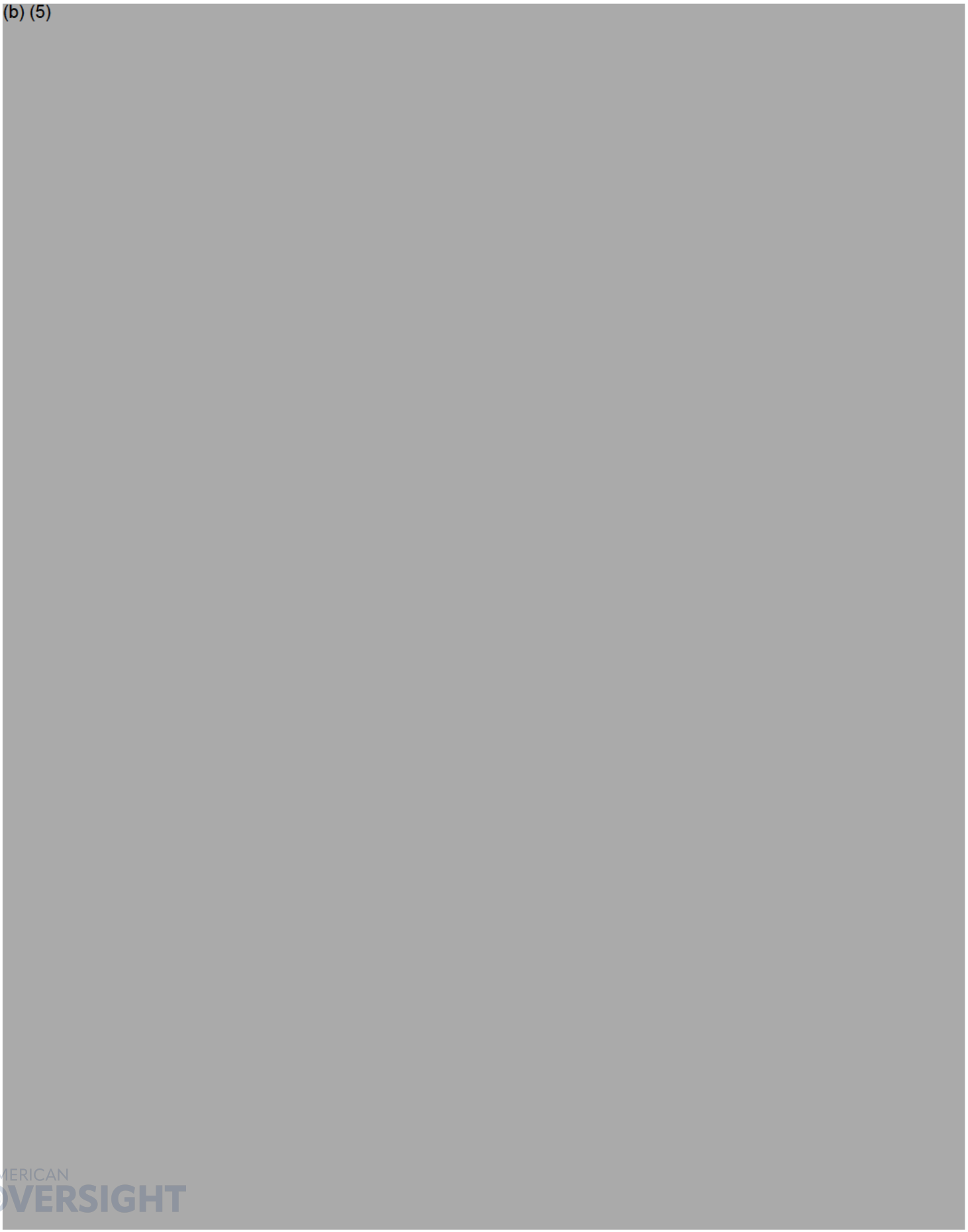
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(b) (5)



AMERICAN OVERSIGHT

(b) (5)



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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/19/2020 5:21:19 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Hi Uwe,

Are you okay with the following changes?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 5:17 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

(b) (5)

Best,
*Tim*

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**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 5:10 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission
**Importance:** High

(b) (5)

- Regulatory strategy

(b) (5)

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 5:04 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Hi Uwe,

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Your edits look good to me. Bringing others in for their information on the status and that we expect to receive the new package in the next day or two and we are focused on turning it around as soon as possible, even beginning work on the current draft that we have.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:01 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Tim,

Laura send me the summary of the conversation we had today. Please see added comments from the team. Anything else that you heard/want to add for clarification.

Thanks, Uwe

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Wednesday, February 19, 2020 2:32 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Good afternoon Uwe,

Thank you again for taking the time to meet with us today to discuss the regulatory considerations for community transmission surveillance. I wanted to share my understanding of the outcome of the meeting to ensure CDC and FDA are on the same page.

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(b) (5)

(b) (5)

[redacted]

Please let me know if I have misunderstood our conversation or if I have missed a key point.

Many thanks,
Laura

==

Laura E. Rose, RAC

CREDENTIALED PROFESSIONAL RAC RAC US

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

OLSS Office of Laboratory Science and Safety
*Strengthening the culture of laboratory science and safety at CDC*

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/18/2020 11:06:41 AM
**To:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) [mai9@cdc.gov]
**CC:** Salerno, Reynolds M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=049f0ba7591d4296a05476b62825fc16-HHS-yyw2-cd]; Clark, David W (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a61a4e3fd8dc4ba78aa44dd2181415b1-HHS-dqc5-cd]; Sen, Oishee (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50f36c7e65c34f21ad6c81277ec8f8df-HHS-qam3-cd]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: CDC Coronavirus assay question.

Thanks Michael,

I appreciate the help and getting to the answer. Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Jennifer.Campbell@fda.hhs.gov

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---

**From:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Sent:** Tuesday, February 18, 2020 10:53 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Salerno, Reynolds M (CDC) <yyw2@cdc.gov>; Clark, David W (CDC) <dqc5@cdc.gov>; Sen, Oishee (CDC) <qam3@cdc.gov>
**Subject:** RE: CDC Coronavirus assay question.

Very interesting, Tim. Ren help guide you to the answer, which could include Wendi. (b) (5) [redacted]

In a "response" (where we activate the EOC for an emergency), we (CDC) must go through the EOC for all questions and answers, and not to programs. You cannot be expected to figure that out.

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Ren, with Mr. Clark's help, can navigate the question from FDA, CSELS, to the response. Ren's division of laboratory system is the CDC focal point for all clinical laboratories at CDC.

Dr. Wendi Kuhnert is the senior laboratory advisor to the Deputy Director for Infectious Diseases, which overseas the three infectious disease centers. More importantly in this instance, Wendi is one of three deputy incident managers in the response. Lab Task Force is covered under her.

Also do note that FDA has a liaison to the response, I think. Mr. Clark will let you know who that is (if you don't know), and take a reinforcing approach through the FDA liaison, who at a minimum should be kept in the loop.

Looking forward to see you later this week.

Best, Michael

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 9:56 AM
**To:** Iademarco, Michael (CDC/DDPHSS/CSELS/OD) <mai9@cdc.gov>
**Subject:** CDC Coronavirus assay question.

Hi Michael,

I have a question for the CDC and don't know who to ask and am hoping you can help.

(b) (5)

We are getting (b) (5) and wanted to check on this as well.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/18/2020 8:59:50 AM
**To:** Humes, Rosemary (OS/ASPR/BARDA) [Rosemary.Humes@hhs.gov]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: BY noon tomorrow?

Hi Rosemary,

Can you tell me who is (b) (5) Or at least their affiliations? This will help guide Jeff when I ask him.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Tuesday, February 18, 2020 6:44 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Tim,
One other point. (b) (5)
(b) (5)

Thanks,
Rosemary

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On: 17 February 2020 21:50,
"Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov> wrote:

Hi Rosemary, That is news about the CDC assay. Thanks! Best, Tim

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Date:** February 17, 2020 at 8:47:31 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Re: BY noon tomorrow

Hi Tim,
Thanks for the response. (b) (5)
(b) (5)

Look forward to feedback from you and Uwe on talking points and landscapes.
Rosemary

---

On: 17 February 2020 17:57,
"Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov> wrote:

Hi Rosemary, Here it is.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 17, 2020 at 1:05:25 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Thank you.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 17, 2020 at 12:40:22 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Uwe, My POC thoughts below. Copying Jeff for his awareness.

(b) (5)

Need today -

AMERICAN OVERSIGHT

(b) (5)

Dear Rosemary,

Here are my thoughts.

(b) (5)

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 17, 2020 at 9:59:06 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: BY noon tomorrow

Tim,

I need your help on this request, since I will not find time to provide feedback to Rosemary.

I am working with CDC on (b) (5)

Thanks,
Uwe

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**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 8:36 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** BY noon tomorrow

Uwe and Wendi,
We have been asked to put together a one-pager and landscape on POC diagnostics discussing time (development and manufacturing (b) (5) ), costs and issues with developing a hand held diagnostic/tests.
(b) (5)

Need today -

1. throw some thoughts for what we can put in the one-pager into an email – will get a joint draft ready ASAP.

a. Uwe, please address regulatory issues, (b) (5) .

2. provide some ideas on what we can do to reality set this expectation.

Thanks very much,
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
Cell: (b) (6)

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 8:52:17 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Re: APHL Letter for FDA

Yes. That is why the 9 am meeting is happening. Path is clear. TY.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 24, 2020 at 8:47:26 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: APHL Letter for FDA

Hopefully, CDC also let you into their lab where the lots were made. I asked Steve to ask Bob Redfield to help make it happen and Steve said he spoke with Bob.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 24, 2020 at 8:40:59 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: APHL Letter for FDA

Thanks. I was able to get more status information this afternoon and the 3 pm meeting today that was cancelled has now been rescheduled for 9 am tomorrow.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 24, 2020 at 8:36:29 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: APHL Letter for FDA

Thank you. We've already responded to a press inquiry.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 24, 2020 at 8:34:10 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: APHL Letter for FDA

FYI

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**From:** Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>
**Date:** February 24, 2020 at 8:20:42 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Fwd: APHL Letter for FDA

FYI

---

**From:** Becker, Scott | APHL <Scott.Becker@aphl.org>
**Sent:** Monday, February 24, 2020 11:22 AM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD); Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS)
**Subject:** APHL Letter for FDA

Dear Wendi and Ren:

I am writing to let you know that the APHL Board of Directors approved sending a letter urging the FDA Commissioner to consider enforcement discretion to allow governmental public health laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). In the letter we state that to the extent possible, public health laboratories could work together to:

- Utilize a standard protocol or use a limited set of protocols
- Purchase reagents including primers and probes from a common source
- Utilize a standard validation panel
- Recommend a minimum standard validation approach
- Enable confirmation at another PHL while cases remain sporadic. It is also possible to consider the use of LRN advanced labs to serve as a confirmatory lab if resources are available to do so.

We recognize that not all PHL's will develop and implement an LDT. If PHL's decided against the use of an LDT for whatever reason, they could: 1) wait for the availability of the new CDC replacement kit, 2) coordinate with a PHL that has developed an LDT (this is not uncommon for PHLs to work together), or 3) use a commercially available assay once approved by FDA under an EUA.

We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request.

We will let you know the outcome of our communication with FDA, which is attached. The letter was sent to the FDA Commissioner, copy to his chief of staff; Dr. Redfield, copy to Dr. Jernigan.

Sincerely,

Scott Becker

---
Scott Becker MS
Executive Director
Association of Public Health Laboratories
Silver Spring MD
240.485.2747
---

AMERICAN OVERSIGHT

**Scott J. Becker** (he/him)
Chief Executive Officer
**P** +1 240.485.2747 | **M** +1 301.526.5704
scott.becker@aphl.org | @scottjbecker

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Silver Spring, MD 20910
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ID Lab Con 2020 | APHL 2020 Why Attend? (video)

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/22/2020 2:16:59 PM
**To**: Wilson, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a78919ec52b7440e94f5928758847404-wilsonc]; Garcia, Mayra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7db05677732d4023bcdf772ee0474055-GarciaM]; Wang, Tony [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17daf80bb07e4c57a851dcb4b1b245d1-Tony.Wang]; Lien, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=725ede41d4824f1ebb63793980911947-Christopher]; Liu, Shufeng [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ab78e81fe094f8693fbb71df0cec1db-Shufeng.Liu]
**CC**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; McGivern, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9d2b3132394444e979dd4cdbdaded4e-David.McGiv]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Coronavirus and MERS culturing

Hi Carolyn,

That would be fantastic. I just landed in Atlanta and will be working with the CDC. Could you arrange the meeting allowing me to call in?

Thanks! :)

Best,
Tim

---

**From:** Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
**Date:** February 22, 2020 at 1:43:03 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>, Wang, Tony <Tony.Wang@fda.hhs.gov>, Lien, Christopher <Christopher.Lien@fda.hhs.gov>, Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, McGivern, David <David.McGivern@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Tim,

Let us know if you would like us to set-up a meeting to review logistics and develop a tentative timeline, as Mayra suggested.

As noted by others, CBER certainly recognizes that this is a high priority, and our scientists and safety officers have been giving this a great deal of attention. However, even with all that, it has taken time to get all the safety pieces lined up, such as the occ health program, appropriate training of staff, developing the protocols and manuals, and finally the IBC review and approval this week. We are eager to get the work started once we have all the appropriate safeguards in place.

AMERICAN OVERSIGHT

Thanks,

Carolyn

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 11:16 AM
**To:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>; Wang, Tony <Tony.Wang@fda.hhs.gov>; Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; McGivern, David <David.McGivern@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Thank you Tony and Mayra! Greatly appreciate your help. Best, Tim

---

**From:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Date:** February 22, 2020 at 8:58:35 AM EST
**To:** Wang, Tony <Tony.Wang@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Lien, Christopher <Christopher.Lien@fda.hhs.gov>, Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, McGivern, David <David.McGivern@fda.hhs.gov>, Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Dear Tim,

As I mentioned to Uwe yesterday, the idea was to handle the COVID-19 materials for the CDRH devices as we did for Zika. CBER has the laboratories and knowledge to propagate the virus. DMD will be able to design the panel that will best challenge the sensitivity and specificity of the devices we are getting in house. Therefore, after Tony grows and inactivates the BSL-3 stocks, I would be preparing the dilutions of the viral stocks with David's help to formulate the final panel. In addition, I was also the one receiving at CDRH the orders, distributing the panels when available to the companies, as well as receiving the results of the testing. This strategy allowed DMD to have knowledge of the progress companies where doing with the panel testing and compile all the results for the EUA devices.

The preparation of the panel will take some time as the virus strains need still to be grown (and as Tony said the BSL-3 just got validated to work with COVID-19), inactivated, titrated, and the panel will have to be prepared with different dilutions that could satisfy the sensitivity observed in our devices.

I proposed a meeting with CBER for next week, now that that the BSL-3 and the funds are available since 2/21/2020, to set up a timeline for the next steps.

Regards,

Mayra

---

**From:** Wang, Tony <Tony.Wang@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 8:27 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; McGivern, David <David.McGivern@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

AMERICAN OVERSIGHT

Dear Tim,

I am adding Drs. Carolyn Wilson, Mayra Garcia from CDRH and David McGivern to this email chain for communication purpose. Dr. Wilson is the director of office of research at CBER who oversees all 2019-nCoV activities. Dr. McGivern at the Office of Blood Research and Review at CBER will work with Mayra at CDRH to generate reference standards for industry to use.

My group is to propagate virus and then work with David's group to establish conditions for heat-inactivation of the virus. We have just received the approval to conduct the work, but there are a few house-keeping items that we need to take care of before we can start the work.

I would leave to Dr. Wilson, Mayra and Dr. McGivern to speak on the part regarding dialogues with industries.

Best,

Tony

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 3:14 PM
**To:** Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>; Wang, Tony <Tony.Wang@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Coronavirus and MERS culturing

Hi Tony, Shufeng and Christopher,

We are getting inquiries from IVD test developers who are ready to finish the validation of their molecular Coronavirus assays so they can submit them to CDRH for EUA authorization. I have heard that you are developing a source of Coronavirus and mers and was wondering if you are in dialogue with companies already and if we can introduce them to you so they can get in line to receive samples when they are ready.

Thanks so much in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:42 PM

**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Hello Tim,
Likewise, I am delighted to meet you today. Please see attached for the (b) (4) received from CBER for review and approval. We will have to contact the PI's at CBER to find out when they will have the materials ready. (b) (4)
(b) (5)
Hope this is helpful and let me know if I can be of further assistance. Take care.

Pillai

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:13 PM
**To:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Coronavirus and MERS culturing

Hi Pillai,

Great to meet you today! I wanted to reach out and have copied Jeff to find out more details about the coronavirus and mers cultures. We have a number of test developers who cannot complete validation of their EUA assays until they have at least mock samples made with virus to test.

How soon will virus be available?
Can we connect developers with someone here at the agency so they can coordinate access?

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/23/2020 10:57:29 AM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Thank Uwe, Copy me or let me know so if asked in the briefing I can let them know. Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:55 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Thanks, I will get the email out asap.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:54 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear Uwe,

Please find attached the final documents to share back with Laura Rose at CDC.

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:45 AM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Awesome. I am at the CDC in the Emergency Operations Center and have connected with Wendi and working in the Lab Office. I am going to an 11 am briefing shortly.

Thanks!

Best,
*Tim*

AMERICAN OVERSIGHT

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:42 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Confirming they have OCC's okay! Thanks, all.

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 23, 2020 at 10:35:28 AM EST
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

If OCC is fine with these, then OIR can send them to CDC. Thanks!

---

**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Date:** February 23, 2020 at 8:54:28 AM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

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Nothing further from me, thanks.

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 8:12 AM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Thanks Claire

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch

Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

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Ph: (301) 796-0311

Kim.Sapsford@fda.hhs.gov






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**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 8:11 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

(b) (5)

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 8:03 AM

**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hello,

I have two minor comments in the letter, highlighted in yellow and as a comment at the end of the letter and

One minor edits in one of the comments in the procedure (yellow) and a recommendation for clarification in the second to last sentence under the Consideration for Individuals Tested.

Thanks,

Uwe

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 7:27 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hello,

I had one minor comment on the letter, highlighted in yellow.

Thanks,

Jennifer

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 12:19 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

AMERICAN OVERSIGHT

Please find attached the final documents with edits/comments back to CDC for your final review. I would like to send them back to CDC tomorrow morning. I will be unavailable 9-10:30am and 11:30 am – 1:00pm. If I could get any comments before 10:30 am hopefully I can send final docs back to CDC in the 10:30-11:30 window.

Thanks

Best regards

Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch

Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311

Kim.Sapsford@fda.hhs.gov






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---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 6:22 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Importance:** High

Hi Team,

I just heard from Jeff. We have to get these documents cleaned up and back to CDC ASAP, per direction of the FDA Commissioner and the CDC Director.

AMERICAN OVERSIGHT

(b) (5)

(b) (5)

[redacted]

Thanks,

Ellen

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 3:19 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Thanks Ellen,

Some comments/suggestions based on your feedback

Best regards

Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch

Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-0311

Kim.Sapsford@fda.hhs.gov






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AMERICAN OVERSIGHT

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 2:08 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hi all,

I attached two of the documents with my comments and suggestions.

(b) (5) [redacted]

Thanks,
Ellen

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 12:35 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

Revised documents attached for your review. (b) (5) [redacted]

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311

AMERICAN OVERSIGHT

Kim.Sapsford@fda.hhs.gov





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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 10:57 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

My comments are in the attached. I am struggling with removing reference to surveillance through-out the documents as the testing really an extension of a surveillance activity – (b) (5)

Anyway let me know what you think

Thanks

Best regards

Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch

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Ph: (301) 796-0311

Kim.Sapsford@fda.hhs.gov



AMERICAN OVERSIGHT

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**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 9:19 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hi all,

(b) (5)
[redacted]

Thanks!

Claire

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 5:22 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: DRAFT CDC EUA Request for Sentinel Surveillance Activities

All,

Here the draft EUA request we just discussed. Thanks for getting this addressed so quickly.

Uwe

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Friday, February 21, 2020 10:40 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** DRAFT CDC EUA Request for Sentinel Surveillance Activities

AMERICAN OVERSIGHT

Good morning Kim and Uwe,

Please find attached a draft EUA request submission for the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in sentinel surveillance activities. We would appreciate your review of this draft submission to ensure it contains the information and wording request necessary to support FDA's planned issuance of a second letter of authorization for the diagnostic panel to support this critical epidemiologic activity.

Please do not hesitate to reach out with questions, ideas, recommendations as you review the attached. I look forward to hearing from you.

Warm regards,

Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*

*Office of Laboratory Science and Safety (OLSS)*

**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

OLSS Office of Laboratory Science and Safety

*Strengthening the culture of laboratory science and safety at CDC*

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/20/2020 9:43:12 AM
**To:** Ellen Flannery (Ellen.Flannery@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC:** Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: Draft Letter - EUA for CDC "surveillance"
**Attachments:** Draft CDC Protocol EUA 2019-nCoV Letter of Authorization 2-20-20.doc

Hi Ellen,

On the 8:30 am call today, I asked to make sure to include you. If you want to comment now that would be fine.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 9:41 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** Draft Letter - EUA for CDC "surveillance"

Kim and Uwe,

(b) (5)

Thanks,

AMERICAN OVERSIGHT

Jennifer

-----Original Appointment-----
**From:** Ross, Jennifer
**Sent:** Wednesday, February 19, 2020 8:26 PM
**To:** Ross, Jennifer; Busch, Marcy; Dennis, Claire; Sadove, Elizabeth; Scherf, Uwe; Sapsford, Kim E
**Cc:** Stenzel, Timothy; Flannery, Ellen
**Subject:** Update on EUA for CDC "surveillance"
**When:** Thursday, February 20, 2020 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
**Where:** webex

CDC says they will submit a new EUA referencing the data in their first EUA in a day or two.
Protocol attached.
It would be good to touch base to ensure we are all on the same page for next steps.

Maybe we would also be able to discuss a little about the draft letter of authorization:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the SARS-CoV-2 (formerly 2019-nCoV) in nasopharyngeal (NP) or oropharyngeal (OP) respiratory specimens collected from individuals consented or notified prior to sample collection that SARS-CoV-2 testing would be performed if specimens are negative for influenza and other respiratory pathogens in order to determine if unrecognized community transmission of SARS-CoV-2 is occurring, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing is limited to qualified laboratories designated by CDC to conduct testing according to protocol xxx and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

-- Do not delete or change any of the following text. --

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Meeting password: (b) (6)

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Global call-in numbers | Toll-free calling restrictions

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If you are a host, go here to view host information.

Need help? Go to http://help.webex.com

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/19/2020 4:51:36 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

Yes, the CDC says they will submit a new EUA referencing the data in their first EUA in a day or two.

Marcy, it may be beneficial for you to come up to speed with our help to understand the current draft now (b) (5)

(b) (5)

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:43 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

Uwe clarified for me that (b) (5)

---

**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:41 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

AMERICA'S OVERSIGHT

**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

(b) (5)

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:26 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

**CDC announced they are doing this –**

CDC Will Implement Novel Coronavirus Surveillance in Select Public Health Labs

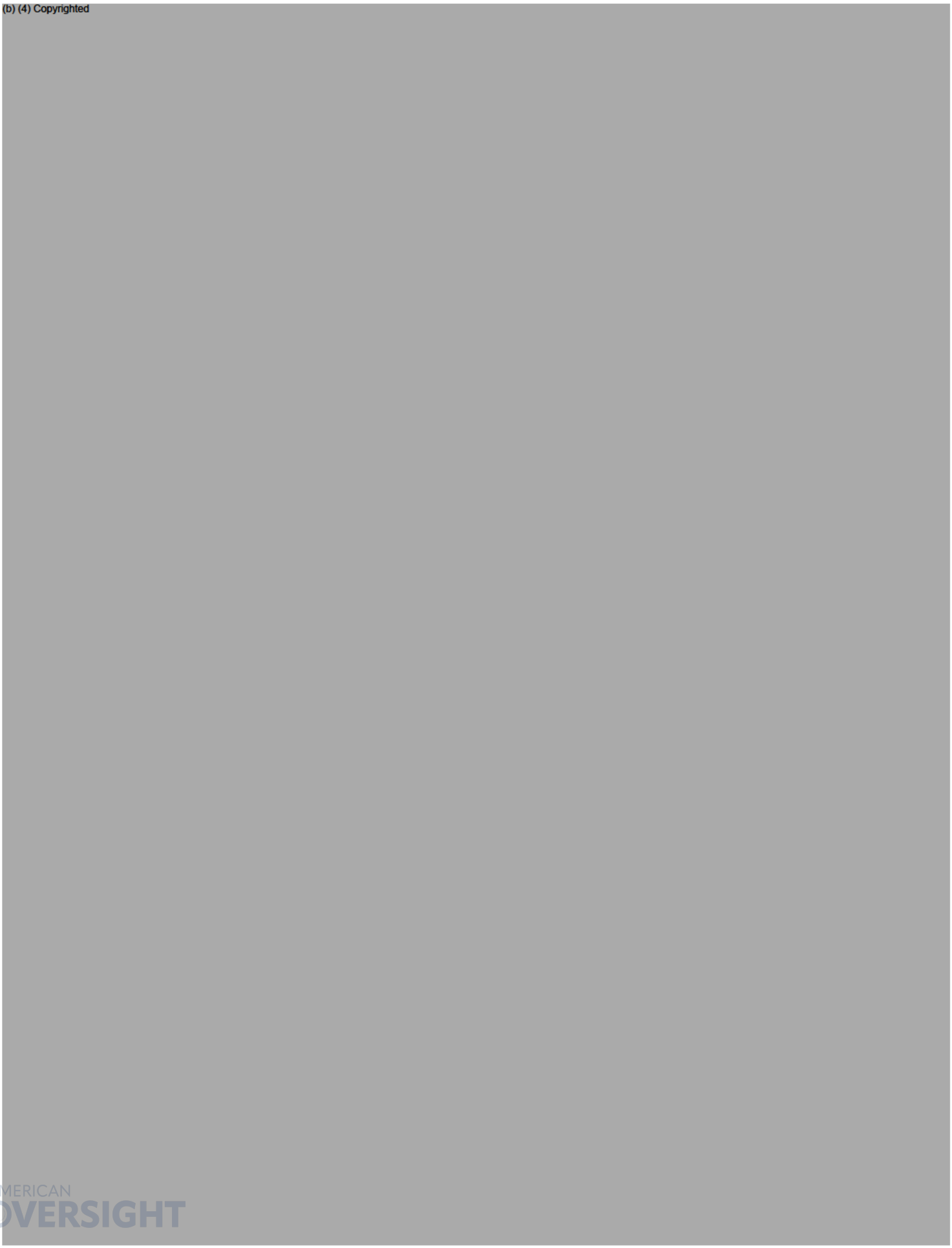
Feb 19, 2020

Madeleine Johnson

(b) (4) Copyrighted



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(b) (4) Copyrighted



**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 11:07 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

Ellan & Marcy,

We just got the updated information from CDC regarding their Sentinel Surveillance to Detect 2019-nCoV.

The human subject considerations now state:

(b) (4), (b) (5)



Uwe

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/18/2020 10:39:20 AM
**To**: Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: BY noon tomorrow

Source of push back on plan….

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Tuesday, February 18, 2020 10:16 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: BY noon tomorrow

Thanks Tim. These requests roll-down to us from BARDA Director, so I am trying to confirm the source for you.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 10:09 AM
**To:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: BY noon tomorrow

Hi Rosemary,

Do you need our comments on these documents? Jeff has forwarded my request for Commissioner's Office support. I need to know who they should reach out to and when.

AMERICAN OVERSIGHT

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 6:01 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: BY noon tomorrow

Tim,
These are 2 documents that were developed (b) (5) to address early questions. Language in these may also be helpful.
Thanks again for taking time to talk this afternoon.
Rosemary

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 5:57 PM
**To:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Subject:** Fwd: BY noon tomorrow

Hi Rosemary, Here it is.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 17, 2020 at 1:05:25 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Thank you.

Jeff

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 17, 2020 at 12:40:22 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Uwe, My POC thoughts below. Copying Jeff for his awareness.

(b) (5)

Need today -

(b) (5)

Dear Rosemary,

Here are my thoughts.

(b) (5)

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 17, 2020 at 9:59:06 AM EST

**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: BY noon tomorrow

Tim,

I need your help on this request, since I will not find time to provide feedback to Rosemary.

I am working with CDC on their change in cut-off proposal.

Thanks,
Uwe

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 8:36 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** BY noon tomorrow

Uwe and Wendi,
We have been asked to put together a one-pager and landscape on POC diagnostics discussing time (development and manufacturing (b) (5) costs and issues with developing a hand held diagnostic/tests.
(b) (5)

Need today -

1. throw some thoughts for what we can put in the one-pager into an email – will get a joint draft ready ASAP.

a. Uwe, please address regulatory issues, (b) (5) .

2. provide some ideas on what we can do to reality set this expectation.

Thanks very much,
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
Cell: (b) (6)

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/27/2020 12:40:21 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Yes

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 27, 2020 at 10:54:07 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Tim,

CDC will have someone participate. Can you participate by phone if I'm Atlanta or in person if back in town? Keagan just pinged me.

Jeff

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 27, 2020 at 7:52:00 AM EST
**To:** Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Please see the request from Julie Khani at the beginning of this email trail. Is this something you and Dan might consider doing together by videoconference, if you are still in Atlanta next week? If you are here I'd have you go in person but you should stay at CDC as long as is necessary (and as long as you are willing).

Jeff

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 7:19 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

(b) (5)

Sent from my iPhone

On Feb 26, 2020, at 7:18 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thoughts? (b) (5)

AMERICAN OVERSIGHT

Sent from my iPhone

Begin forwarded message:

**From:** Julie Khani <jkhani@acla.com>
**Date:** February 26, 2020 at 7:16:24 PM EST
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
**Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing**

It's a hotel ballroom. I could look into videoconferencing?

Also, just FYI, I reached out to Danielle Steele on this as well, re both FDA and CDC participation.

Sent from my iPhone

On Feb 26, 2020, at 5:41 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Not sure we could get anyone to do it in person. Could the FDA person participate by phone?

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**From:** Julie Khani <jkhani@acla.com>
**Sent:** Wednesday, February 26, 2020 2:52 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available here.

I am reaching out because in addition to Commissioner Hahn's remarks, I think the ACLA meeting would provide an excellent opportunity for the FDA to address the diagnostics community about the Coronavirus. I've extended the same invitation to the CDC. There will be approximately 200 people in attendance at the meeting, including CEOs and senior leadership from companies such as LabCorp, Quest, Mayo Clinic Laboratories, Hologic, and Siemens. ACLA and several member companies have a weekly call with the CDC, and the FDA has participated on some of the calls. We have shared information with the CDC about lab capacity and other information, in the event that public health labs are unable to handle testing needs, and surge capacity is necessary.

While these calls have been helpful, numerous questions remain about the availability of the CDC assay to commercial labs, the FDA EUA process, and other issues. I'd be happy to modify the agenda to allow time for a representative from the FDA, CDC, or both, to provide an update an answer questions.

I know the situation is changing quickly, and I can only imagine how busy it is at the FDA. But, as a lot of the key players in the diagnostics community will be together at our meeting next week, I wanted to extend the opportunity.

My office and mobile numbers are below if you have questions or if you would like to discuss.

Thanks.

Julie

**Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) \ (b) (6) (m)**

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**CONFIDENTIAL SETTLEMENT COMMUNICATION PROTECTED BY FED. RULE OF EVIDENCE 408**

Vaughn Index Version 2.0
March 10, 2025

***Vaughn Index (V2) for FOIA Request No. 2020-2531***
***American Oversight v. HHS et. al., Case No. 1:20-cv-0947 (D.D.C.)***

| Doc Start* | Doc. End* | Date of Redacted Doc | Author(s) of Redacted Doc | Document Title | Exemption(s)** | Explanation |
|---|---|---|---|---|---|---|
| 000239 | 000244 | 2/20/2020 | CDRH | Surgical N95 Masks | (b)(4), (b)(5) | FDA-CVD-SHURENJ-00020134.0001 attachment of FDA-CVD-SHURENJ-00020134<br><br>Bates: 000239 – 000244<br>Confidential Commercial Information: The redacted information relates to the production capacity, market share, and anticipated impact of COVID-19 and other factors on the production capabilities of various companies with respect to personal protective equipment (PPE). The release of this information would inform competitors about these companies' operations and would lead to predictable harm.<br><br>Bates: 000239 – 000244<br>Deliberative Process Privilege: The redacted information in this email attachment discusses the production capacity of various companies with respect to surgical N95 masks, non-surgical, industrial N95 masks, surgical masks, isolation gowns, and surgical gowns, and the anticipated impact of COVID-19 on their ability to produce this personal protective equipment (PPE). The release of this information would cause foreseeable harm as it would reveal internal deliberations and strategy and would compromise the agency's ability to receive candid and informed opinions. |
| 000245 | 000246 | 3/1/2020 | Jeff Shuren, M.D., J.D. | Re: Three items | (b)(5) | FDA-CVD-SHURENJ-00034460<br><br>Bates: 000245<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about questions FDA and the Center for Devices and Radiological Health (CDRH) were receiving from the press about the availability and regulation of tests for SARS-CoV-2, and internal discussions about how to prepare for and respond to these inquiries, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the |

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| | | | | | | agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000247 | 000251 | 3/1/2020 | Jeff Shuren, M.D., J.D. | Re: [champ] - RE: AMP Advocacy Update Regarding COVID-19 | (b)(6) | FDA-CVD-SHURENJ-00034502<br><br>Bates: 000248<br>Personal Privacy Information: The redacted information contains the private telephone and cell phone numbers of a Cepheid employee. |
| 000255 | 000258 | 3/1/2020 | Jeff Shuren, M.D., J.D. | FW: NYS Wadsworth Center COVID-19 Test | (b)(5) | FDA-CVD-SHURENJ-00019598<br><br>Bates: 000255<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations between FDA employees about the New York State Department of Health (NYSDOH) Wadsworth Center's application for Emergency Use Authorization (EUA) for its test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002560 | 002562 | 3/1/2020 | Jeff Shuren, M.D., J.D. | RE: applicant name | (b)(4), (b)(6) | FDA-CVD-SHURENJ-00020134<br><br>Bates: 000260<br>Confidential Commercial Information: The redacted information relates to daily testing capacity the University of Washington anticipates offering after it secures Emergency Use Authorization (EUA) for its test for SARS-CoV-2. The release of this information would inform competitors about the University of Washington's operations and would lead to predictable harm.<br><br>Bates: 000262<br>Personal Privacy Information: The redacted information contains the private cell phone number of a University of Washington employee. |

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Vaughn Index Version 2.0
March 10, 2025

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| 000265 | 000267 | 2/28/2020 | Jill Taylor | Two pre-EUA questions.... advice please | (b)(4) | FDA-CVD-SHURENJ-00034791<br><br>Bates: 000265 – 000267<br>Confidential Commercial Information: The redacted information relates to the reagent probes the New York State Department of Health (NYSDOH) Wadsworth Center was considering using in its clinical evaluation of its test for SARS-CoV-2, as well as questions related to information that might be included in the Center's potential EUA submission. The release of this information would inform competitors about the NYSDOH Wadsworth Center's operations, and the operations of the third party companies that manufacture the relevant reagent probes, and this would lead to predictable harm. |
| 000268 | 000268 | 3/1/2020 | Jeff Shuren, M.D., J.D. | RE: HOLD for Hill Call with CDC | (b)(5) | FDA-CVD-SHURENJ-00034794<br><br>Bates: 000268<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about discussion items for a call between FDA, CDC, and congressional staff members regarding the status of tests for SARS-CoV-2 and personal protective equipment (PPE), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000269 | 000272 | 2/29/2020 | Jeff Shuren, M.D., J.D. | RE: Letter from the American Society for Microbiology re COVID 19 EUA and clinical testing | (b)(6) | FDA-CVD-SHURENJ-00034479<br><br>Bates: 000269<br>Personal Privacy Information: The redacted information contains a meeting access code and the private phone number of an American Society for Microbiology employee.<br><br>Bates: 000271, 000272<br>Personal Privacy Information: The redacted information contains the private phone number of an American Society for Microbiology employee. |

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Vaughn Index Version 2.0
March 10, 2025

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| 000273 | 000274 | 2/29/2020 | Jeff Shuren, M.D., Ph.D. | RE: IDT | (b)(5) | FDA-CVD-SHURENJ-00034838<br><br>Bates: 000274<br>Deliberative Process Privilege: The redacted information in this email exchange contains draft language for and revisions to an email discussing Integrated DNA Technologies' (IDT) test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000277 | 000279 | 2/28/2020 | Jeff Shuren, M.D., J.D. | Re: Two pre-EUA questions.... advice please | (b)(4) | FDA-CVD-SHURENJ-00034843<br><br>Bates: 000278, 000279<br>Confidential Commercial Information: The redacted information relates to the reagent probes the New York State Department of Health (NYSDOH) Wadsworth Center would like to use in its clinical evaluation of its test for SARS-CoV-2, as well as questions related to information that might be included in the Center's potential EUA submission. The release of this information would inform competitors about the NYSDOH Wadsworth Center's operations, and the operations of the third party companies that manufacture the relevant reagent probes, and this would lead to predictable harm. |
| 000280 | 000282 | 2/27/2020 | Jeff Shuren, M.D., Ph.D. | RE: Azar says 40 public health labs can test for coronavirus | (b)(5) | FDA-CVD-SHURENJ-00034853<br><br>Bates: 000280 – 000281<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the nature of the agency's response to a media inquiry about Secretary Azar's statement regarding the number of laboratories that are capable of testing for COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to |

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| | | | | | | receive candid and informed opinions and recommendations from its subject matter experts. |
| 000283 | 000284 | 2/28/2020 | Jeff Shuren, M.D., Ph.D. | RE: Press | (b)(6) | FDA-CVD-SHURENJ-00034636<br><br>Bates: 000283<br>Personal Privacy Information: The redacted information contains the private email address of a ThermoFisher employee. |
| 000285 | 000287 | 2/28/2020 | Jeff Shuren, M.D., Ph.D. | Fwd: Two pre-EUA questions.... advice please | (b)(4) | FDA-CVD-SHURENJ-00034649<br><br>Bates: 000286, 000287<br>Confidential Commercial Information: The redacted information relates to the reagent probes the New York State Department of Health (NYSDOH) Wadsworth Center would like to use in its clinical evaluation of its test for SARS-CoV-2, as well as questions related to information that might be included in the Center's potential EUA submission. The release of this information would inform competitors about the NYSDOH Wadsworth Center's operations, and the operations of the third party companies that manufacture the relevant reagent probes, and this would lead to predictable harm. |
| 000288 | 000290 | 3/1/2020 | Jeff Shuren, M.D., Ph.D. | Re: Minimal Criteria for test validation | (b)(5) | FDA-CVD-SHURENJ-00034681<br>Bates: 00289<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the minimum criteria entities need to meet to validate their tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000291 | 000293 | 2/28/2020 | Jeff Shuren, M.D., J.D. | Re: Two pre-EUA questions .... advice please | (b)(4) | FDA-CVD-SHURENJ-00034893<br><br>Bates: 000292, 000293 |

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| | | | | | | Confidential Commercial Information: The redacted information relates to the reagent probes the New York State Department of Health (NYSDOH) Wadsworth Center would like to use in its clinical evaluation of its test for SARS-CoV-2, as well as questions related to information that might be included in the Center's potential EUA submission. The release of this information would inform competitors about the NYSDOH Wadsworth Center's operations, and the operations of the third party companies that manufacture the relevant reagent probes, and this would lead to predictable harm. |
| 000302 | 000303 | 2/25/2020 | Jeff Shuren, M.D., J.D. | RE: Breakout of funding: coronavirus supplemental funding | (b)(5) | FDA-CVD-SHURENJ-00034918<br><br>Bates: 000302, 000303<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations regarding how FDA may potentially spend funding transferred from the Department of Health and Human Services (HHS) to FDA's Center for Devices and Radiological Health (CDRH) pursuant to statutory authority to detect, treat, and prevent the spread of SARS-CoV-2. The release of this information would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000314 | 000314 | 2/29/2020 | Jeff Shuren, M.D., J.D. | Re: NYS Wadsworth | (b)(4), (b)(5) | FDA-CVD-SHURENJ-00034965<br><br>Bates: 000314<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the New York State Department of Health (NYSDOH) Wadsworth Center's application for Emergency Use Authorization (EUA) for its SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 000314 |

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| | | | | | | Confidential Commercial Information: The redacted information relates to elements of the New York State Department of Health (NYSDOH) Wadsworth Center's application for Emergency Use Authorization (EUA) for its SARS-CoV-2 test. The release of these information would inform competitors about the NYSDOH Wadsworth Center's operations and would lead to predictable harm. |
| 000315 | 000319 | 2/25/2020 | Jeff Shuren, M.D., Ph.D. | RE: RE: 2019 nCoV | (b)(4), (b)(6) | FDA-CVD-SHURENJ-00034967<br><br>Bates: 000316, 000317<br>Confidential Commercial Information: The redacted information relates to LabCorp's process of developing a test for SARS-CoV-2. The release of this information would inform competitors about LabCorp's operations and would lead to predictable harm.<br><br>Bates: 000316 – 000319<br>Personal Privacy Information: The redacted information contains the private email address and cell number of a LabCorp employee. The redacted information also contains the private phone number of an FDA employee. |
| 000351 | 000354 | 2/28/2020 | Jeff Shuren, M.D., J.D. | Pre-EUA IVD template request | (b)(4), (b)(5) | FDA-CVD-SHURENJ-00034968<br><br>Bates: 000351, 000354<br>Confidential Commercial Information: The redacted information relates to the New York State Department of Health (NYSDOH) Wadsworth Center's development of its test for SARS-CoV-2. The release of this information would inform the NYSDOH Wadsworth Center's competitors about its operations and would lead to predictable harm.<br><br>Bates: 000351<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the New York State Department of Health (NYSDOH) Wadsworth Center's development of its test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise |

**Commented [LF1]:** I added 319 b/c originally it only went up to 318 and 319 has a b6 redaction

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| | | | | | | the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000357 | 000357 | 2/28/2020 | Jeff Shuren, M.D., J.D. | FW: Letter from the American Society for Microbiology re COVID 19 EUA and clinical testing | (b)(6) | FDA-CVD-SHURENJ-00034987<br>Bates: 000357<br>Personal Privacy Information: The redacted information contains the private phone number of an American Society for Microbiology employee. |
| 000358 | 0000359 | 2/25/2020 | Jeff Shuren, M.D., J.D. | EUA Letter to FDA on COVID_final.pdf | (b)(4) | FDA-CVD-SHURENJ-00034993.0001 attachment of FDA-CVD-SHURENJ-00034993<br>Bates: 000358<br>Confidential Commercial Information: The redacted information relates to the New York State Department of Health (NYSDOH) Wadsworth Center's development of its test for SARS-CoV-2, including the primers and reagent probes it used while conducting clinical evaluations of this test. The release of this information would inform the NYSDOH Wadsworth Center's competitors about its operations and would lead to predictable harm. |
| 000361 | 000362 | 2/25/2020 | Jeff Shuren, M.D., J.D. | Re: IDT provides 2019-nCoV Kits that include the wm 2019-nCoV/SARS-CoV-2 published assays in individual tubes | (b)(5) | FDA-CVD-SHURENJ-00034995<br><br>Bates: 000361-000362<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations about the potential use of SARS-CoV-2 test kits from Integrated DNA Technologies (IDT) in light of the Emergency Use Authorizations (EUAs) in place at the time of this message, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000365 | 000365 | 2/29/2020 | Jeff Shuren, M.D., J.D. | IDT | (b)(5) | FDA-CVD-SHURENJ-00035040 |

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| | | | | | | Bates: 000365<br>Deliberative Process Privilege: The redacted information in this email exchange contains draft language for and revisions to an email discussing Integrated DNA Technologies' (IDT) test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000370 | 000371 | 2/27/2020 | Jeff Shuren, M.D., J.D. | RE: Forgot to ask, did you or one of your folks connect with Co-Diagnostics or the other two test makers for South Korea and Germany? | (b)(4) | FDA-CVD-SHURENJ-00035149<br><br>Bates: 000370<br>Confidential Commercial Information: The redacted information relates to Mammoth Biosciences' development of a CRISPR-based diagnostic platform for SARS-CoV-2. The release of this information would inform Mammoth Biosciences' competitors about its operations and would lead to predictable harm. |
| 000372 | 000376 | 2/25/2020 | Jeff Shuren, M.D., J.D. | RE: Public health labs press FDA to allow homegrown coronavirus tests | (b)(5) | FDA-CVD-SHURENJ-00035153<br><br>Bates: 000372<br>Deliberative Process Privilege: The redacted information in this email exchanges contains internal deliberations about the legal requirements surrounding Emergency Use Authorization (EUA) applications for the various public health laboratories that might use the same test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000380 | 000380 | 2/28/2020 | Jeff Shuren, M.D., J.D. | RE: Press | (b)(6) | FDA-CVD-SHURENJ-00035179<br><br>Bates: 000380 |

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| | | | | | | Personal Privacy Information: The redacted information contains the private email address of a ThermoFisher employee. |
| 000411 | 000413 | 2/27/2020 | Jeff Shuren, M.D., J.D. | FW: Pre-EUA IVD template request | (b)(4), (b)(5) | FDA-CVD-SHURENJ-00035203<br><br>Bates: 000411, 000413<br>Confidential Commercial Information: The redacted information relates to the New York State Department of Health (NYSDOH) Wadsworth Center's development of its test for SARS-CoV-2. The release of this information would inform the NYSDOH Wadsworth Center's competitors about its operations and would lead to predictable harm.<br><br>Bates: 000411<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the New York State Department of Health (NYSDOH) Wadsworth Center's development of its test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000414 | 000415 | 2/29/2020 | Jeff Shuren, M.D., J.D. | RE: IDT No Objection Language | (b)(5) | FDA-CVD-SHURENJ-00035224<br><br>Bates: 000414, 000415<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about draft language for an email to Integrated DNA Technologies (IDT) regarding its test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000422 | 000423 | 2/25/2020 | Jeff Shuren, M.D., J.D. | RE: Two items re COVID-19 Hill Briefing | (b)(5) | FDA-CVD-SHURENJ-00035270<br><br>Bates: 000422<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about talking points and potential |

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| | | | | | | questions and responses for a briefing for Congress about FDA's COVID-19 response as it relates to the approval and/or authorization of tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000426 | 0000426 | 2/27/2020 | Jeff Shuren, M.D., J.D. | COVID-19 Test Update | (b)(5) | FDA-CVD-SHURENJ-00035291<br><br>Bates: 000426<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the shipment and configuration of CDC's test for SARS-CoV-2 with Integrated DNA Technologies' (IDT) primers and reagent probes to public health laboratories for validation, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000437 | 000441 | 2/28/2020 | Jeff Shuren, M.D., J.D. | RE: Minimal Criteria for test validation | (b)(5) | FDA-CVD-SHURENJ-00035310<br><br>Bates: 000438 – 000441<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the minimum acceptance criteria entities need to meet to validate their tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

* Page prefix is FDACDRH-p3-A-000239-O00441
** Exemption codes refer to sections of the Freedom of Information Act, *see* 5 U.S.C. § 552(b).

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 9:16:06 PM
**To:** Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Inbios

Tim,

Inbios' Smart Detect 2019-nCoV, testing ORF1b, E-gene, and N-gene, is completing their SARS-like assay design and has contacted (b) (4) to obtain extracted RNA..

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/18/2020 10:48:47 PM
**To:** Javan Esfandiari (b)(6)
**CC:** Garcia, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ec44354adae4472a61ac05123d291d3-Maria.Garci]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Tom Ippolito (b)(6) Louise Sigismondi (b)(6) Paul Lambotte (b)(6)
**Subject:** RE: Remaining items

Javan,

Thanks for the update and the conversation during the meeting. We look forward to working with you.

Best regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Javan Esfandiari <(b)(6)>
**Sent:** Tuesday, February 18, 2020 9:28 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Tom Ippolito (b)(6) Louise Sigismondi (b)(6) Paul Lambotte (b)(6)
**Subject:** RE: Remaining items

Dear Uwe,

It was great to meet you, Kim and Myra during the FDA meeting recently.
As you see from communication between Louise and Myra, we are trying to close the remaining open issues for our DPP Zika IgM System and submit the 510K this week if we get final comments from Myra.
We appreciate all the support we have received from the FDA team during the interactive review of our submission and look forward to completing this project as soon as possible.

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Also, as we briefly discussed during the meeting, we look forward to working with your team in the next project, such as a DPP COVID-19. We are currently (b)(4) (b) (4) (b) (4) and we would like to discuss it with you our proposal for a possible FDA-EUA as soon we are ready.

Best regards

Javan

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**Javan Esfandiari | Executive VP & CSTO**

Chembio Diagnostic Systems Inc
3661 Horseblock Road , Medford NY 11790 USA
Phone: +1631-924-1135 (x112) | Mobile: +1-631-839-5615
Email: (b)(6)
Web: www.chembio.com

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**From:** Louise Sigismondi
**Sent:** Tuesday, February 18, 2020 2:50 PM
**To:** 'Garcia, Mayra' <Mayra.Garcia@fda.hhs.gov>
**Cc:** (b) (4) @docs.fda.gov' <(b) (4) @docs.fda.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Tom Ippolito (b)(6) ; Javan Esfandiari <(b)(6)
**Subject:** RE: Remaining items

Hi Mayra,

Easy enough for me to make the edits on the two documents you sent back.

I am attaching the corrected Section 9.

The remaining outstanding items, as I understand, is the clinical section and the software section as I have not heard feedback on the later as of yet.

Please advise. We are aiming to submit the ecopy by week's end. I have completed the 510K Summary and Executive summary based on the last draft of the clinical section.

They are also attached here. The IFU has also been written based on the already completed sections.

Best,

**Louise Muscat Sigismondi, Ph.D.| Regulatory Affairs Director of Research & Development**

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CHEMBIO
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(b)(6)
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**From:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 12:43 PM
**To:** Louise Sigismondi <(b)(6)
**Cc:** (b) (4) @docs.fda.gov' <(b) (4) @docs.fda.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Tom Ippolito <(b)(6) Javan Esfandiari <(b)(6)
**Subject:** RE: Remaining items

Louise,

The RTA form you used is an old version. Please see current one attached.

Some questions about the other section.

Thanks,

Mayra

**From:** Louise Sigismondi <(b)(6)
**Sent:** Friday, February 14, 2020 1:51 PM
**To:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Cc:** (b) (4) @docs.fda.gov' <(b) (4) @docs.fda.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Tom Ippolito <(b)(6) Javan Esfandiari <(b)(6)
**Subject:** Remaining items

Hi Mayra,

I am attaching the remaining items if you would like to review those as well.

Best,
Louise

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/18/2020 4:22:51 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Mielech, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]
**Subject:** RE: Qiagen PEUA

Li,

Yes, since that will take time, (b)(5) [redacted] Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 4:06 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** Qiagen PEUA

The FDA cleared Qiagen RP panel (QIAstat-Dx Respiratory Panel) has the following claimed pathogens:
Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus A+B, Influenza A, Influenza A H1, Influenza A H3, Influenza A H1N1/pdm09, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Rhinovirus/Enterovirus, Respiratory Syncytial Virus A+B, *Bordetella pertussis*, *Chlamydophila pneumoniae* and *Mycoplasma pneumoniae*.

(b)(5) [redacted]

Just want to bring this potential issue to your attention when we review (b)(5) [redacted]
(b)(5) [redacted]

Thanks,
Li

**Li Li**
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 762-6200 | Fax: (301) 847-8512
li.li2@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/18/2020 10:31:54 PM
**To**: Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: Contract Manufacturer

Great, thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 9:24 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Contract Manufacturer

Looks good to me – I included a few minor, additional revisions below in red.

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 6:40 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: Contract Manufacturer

Predecisional/Deliberative

See suggested edits below.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 6:07 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Contract Manufacturer

Ellen and Marcy,

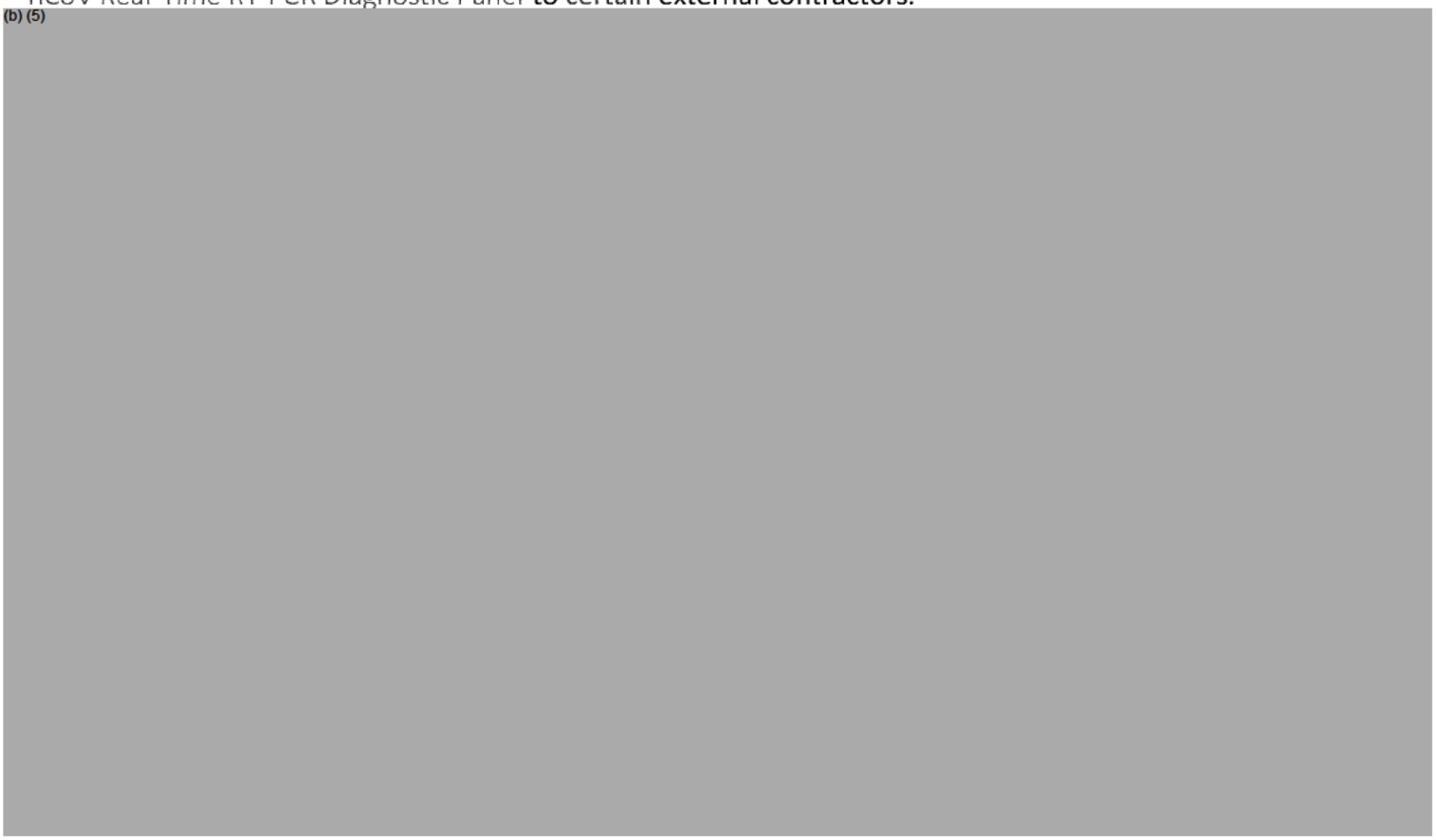
Here the draft for the response to CDC regarding their wish to contract out the manufacturing. I tried to capture as much from our conversation as I could. Please provide any edits you have. Uwe

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Predecisional/Deliberative:

CDC has communicated to FDA that you wish to contract out primer & probe manufacturing for the 2019-nCoV Real-Time RT-PCR Diagnostic Panel to certain external contractors.

(b) (5)



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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/19/2020 8:37:17 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]

**Subject:** Fwd: Update on EUA for CDC "surveillance"
**Attachments:** COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx
**Location:** webex

**Start:** 2/20/2020 8:30:00 AM
**End:** 2/20/2020 9:00:00 AM
**Show Time As:** Tentative

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Date:** February 19, 2020 at 8:25:54 PM EST
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Update on EUA for CDC "surveillance"

CDC says they will submit a new EUA referencing the data in their first EUA in a day or two.
Protocol attached.
It would be good to touch base to ensure we are all on the same page for next steps.

Maybe we would also be able to discuss a little about the draft letter of authorization:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the SARS-CoV-2 (formerly 2019-nCoV) in nasopharyngeal (NP) or oropharyngeal (OP) respiratory specimens collected from individuals consented or notified prior to sample collection that SARS-CoV-2 testing would be performed if specimens are negative for influenza and other respiratory pathogens in order to determine if unrecognized community transmission of SARS-CoV-2 is occurring, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing is limited to qualified laboratories designated by CDC to conduct testing according to protocol xxx and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.
-- Do not delete or change any of the following text. --

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Meeting password: (b) (6)

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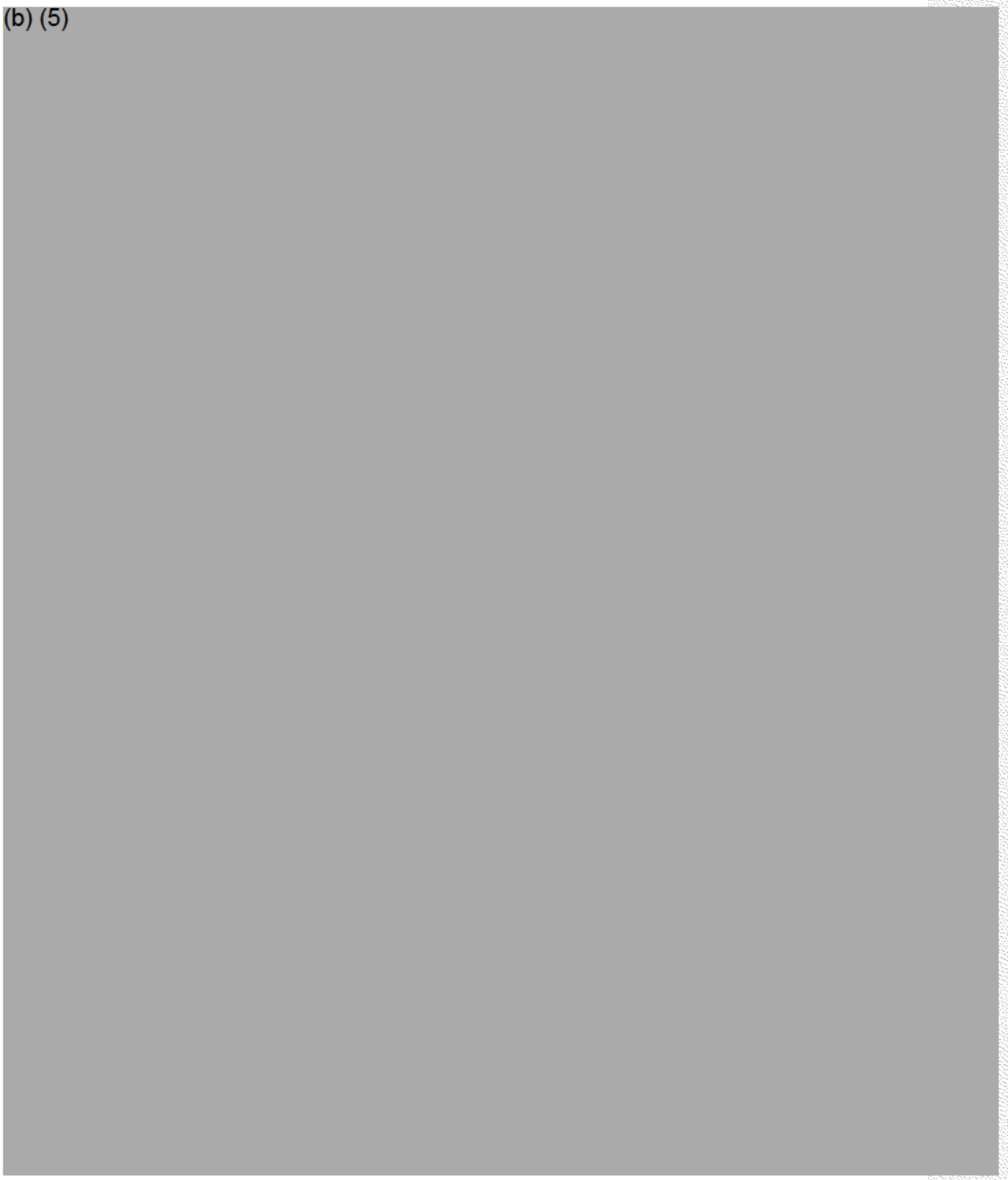
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(b) (5)

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(b) (5)

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(b) (5)

DRAFT



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/23/2020 12:03:44 PM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Tim,

Getting the authorization letter done, need to touch base where we are on this.

Drafting the review memo, Kim will do that this afternoon.

Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:59 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hi Uwe,

What is the next step on this EUA?

Thanks!

Best,
Tim

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 23, 2020 at 11:53:55 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Importance:** High

Jeff,

The draft edits for the document for the surveillance study just went out to CDC.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:13 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

The following email just went out to CDC. Thank you all for the fast turnabout to get this done.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:09 AM
**To:** Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Spies, Stacey (CDC) <(b)(6)@cdc.gov>; Langley, Gayle E (CDC) <(b)@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <(b)(6)@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear Laura,

Attached please find the following documents you submitted on February 21, 2020 to support the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in surveillance activities. These documents have been reviewed and edited by FDA's OCET and OCC.

1. Draft COVID-19 sentinel surveillance
2. Draft SARS-CoV-2 surveillance risk benefit
3. Draft CDC Surveillance EUA Request Cover letter

Please do not hesitate to reach out to me with questions.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/25/2020 10:52:40 PM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject**: RE: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

Thanks, Uwe

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 5:20 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

Uwe,

Below is the table updated today. (b)(5) pre-EUAs are logged in CTS and we have (b)(5) more that are not logged in yet but we are reviewing them anyway (except the last one from (b)(5) which I will assign tomorrow)

(b)(5)

[redacted]

AMERICAN OVERSIGHT

(b)(5)

[redacted]

Tamara

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 5:13 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** FW: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers
**Importance:** High

Tamara,

Do you have any update on the submitted pre-EUA numbers?

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:41 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** RE: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers
**Importance:** High

Good evening all,

Are there any updates to the numbers below? Jeff is briefing Senate HELP staff tomorrow so wanted to check in.

Best,

Jennifer

(b)(5)

[redacted]

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:18 AM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

Jennifer, see edits below.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 5:26 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers
**Importance:** High

Uwe, Kim, and Toby,

(b)(5) [redacted]

(b)(5) [redacted] Can you review the four points below by 9 am on Monday morning? Feel free to add anything else you think is responsive and helpful.

Sorry for the quick turnaround (once again).

Thanks very much for your help.

Best,

Jennifer

(b)(5) [redacted]

AMERICAN OVERSIGHT

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/25/2020 4:00:44 PM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Draft language with the revised numbers

Dear L, Joe, and Tamara,

Excellent job, thank you so much for getting the analysis done so quickly.

Thank you!!

Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:12 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>
**Subject:** FW: Draft language with the revised numbers

Hi Uwe,

Please find below the draft language for your consideration. (b)(5) [redacted]

(b)(5) [redacted]

(b)(5) [redacted]

(b)(5) [redacted]

(b)(5) [redacted]

Thanks,
Li

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 2:26 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>
**Subject:** Draft language with the revised numbers

(b)(5) [redacted]

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(b)(5)

[redacted]

**Li Li**
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6200 | Fax: (301) 847-8512
li.li2@fda.hhs.gov






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AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/18/2020 11:04:57 AM
**To:** Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]
**Subject:** RE: IDE and reporting requirements for CDC's coronavirus diagnostic

NO not yet. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 10:41 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: IDE and reporting requirements for CDC's coronavirus diagnostic

Hi Uwe,

I'm in training this morning, (b)(5) [redacted]
(b)(5) [redacted]

(b)(5) [redacted]

I can swing by to discuss (b)(5) [redacted]

Brittany

---

**From:** Dreher, Maureen L <Maureen.Dreher@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 7:09 AM
**To:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** IDE and reporting requirements for CDC's coronavirus diagnostic

Hi Brittany,
(b)(5) [redacted]

(b)(5) [redacted] But your schedule looks worse than mine! Please let me know if you would have time to discuss. I'm assuming that you're working on a tight timeframe.

AMERICAN OVERSIGHT

Thanks,
Maureen

Maureen L. Dreher, Ph.D.
*Assistant Director, Policy & Operations Team*
*DCEA1: Division of Clinical Science & Quality*
OCEA: Office of Clinical Evidence & Analysis
Office of Product Evaluation & Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 1545 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: (301) 796-2505 |maureen.dreher@fda.hhs.gov

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AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/24/2020 6:53:43 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: 2/24/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/24/20 6 AM update:

**Status of activities on diagnostics:**

(b)(5)

[redacted]

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 8:57:43 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]
**CC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: nCoV: Draft for review by OCC legal counsel

Update: Ellen,

(b)(5)
(b)(5) We will work as fast as we can to finish the review and provide the recommendation.

Uwe

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 3:23 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: nCoV: Draft for review by OCC legal counsel

REVISED DRAFT FOR REVIEW BY OCC LEGAL COUNSEL / DELIBERATIVE / PREDECISIONAL

Per Uwe, I made one change below, highlighted in yellow. He said he still needs an hour or so to review the data.

---

**From:** Flannery, Ellen
**Sent:** Monday, February 24, 2020 3:10 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** nCoV: Draft for review by OCC legal counsel
**Importance:** High

DRAFT FOR REVIEW BY OCC LEGAL COUNSEL / DELIBERATIVE / PREDECISIONAL

Dear OCC,

Please see below a draft enforcement discretion email. I am asking Uwe and Tim to review the facts to be sure they are correct.

Thanks,
Ellen

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DRAFT FOR OCC REVIEW:

(b)(5)

[redacted]

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/18/2020 4:13:00 PM
**To**: Post, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f49ffd1c43b74667b0babca31650e08d-Justin.Post]
**CC**: Hwang, Leroy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5da97657ec944cebf943616bd848105-Leroy.Hwang]
**Subject**: RE: Summary of CDC 2019-nCoV RT-PCR Diagnostic Panel (EUA) and Interactions with CDC

Justin,

Thank you very much. I might have some simple follow up questions tomorrow. Uwe

---

**From:** Post, Justin <Justin.Post@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 4:07 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Subject:** Summary of CDC 2019-nCoV RT-PCR Diagnostic Panel (EUA) and Interactions with CDC

Hi Uwe,

Please see attached presentation per your request and feel free to use or edit as you see fit. The presentation starts out with a summary of the test and then proceeds in chronological order with the recent interactions between FDA and CDC.

Summary:
(b)(5)
[redacted]

Further information:
(b)(5)
[redacted]

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(b)(5)

[redacted]

I hope this helps!

**Justin Post**
*Biologist/Reviewer*
*Post-market Compliance Group*

Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3115 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (240) 402-3720
Justin.Post@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/18/2020 11:04:08 AM
**To:** Hwang, Leroy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5da97657ec944cebf943616bd848105-Leroy.Hwang]
**Subject:** FW: Manufacturing of EUA CDC Assay

Some additional info on the manufacturing I needed to put together, please add to the manufacturing write up.

Thanks, Uwe

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 11:02 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Manufacturing of EUA CDC Assay

Tim,

Here the information:

(b)(4), (b)(5)

[redacted]

(b)(4), (b)(5)

[redacted]

Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 10:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Manufacturing of EUA CDC Assay

Hi Uwe,

AMERICAN OVERSIGHT

Can you send me the list of assay components that the CDC uses to manufacture their assay? (b)(5) [redacted]
(b)(5) [redacted]

We are wondering (b)(5) [redacted]

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/27/2020 9:15:20 AM
**To:** Hill, Allen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36465afb79514f19a490a0912255fcc9-John.Hill]
**Subject:** RE: RAPID COVID-19 SCREEN

Allen,

I need their email to respond. The are not listed below. Uwe

---

**From:** Hill, Allen <John.Hill@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 9:00 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Gitterman, Steven <Steven.Gitterman@fda.hhs.gov>
**Cc:** Breakthrough Devices Program <BreakthroughDevicesProgram@fda.hhs.gov>
**Subject:** FW: RAPID COVID-19 SCREEN

Hi Uwe and Steve,

Would a COVID-19 diagnostic be reviewed in DMD?

I expect the Breakthrough Program will reply to the email below with standard information about how to submit a Breakthrough Designation (Breakthrough guidance, eCopy guidance, address, etc.). If you find the below of interest and want to reach out, that would be fine, too. Just let the program know if you do.

Regards,
Allen

**J. Allen Hill, M.A.**
*Physicist/Policy Analyst*

510(k) Third Party Review Program Team
Division of Program Operations and Management | OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health | Food and Drug Administration
Tel: 301-796-7086
john.a.hill@fda.hhs.gov






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---

**From:** (b) (4) [redacted]
**Sent:** Wednesday, February 26, 2020 10:24:34 PM (UTC+00:00) (b) (4) [redacted]
**To:** Breakthrough Devices Program
**Cc:** (b) (4) [redacted]
**Subject:** RAPID COVID-19 SCREEN

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CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

February 20, 2020
Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
CDRH Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(5)

[redacted]

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(b)(5)



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(b)(5)





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(b)(5) Draft Release

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/25/2020 3:56:45 PM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Deliberative/Predecisional

(b)(5) [redacted]

Best,
Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 1:37 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Deliberative/Predecisional

(b)(5) [redacted]

Best,
*Tim*

AMERICAN OVERSIGHT

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*

*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 1:35 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Jeff,

(b)(5) [redacted]

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 1:21 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Uwe – (b)(5) [redacted]

Tim – (b)(5) [redacted]
(b)(5) [redacted]

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 1:05 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen

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<Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

(b)(5) [redacted]

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 12:51 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Deliberative/PreDecisional

(b)(5) [redacted]

(b)(5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 25, 2020 at 12:11:07 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

(b)(5) [redacted]

(b)(5) [redacted]
(b)(5) [redacted]

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 25, 2020 at 11:24:51 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

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Tim, Ellen, Jeff,

(b)(5)



Uwe

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/20/2020 7:18:44 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: Problems with CDC coronavirus test delay expanded US screening
**Attachments:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Jeff,

I spoke with Tim, the following message went out to CDC.

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 5:27 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Problems with CDC coronavirus test delay expanded US screening
**Importance:** High

Please see the story in POLITICO Pro below. (b)(5) [redacted]

(b)(5) [redacted]

(b)(5) [redacted]

Jeff

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 5:19 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** FW: Problems with CDC coronavirus test delay expanded US screening

FYI

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

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**From:** POLITICO Pro <politicoemail@politicopro.com>
**Sent:** Thursday, February 20, 2020 5:04 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Problems with CDC coronavirus test delay expanded US screening

## Problems with CDC coronavirus test delay expanded US screening

By David Lim

02/20/2020 05:03 PM EST

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

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Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

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**Sent:** 2/18/2020 11:02:28 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject:** RE: Manufacturing of EUA CDC Assay

Tim,

Here the information:

(b) (4), (b) (5)

Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 10:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Manufacturing of EUA CDC Assay

Hi Uwe,

Can you send me the list of assay components that the CDC uses to manufacture their assay? I (b) (4)
(b) (4)

We are wondering if anything is manufactured outside the CDC and (b) (4)

Thanks!

Best,

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*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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**Sent:** 2/25/2020 3:52:36 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Ellen Flannery (Ellen.Flannery@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Exclusion of N3

**Importance:** High

My team analyzed the (b)(5) [redacted]

(b)(5) [redacted]

Best,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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**Sent**: 2/19/2020 6:51:12 PM
**To**: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx
**Attachments**: Draft CDC 2nd 2019-nCoV Letter of Authorization 2-19-20.doc

Here some preliminary notes.

Mary is trying to set up a meeting tomorrow. We will make sure you will be invited to this call. Thanks, Uwe

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:19 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

Draft EUA letter of authorization. I could set up a meeting in the morning to touch base with you (b) (5) [redacted]

Thanks,

Jennifer

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 1:57 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

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U.S. FOOD & DRUG ADMINISTRATION

Febuary xx, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Dear Dr. Redfield:

(b)(5) Draft

[redacted]

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(b)(5) Draft

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(b)(5) Draft

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/18/2020 8:54:19 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** RE: (b) (4) Smart Detect 2019-nCoV rRT-PCR kit

Thank you for getting this out today. Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 6:04 PM
**To:** Estela Raychaudhuri (b) (6)
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** (b) (4) Smart Detect 2019-nCoV rRT-PCR kit

Dear Estela,

I was assigned as the lead reviewer for (b) (4) for the Smart Detect 2019-nCoV rRT-PCR kit. Attached please find our comments to the draft Pre EUA template you submitted for FDA review.

Please let me know if you have any questions or concerns regarding the FDA review comments.

Best Regards,
Li

**Li Li**
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 762-6200 | Fax: (301) 847-8512
li.li2@fda.hhs.gov

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**Sent**: 2/24/2020 12:48:43 PM
**To**: Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: nCoV PEUA Assignments-Priority List.xlsx
**Attachments**: nCoV PEUA Assignments-Priority List.xlsx

Tim,

Attached the priority list:

(b)(5) [redacted]

(b)(5) [redacted]

(b)(5) [redacted]

Uwe

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| Document # | Sponsor | Device | Target | Status | Priority |
|---|---|---|---|---|---|
| | | | | | |

(b)(5)

[redacted]

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**Sent**: 2/22/2020 9:03:19 AM
**To**: Garcia, Mayra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7db05677732d4023bcdf772ee0474055-GarciaM]
**Subject**: RE: Coronavirus and MERS culturing

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 9:01 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Coronavirus and MERS culturing

FYI

---

**From:** Garcia, Mayra
**Sent:** Saturday, February 22, 2020 8:59 AM
**To:** Wang, Tony <Tony.Wang@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; McGivern, David <David.McGivern@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Dear Tim,

As I mentioned to Uwe yesterday, the idea was to handle the COVID-19 materials for the CDRH devices as we did for Zika. CBER has the laboratories and knowledge to propagate the virus. DMD will be able to design the panel that will best challenge the sensitivity and specificity of the devices we are getting in house. Therefore, after Tony grows and inactivates the BSL-3 stocks, I would be preparing the dilutions of the viral stocks with David's help to formulate the final panel. In addition, I was also the one receiving at CDRH the orders, distributing the panels when available to the companies, as well as receiving the results of the testing. This strategy allowed DMD to have knowledge of the progress companies where doing with the panel testing and compile all the results for the EUA devices.

The preparation of the panel will take some time as the virus strains need still to be grown (and as Tony said the BSL-3 just got validated to work with COVID-19), inactivated, titrated, and the panel will have to be prepared with different dilutions that could satisfy the sensitivity observed in our devices.

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I proposed a meeting with CBER for next week, now that that the BSL-3 and the funds are available since 2/21/2020, to set up a timeline for the next steps.

Regards,

Mayra

---

**From:** Wang, Tony <Tony.Wang@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 8:27 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; McGivern, David <David.McGivern@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Dear Tim,

I am adding Drs. Carolyn Wilson, Mayra Garcia from CDRH and David McGivern to this email chain for communication purpose. Dr. Wilson is the director of office of research at CBER who oversees all 2019-nCoV activities. Dr. McGivern at the Office of Blood Research and Review at CBER will work with Mayra at CDRH to generate reference standards for industry to use.

My group is to propagate virus and then work with David's group to establish conditions for heat-inactivation of the virus. We have just received the approval to conduct the work, but there are a few house-keeping items that we need to take care of before we can start the work.

I would leave to Dr. Wilson, Mayra and Dr. McGivern to speak on the part regarding dialogues with industries.

Best,

Tony

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 3:14 PM
**To:** Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>; Wang, Tony <Tony.Wang@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Coronavirus and MERS culturing

Hi Tony, Shufeng and Christopher,

We are getting inquiries from IVD test developers who are ready to finish the validation of their molecular Coronavirus assays so they can submit them to CDRH for EUA authorization. I have heard that you are developing a source of Coronavirus and mers and was wondering if you are in dialogue with companies already and if we can introduce them to you so they can get in line to receive samples when they are ready.

Thanks so much in advance!

Best,
*Tim*

AMERICAN OVERSIGHT

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*

*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:42 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Hello Tim,
Likewise, I am delighted to meet you today. Please see attached for the IBC application we received from CBER for review and approval. We will have to contact the PI's at CBER to find out when they will have the materials ready. Based on the application, it seems like they are only preparing nConV19 (SARS CoV 2) and MERS CoV materials. (b) (5) [redacted] Hope this is helpful and let me know if I can be of further assistance. Take care.

Pillai

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:13 PM
**To:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Coronavirus and MERS culturing

Hi Pillai,

Great to meet you today! I wanted to reach out and have copied Jeff to find out more details about the coronavirus and mers cultures. We have a number of test developers who cannot complete validation of their EUA assays until they have at least mock samples made with virus to test.

How soon will virus be available?
Can we connect developers with someone here at the agency so they can coordinate access?

Thanks!

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Best,

*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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*Administrative Assistant*

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**Sent**: 2/27/2020 9:02:56 AM
**To**: Hill, Allen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36465afb79514f19a490a0912255fcc9-John.Hill]; Gitterman, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4747486679444f24aa8d1086cca27390-SRG]
**CC**: Breakthrough Devices Program [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bd0c5d67e6941e3ba485784cf98e3d9-Breakthroug]
**Subject**: RE: RAPID COVID-19 SCREEN

Allen,

This should not be a breakthrough it should be an EUA. I will respond to the request. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Hill, Allen <John.Hill@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 9:00 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Gitterman, Steven <Steven.Gitterman@fda.hhs.gov>
**Cc:** Breakthrough Devices Program <BreakthroughDevicesProgram@fda.hhs.gov>
**Subject:** FW: RAPID COVID-19 SCREEN

Hi Uwe and Steve,

Would a COVID-19 diagnostic be reviewed in DMD?

I expect the Breakthrough Program will reply to the email below with standard information about how to submit a Breakthrough Designation (Breakthrough guidance, eCopy guidance, address, etc.). If you find the below of interest and want to reach out, that would be fine, too. Just let the program know if you do.

Regards,
Allen

**J. Allen Hill, M.A.**
*Physicist/Policy Analyst*

510(k) Third Party Review Program Team
Division of Program Operations and Management | OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health | Food and Drug Administration
Tel: 301-796-7086
john.a.hill@fda.hhs.gov

AMERICAN OVERSIGHT

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**From:** (b) (4)
**Sent:** Wednesday, February 26, 2020 10:24:34 PM (UTC+00:00) (b) (4)
**To:** Breakthrough Devices Program
**Cc:** (b) (4)
**Subject:** RAPID COVID-19 SCREEN

(b) (4)

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/23/2020 7:36:05 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: Call tomorrow - Rational why we need a new EUA

Thanks for digging this out so fast. Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 7:26 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Call tomorrow - Rational why we need a new EUA

Uwe – (b)(5) [redacted]
(b)(5) [redacted]

(b)(5) [redacted]

(b)(5) [redacted]

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 7:08 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Call tomorrow - Rational why we need a new EUA

Kim,

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(b)(5) [redacted]

(b)(5) [redacted]

(b)(5) [redacted]

Any comments, do I miss anything?

Thanks, Uwe

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/23/2020 11:33:45 AM
**To:** Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]
**Subject:** RE: (b)(5) calculations for COVID-19 r (b)(5)

Kris,

Thanks, we should discuss this tomorrow with the pre-EUA reviewers.

Excellent. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:32 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: (b)(5) calculations for COVID-19 (b)(5)

Uwe,

(b)(5)

(b)(5)

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(b)(5) [redacted]

Kris

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:44 AM
**To:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Subject:** RE: (b)(5) [redacted] calculations for COVID-19 (b)(5) [redacted]

Kris,

Thanks, (b)(5) [redacted]

---

**From:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:35 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Hellyer, Tobin <Tobin.Hellyer@fda.hhs.gov>; Sconce, Kimberly <Kimberly.Sconce@fda.hhs.gov>
**Subject:** (b)(5) [redacted] calculations for COVID-19 (b)(5) [redacted]

Hi All,
Thanks to Tobin, Kim and Li for the discussion on Friday. (b)(5) [redacted]

(b)(5) [redacted]

The spreadsheet needs review to ensure 100% accuracy, glad to walk anyone through it on Monday.
Kris

AMERICAN OVERSIGHT

(b)(5)

[redacted]

**Kristian Roth, Ph.D.**
*Branch Chief Bacterial Multiplex and Medical Counter Measures*
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-7024
kristian.roth@fda.hhs.gov




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AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/25/2020 5:19:09 PM
**To:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** RE: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

T(b)(5)

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 5:15 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

(b)(5)

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 5:13 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** FW: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers
**Importance:** High

Tamara,

Do you have any update on the submitted pre-EUA numbers?

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:41 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** RE: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers
**Importance:** High

Good evening all,

Are there any updates to the numbers below? Jeff is briefing Senate HELP staff tomorrow so wanted to check in.

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Best,

Jennifer

(b)(5)

[redacted]

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:18 AM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

Jennifer, see edits below.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 5:26 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers
**Importance:** High

Uwe, Kim, and Toby,

(b)(5)

[redacted]

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Sorry for the quick turnaround (once again).

Thanks very much for your help.

Best,

Jennifer

**FDA Response to COVID-19 By-the-Numbers**

(b)(5)

[redacted]

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/27/2020 10:59:07 AM
**To**: Dreher, Maureen L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1f967e25c149aba137e9b6322b4f8d-MXU]
**Subject**: RE: RAPID COVID-19 SCREEN

Thanks, Uwe

---

**From:** Dreher, Maureen L <Maureen.Dreher@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 10:18 AM
**To:** Breakthrough Devices Program <BreakthroughDevicesProgram@fda.hhs.gov>
**Cc:** Allen, Tamika <Tamika.Allen@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Gitterman, Steven <Steven.Gitterman@fda.hhs.gov>
**Subject:** RE: RAPID COVID-19 SCREEN

Hi everyone,
Here is Dr. (b) (4) email:
(b) (4)

Maureen

Maureen L. Dreher, Ph.D.
*Assistant Director, Policy & Operations Team*
*DCEA1: Division of Clinical Science & Quality*
OCEA: Office of Clinical Evidence & Analysis
Office of Product Evaluation & Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 1545 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: (301) 796-2505 | maureen.dreher@fda.hhs.gov

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---

**From:** Breakthrough Devices Program <BreakthroughDevicesProgram@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 10:04 AM
**To:** Dreher, Maureen L <Maureen.Dreher@fda.hhs.gov>
**Subject:** FW: RAPID COVID-19 SCREEN

---

**From:** Hill, Allen
**Sent:** Thursday, February 27, 2020 3:04:20 PM (UTC+00:00) (b) (4)
**To:** Breakthrough Devices Program
**Cc:** Scherf, Uwe
**Subject:** FW: RAPID COVID-19 SCREEN

AMERICAN OVERSIGHT

Hi Breakthrough Colleagues,

Can one of you look in the Breakthrough inbox and send Dr. Scherf the email address this came from?

Regards,
Allen

**J. Allen Hill, M.A.**
*Physicist/Policy Analyst*

510(k) Third Party Review Program Team
Division of Program Operations and Management | OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health | Food and Drug Administration
Tel: 301-796-7086
john.a.hill@fda.hhs.gov






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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 9:15 AM
**To:** Hill, Allen <John.Hill@fda.hhs.gov>
**Subject:** RE: RAPID COVID-19 SCREEN

Allen,

I need their email to respond. The are not listed below. Uwe

---

**From:** Hill, Allen <John.Hill@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 9:00 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Gitterman, Steven <Steven.Gitterman@fda.hhs.gov>
**Cc:** Breakthrough Devices Program <BreakthroughDevicesProgram@fda.hhs.gov>
**Subject:** FW: RAPID COVID-19 SCREEN

Hi Uwe and Steve,

Would a COVID-19 diagnostic be reviewed in DMD?

I expect the Breakthrough Program will reply to the email below with standard information about how to submit a Breakthrough Designation (Breakthrough guidance, eCopy guidance, address, etc.). If you find the below of interest and want to reach out, that would be fine, too. Just let the program know if you do.

Regards,
Allen

**J. Allen Hill, M.A.**
*Physicist/Policy Analyst*

510(k) Third Party Review Program Team
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Office of Product Evaluation and Quality

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Tel: 301-796-7086
john.a.hill@fda.hhs.gov

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---

**From:** (b) (4)
**Sent:** Wednesday, February 26, 2020 10:24:34 PM (UTC+00:00) (b) (4)
**To:** Breakthrough Devices Program
**Cc:** (b) (4)
**Subject:** RAPID COVID-19 SCREEN

(b) (4)

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/26/2020 1:41:40 PM
**To:** Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]
**Subject:** RE: IFU Kit Supplement.docx

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 12:37 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IFU Kit Supplement.docx

(b)(5)
[redacted]

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 12:19 PM
**To:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** IFU Kit Supplement.docx

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/21/2020 7:44:44 AM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject:** RE: 2/21/20 6 AM update

Yes, it now a good time?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 7:43 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: 2/21/20 6 AM update

Do you have a minute to discuss the plans for CDC?

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 21, 2020 at 7:01:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** 2/21/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/21/20 6 AM update:

**Status of activities on diagnostics:**

(b)(5)



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(b)(5)

[redacted]

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/23/2020 5:53:33 AM
**To**: Pai-Scherf, Lee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54982f2794dd415c894b820903486528-PAISCHERF]
**Subject**: FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Attachments**: DRAFT CDC Surveillance EUA Request Cover letter 20FEB2020 6pm FDA 2.22.2020.docx; DRAFT SARS-CoV-2 surveillance risk benefit 20Feb20_FDA_2.22.2020.docx; COVID_19 sentinel surveillance Feb 21 2020 FINAL CLEAN_FDA 2.22.2020.docx

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 12:19 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

Please find attached the final documents with edits/comments back to CDC for your final review. I would like to send them back to CDC tomorrow morning. I will be unavailable 9-10:30am and 11:30 am – 1:00pm. If I could get any comments before 10:30 am hopefully I can send final docs back to CDC in the 10:30-11:30 window.

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

February 20, 2020
Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
CDRH Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

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Assessment of Benefits and Risks:

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[redacted]

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(b)(5) Draft

[redacted]

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 11:51:23 AM
**To**: Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]
**CC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]
**Subject**: RE: For Review ASAP - Excerpt from HHS Testimony re EUA

Jennifer, I have no comments. Uwe

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 10:53 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** For Review ASAP - Excerpt from HHS Testimony re EUA
**Importance:** High

Uwe and Kim,

Apologies for the quick turnaround on this. We are reviewing HHS testimony on COVID-19 and CDC has some information about the EUA. I've excerpted the information below for your reference. We're being asked to provide any edits by noon today. Can you let me know if we are OK with this language?

(b)(5) Draft



AMERICAN OVERSIGHT

(b)(5) Draft

[redacted]

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/25/2020 3:32:05 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]
**Subject:** RE: Draft language with the revised numbers

Li and Joe, thank you so much. Going through it now. Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:12 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>
**Subject:** FW: Draft language with the revised numbers

Hi Uwe,

Please find below the draft language for your consideration. (b)(5) (b)(5) based on the two excel sheets Julie sent this afternoon.

(b)(5)

(b)(5)
(b)(5)

Thanks,
Li

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 2:26 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>
**Subject:** Draft language with the revised numbers

(b)(5)

AMERICAN OVERSIGHT

**Li Li**
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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li.li2@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/20/2020 11:51:05 AM
**To**: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**Subject**: RE: Draft Letter - EUA for CDC "surveillance"
**Attachments**: Draft CDC Protocol EUA 2019-nCoV Letter of Authorization 2-20-20.doc

Jennifer,

Kim and I worked on updating the draft letter, attached our comments.

Uwe

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 9:41 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** Draft Letter - EUA for CDC "surveillance"

Kim and Uwe,

If you revise the draft letter, then it may be ready for OCC to make edits. (b) (5)

Thanks,

Jennifer

-----Original Appointment-----
**From:** Ross, Jennifer
**Sent:** Wednesday, February 19, 2020 8:26 PM
**To:** Ross, Jennifer; Busch, Marcy; Dennis, Claire; Sadove, Elizabeth; Scherf, Uwe; Sapsford, Kim E
**Cc:** Stenzel, Timothy; Flannery, Ellen
**Subject:** Update on EUA for CDC "surveillance"
**When:** Thursday, February 20, 2020 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
**Where:** webex

CDC says they will submit a new EUA referencing the data in their first EUA in a day or two.
Protocol attached.
It would be good to touch base to ensure we are all on the same page for next steps.

AMERICA'S OVERSIGHT

Maybe we would also be able to discuss a little about the draft letter of authorization:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the SARS-CoV-2 (formerly 2019-nCoV) in nasopharyngeal (NP) or oropharyngeal (OP) respiratory specimens collected from individuals consented or notified prior to sample collection that SARS-CoV-2 testing would be performed if specimens are negative for influenza and other respiratory pathogens in order to determine if unrecognized community transmission of SARS-CoV-2 is occurring, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing is limited to qualified laboratories designated by CDC to conduct testing according to protocol xxx and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.
-- Do not delete or change any of the following text. --

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AMERICAN OVERSIGHT

U.S. FOOD & DRUG ADMINISTRATION

Febuary xx, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Dear Dr. Redfield:

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

[redacted]

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/23/2020 7:08:00 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Call tomorrow - Rational (b)(5)

Kim,

Laura's call tomorrow will have the question why they (b)(5)

Since I was not involved in all the discussion yesterday, (b)(5)
(b)(5)

What comes to my mind is:
(b)(5)

Any comments, do I miss anything?

Thanks, Uwe

AMERICAN OVERSIGHT

Interagency Strategy Recommendation from (b)(5) Draft

(b)(5) Draft

[redacted]

Formatted: Highlight



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(b)(5) Draft

[redacted]



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(b)(5) Draft





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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/27/2020 10:53:36 AM
**To:** (b)(6) [redacted]
**Subject:** RE: contact for donation of coronavirus kit

Here the info:

Kuhnert-Tallman, Wendi L (CDC)
ASSOC. DIRECTOR FOR LAB SCIENCE
wdk1@cdc.gov
Office - 404-639-3103

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** (b)(6) [redacted]
**Sent:** Thursday, February 27, 2020 10:01 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** contact for donation of coronavirus kit

Hi Uwe,
Thank you for taking my call. I appreciate that you can sharing the lead information at CDC for the coronavirus IgG/IgM detection kit donation. The manufacturing will arrange shipping.

Best regards,

Jinjie

---

**Jinjie Hu, PhD**
President and Principle Consultant
**Axteria BioMed Consulting Inc.**
**Cell:** (301) 814-4985
Email: (b)(6) [redacted]

---

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/18/2020 3:56:49 PM
**To:** Garcia, Mayra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7db05677732d4023bcdf772ee0474055-GarciaM]
**Subject:** Info

1. Testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship

(b)(5) [redacted]

2. (b)(5) [redacted]
(b)(5) [redacted]

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/20/2020 8:29:55 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]
**CC:** Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]
**Subject:** RE: 2/20/20 6 AM update

Tim,

Correct. (b)(5) [redacted]
(b)(5) [redacted]

Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 8:23 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** RE: 2/20/20 6 AM update

(b)(5) [redacted]

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

AMERICAN OVERSIGHT

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 8:09 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/20/20 6 AM update

Jeff,

(b)(5) [redacted]

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:02 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: 2/20/20 6 AM update

Uwe,

Thank you. (b)(5) [redacted]
(b)(5) [redacted]

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 20, 2020 at 6:53:50 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, St. Pierre, Don J.

AMERICAN OVERSIGHT

<don.st.pierre@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** 2/20/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/20/20 6 AM update:

**Status of activities on diagnostics:**

(b)(5) [redacted]

(b)(5) [redacted]

(b)(5) [redacted]

(b)(5) [redacted]

Uwe

AMERICAN OVERSIGHT

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/23/2020 11:21:40 AM
**To**: Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) [zey9@cdc.gov]
**CC**: Spies, Stacey (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e485767534a483f864f0222cf10a505-HHS-khq7-cd]; Langley, Gayle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09640f099c74468d9480b73a6d194d5d-HHS-fez7-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Attachments**: COVID_19 sentinel surveillance Feb 21 2020 FINAL CLEAN_FDA 2.23.2020.docx; DRAFT SARS-CoV-2 surveillance risk benefit 20Feb20_FDA_2.23.2020.docx; DRAFT CDC Surveillance EUA Request Cover letter 20FEB2020 6pm FDA 2.23.2020.docx

**Importance**: High

**Please disregard the previous email send today at 11:09 AM. It was send in error. This is the correct version with our edits to your draft documents.**

Dear Laura,

Attached please find the following documents you submitted on February 21, 2020 to support the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in surveillance activities. These documents have been reviewed and edited by FDA's OCET and OCC.

1. Draft COVID-19 sentinel surveillance
2. Draft SARS-CoV-2 surveillance risk benefit
3. Draft CDC Surveillance EUA Request Cover letter

Please do not hesitate to reach out to me with questions.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

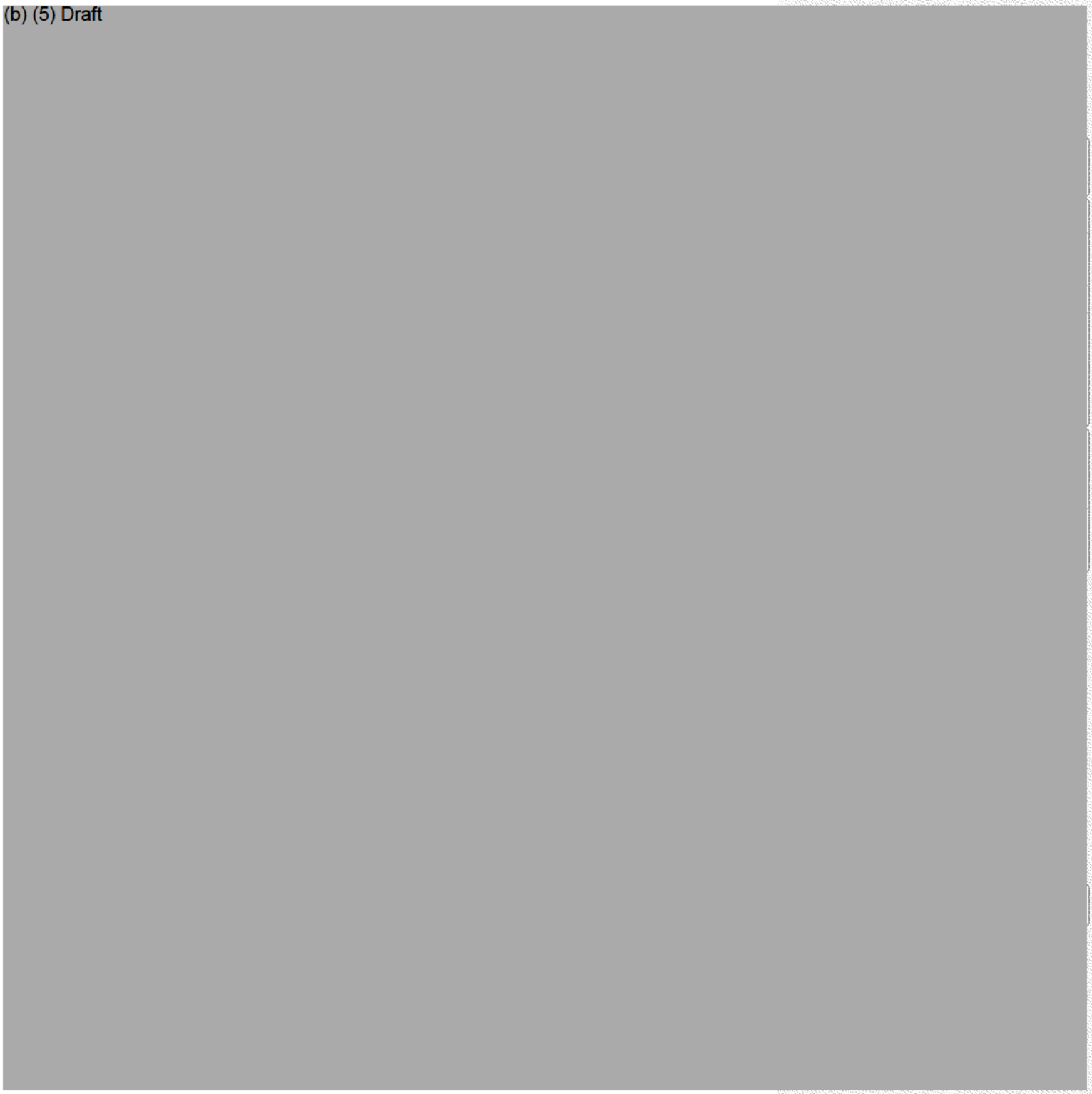
OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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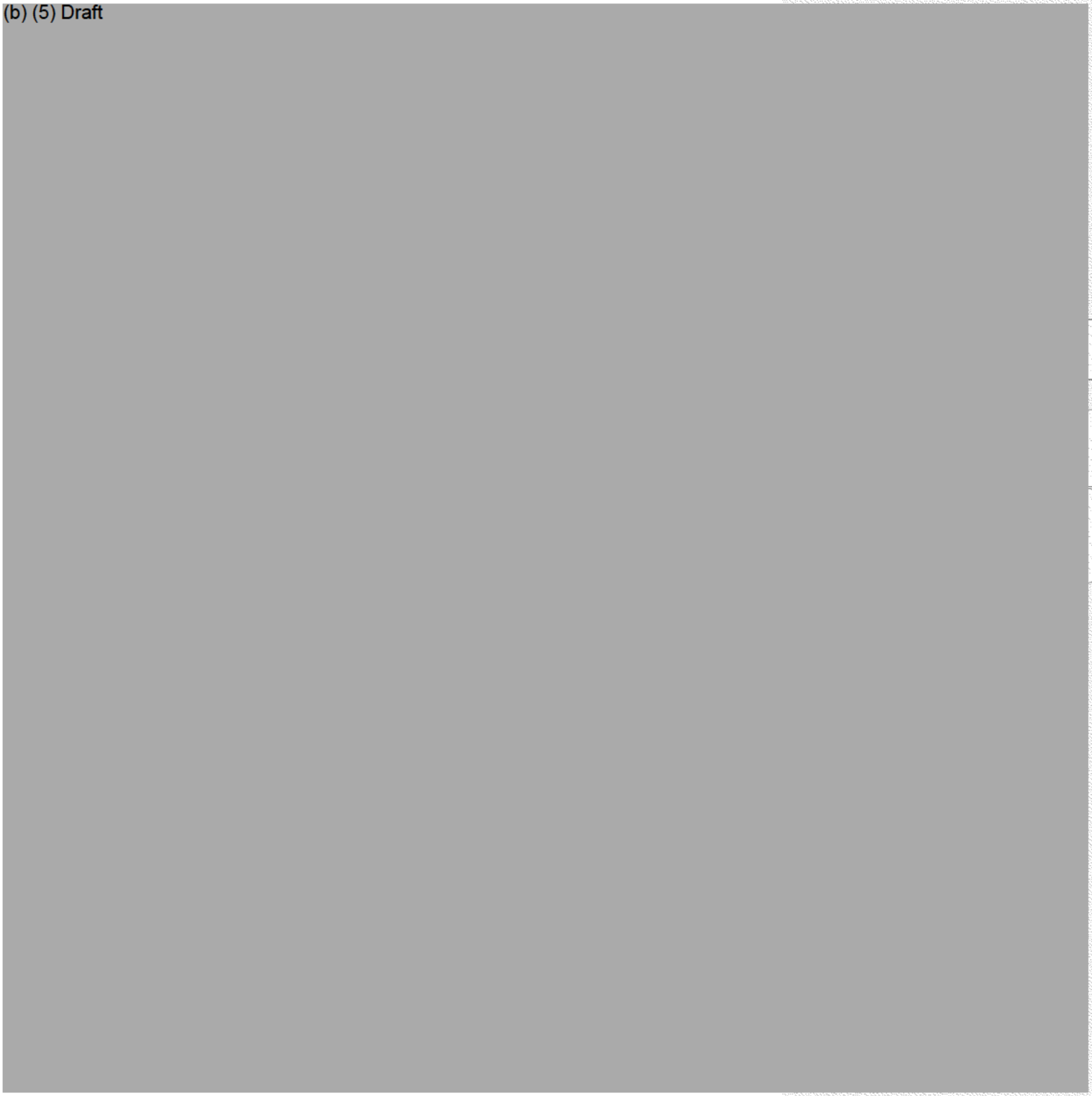
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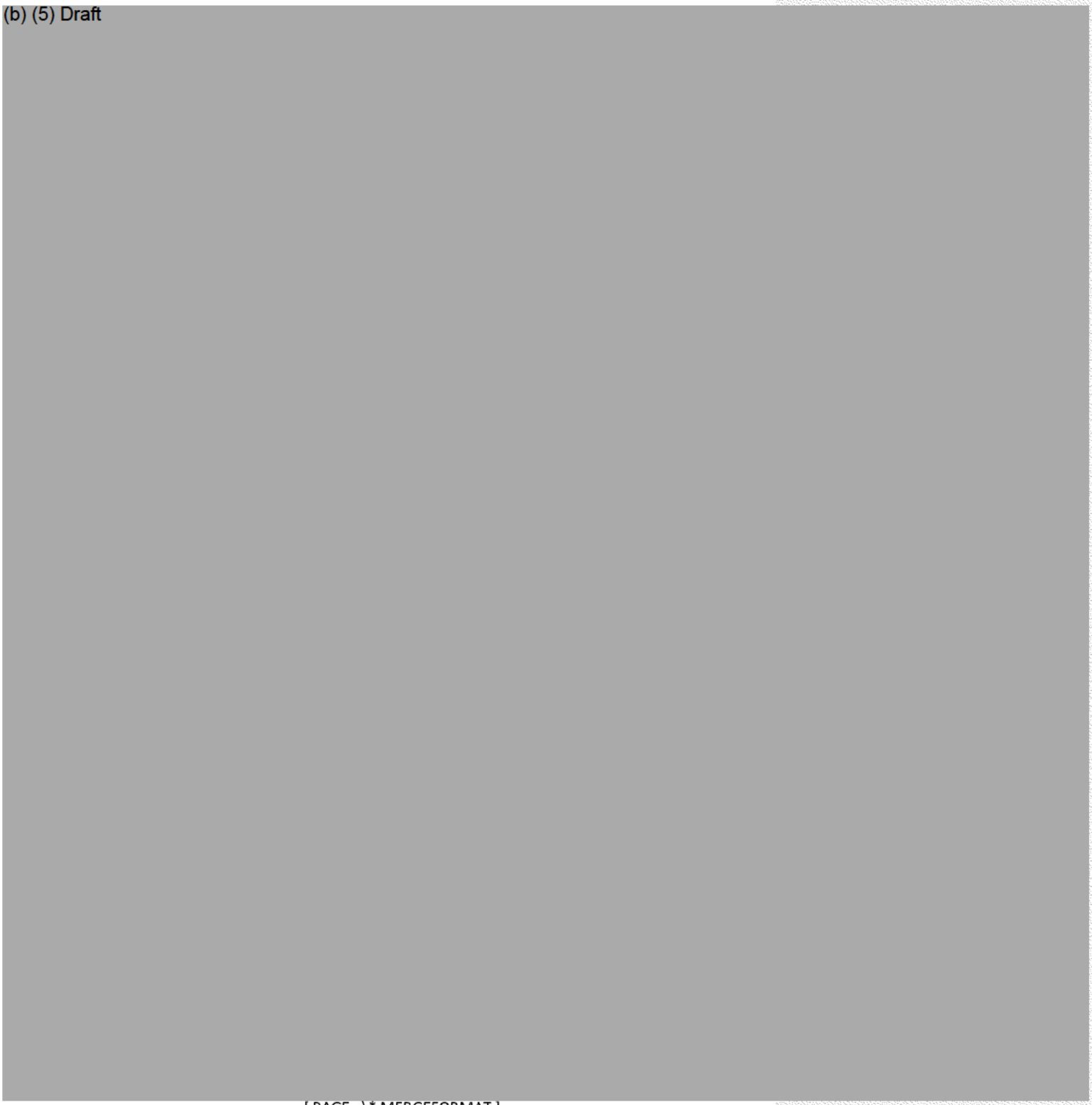
(b) (5) Draft





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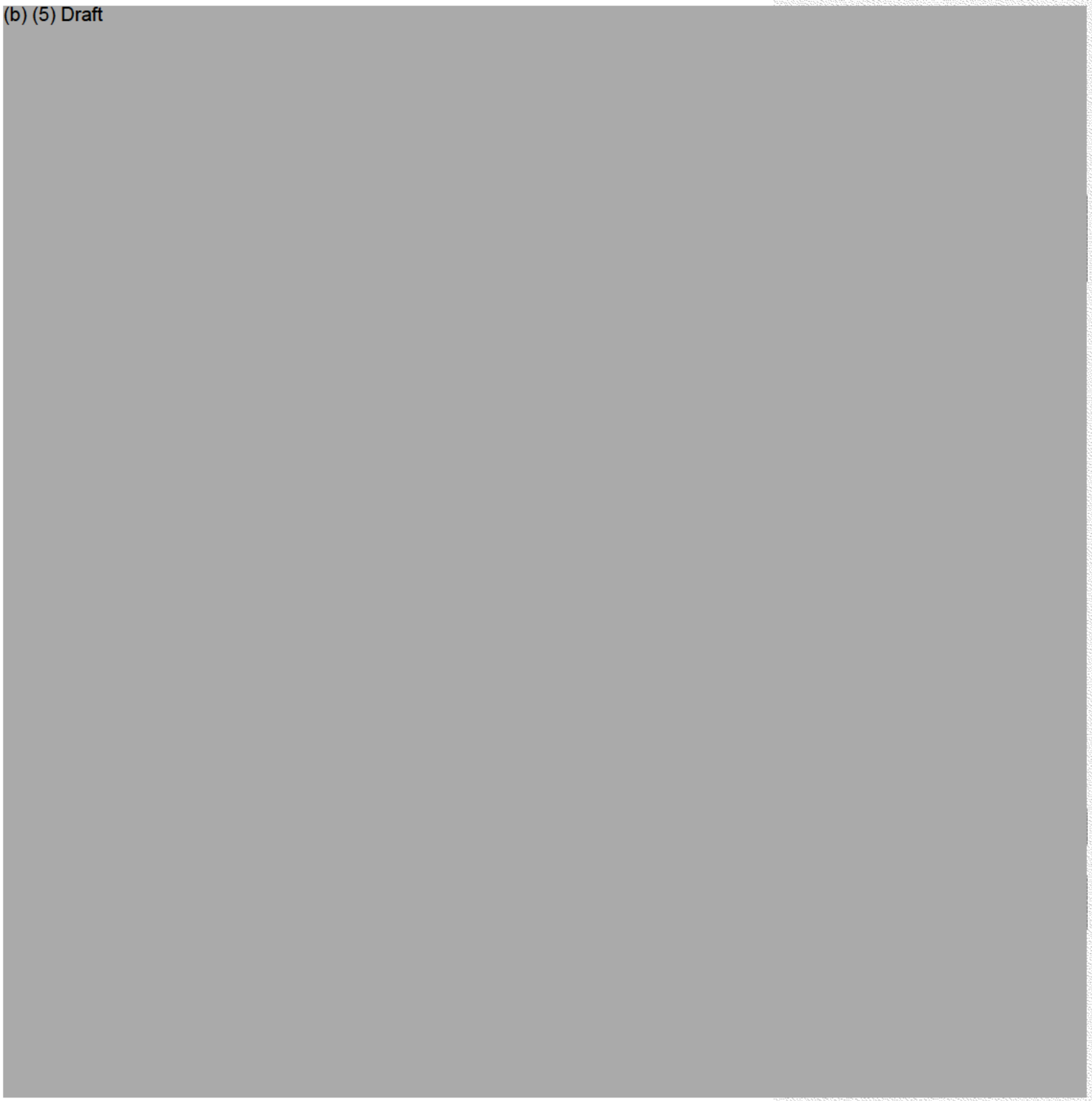
(b) (5) Draft





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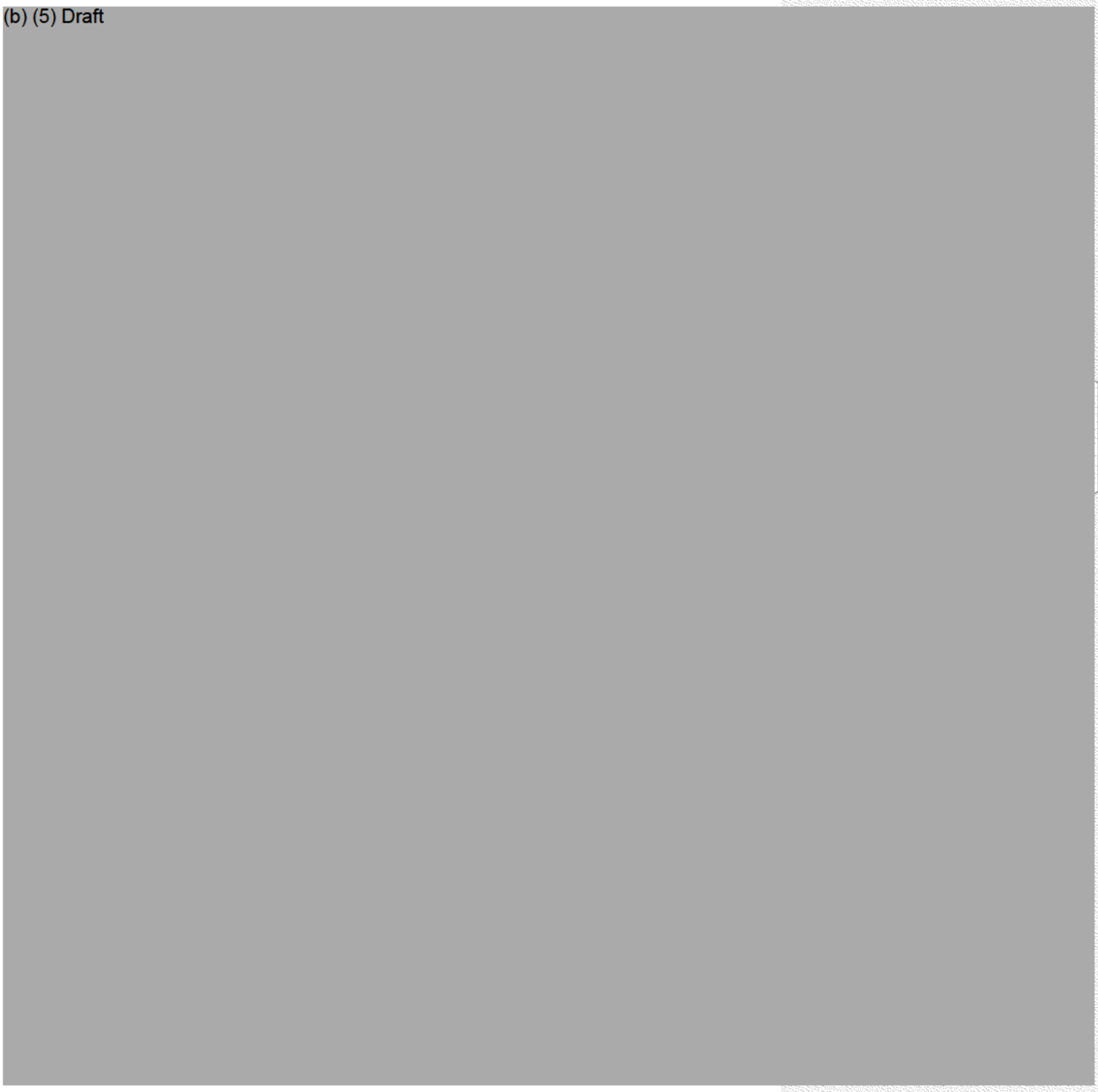
(b) (5) Draft





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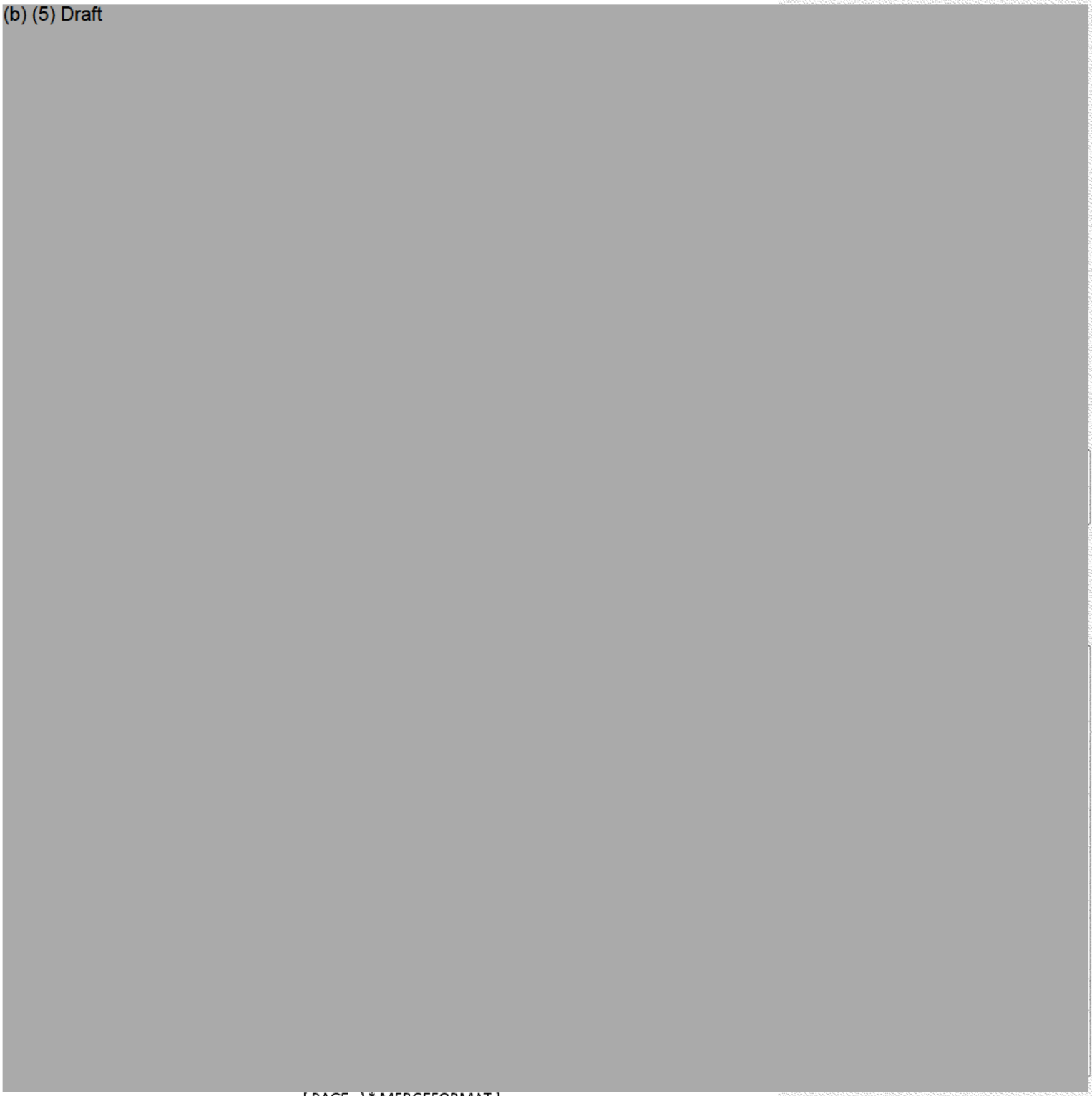
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Assessment of Benefits and Risks:

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T OF HEALTH & HUMAN SERVICES
Service

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

February 20, 2020
Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
CDRH Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Request for Emergency Use Authorization:**
**CDC 2019 Novel Coronavirus (nCoV) Real-Time RT-PCR Diagnostic Panel (EUA200001)**

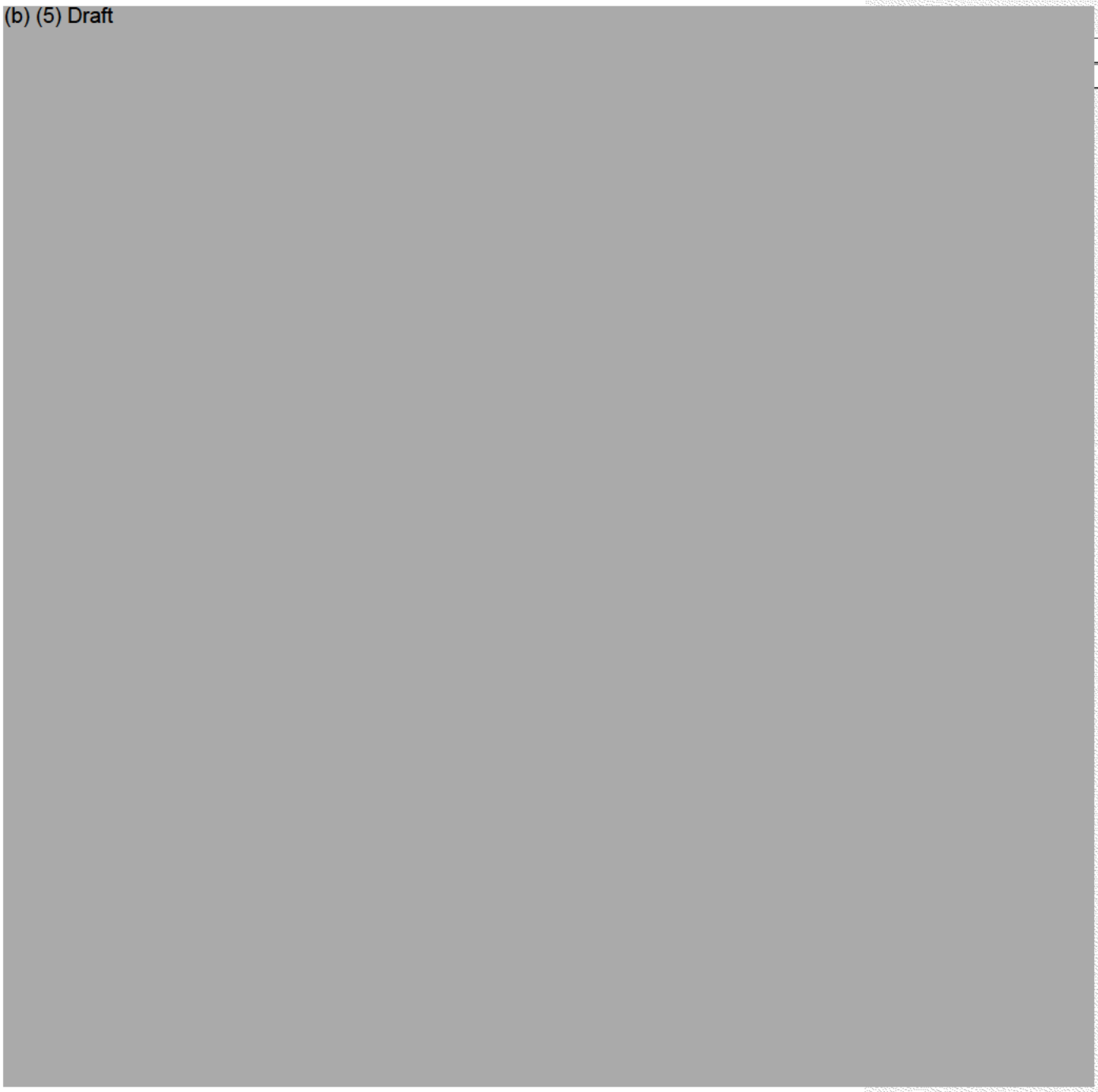
Dear Dr. Hahn,

(b) (5) Draft



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(b) (5) Draft





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(b) (5) Draft





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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 10:13:31 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: 2/24/20 6 AM update
**Attachments:** MERS-CoV_CDC.pdf

Tim,

Here the MERS-CoV authorization letter

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 8:56 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/24/20 6 AM update

Hi Uwe,

Thanks, if the MERS CDC EUA authorization letter is handy, I would like to review. The CDC is asking for the same sort of authorization now.

Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 8:50 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2/24/20 6 AM update

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Good morning Tim,

We are meeting at 9 to get the latest update on the status of the Developers, will get the update right after the meeting. Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 8:45 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/24/20 6 AM update

Morning Uwe,

Hope you are doing well. Could I get a list of all the developers interested in the EUA, perhaps with those who are furthest along tagged?

We would like to get more testing available as soon as possible and I while I am working on making positive material more available it might be good for me to connect with developers. I would also like to understand what they require to get started and what they require to complete their EUA validations.

Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:54 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/24/20 6 AM update

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Jeff, Elizabeth, Ellen, Bill and Tim:

2/24/20 6 AM update:

**Status of activities on diagnostics:**

- Prospective Community Transmission Surveillance:

Objective: Conduct testing of respiratory specimens collected from patients with respiratory illness at select locations to detect whether unrecognized community transmission of SARS-CoV-2 is occurring.

- CDC submitted draft request to conduct testing activity on 2/21/20.
- CDRH/OCET/OCC drafted feedback to draft request.
- CDC determined that the need is urgent and requested immediate implementation of testing, CDRH did not object to CDC's request but added certain conditions 2/22/20.
- FDA's feedback on the request to conduct testing was sent to CDC 2/23/20.
- DMD is actively working with 9 IVD developers with Pre-EUA submissions with more expected.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

June 10, 2014

Thomas R. Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
Atlanta, GA 30333

Dear Dr. Frieden:

On June 5, 2013, based on a request by the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in patients with signs and symptoms of MERS-CoV infection in conjunction with clinical and epidemiological risk factors, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3), by qualified laboratories.[1] On May 22, CDC submitted a request for an amendment to the Emergency Use Authorization (EUA). In response to that request, and having concluded that revising the June 5, 2013, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), the June 5, 2013, letter authorizing the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay is being reissued in its entirety with the amendments incorporated.[2]

On May 29, 2013, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such an agent or agents - in this case, MERS-CoV.[3] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of

[1] U.S. Food and Drug Administration. *Authorization of Emergency Use of an In Vitro Diagnostic for Detection of Middle East Respiratory Syndrome Coronavirus; Availability*. 78 Fed. Reg. 42779 (July 17, 2013).

[2] The amendments to the June 5, 2013, letter authorize the expanded use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay to include the *in vitro* qualitative detection of genomic RNA from MERS-CoV in clinical specimens collected from individuals meeting certain epidemiological criteria (e.g., contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation) who may or may not exhibit clinical signs and symptoms associated with MERS-CoV infection. The amendments also include a new Fact Sheet for Contacts of MERS Cases and revisions to the Instructions for Use, product insert, and Fact Sheets for Health Care Professionals and Patients.

[3] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

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*in vitro* diagnostics for the detection of MERS-CoV, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[4]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay (as described in the scope section of this letter (Section II)) for the presumptive detection of MERS-CoV in individuals meeting MERS-CoV clinical and/or epidemiological criteria (e.g., clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation) by qualified laboratories, subject to the terms of this authorization.

## I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of MERS-CoV in individuals meeting MERS-CoV clinical and/or epidemiological criteria (e.g., clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation) meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. MERS-CoV can cause a serious or life threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay may be effective in diagnosing MERS-CoV, and that the known and potential benefits of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay, when used for diagnosing MERS-CoV infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for diagnosing MERS-CoV.[5]

## II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of MERS-CoV in individuals meeting MERS-CoV clinical and/or epidemiological criteria (e.g., clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations

[4] U.S. Department of Health and Human Services. *Determination and Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV)*. 78 Fed. Reg. 33842 (June 5, 2013).

[5] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

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where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation).

**The Authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay:**

The CDC Novel Coronavirus 2012 Real-time RT-PCR Assay is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection of MERS-CoV viral RNA from respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputa, lower respiratory aspirates/washes), sera, and stool from individuals meeting MERS-CoV clinical and/or epidemiological criteria (e.g., clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation). The testing procedure consists of nucleic acid extraction followed by rRT-PCR on the FDA cleared Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument.

The CDC Novel Coronavirus 2012 Real-time RT-PCR Assay includes the following primer and probe sets:

| | |
|---|---|
| **NCV.N2** | targets the MERS-CoV nucleocapsid protein gene |
| **NCV.N3** | targets the MERS-CoV nucleocapsid protein gene |
| **NCV.upE**[6] | targets the MERS-CoV region upstream of envelope protein gene |
| **RP**[7] | targets the human Ribonuclease P gene. This primer and probe set is included as a control for specimen quality, to confirm that human nucleic acid was successfully extracted from the clinical specimen. |

The CDC Novel Coronavirus 2012 Real-time RT-PCR Assay also includes the following control materials:

- **Positive Control:** NCV-2012 rRT-PCR Assay Positive Control (VTC)
- **Negative Controls:** Sterile, nuclease-free water, used as No Template Control (NTC)
  1. **PCR No Template Control ($NTC_1$)**
  2. **Extraction control ($NTC_2$)**

The above described CDC Novel Coronavirus 2012 Real-time RT-PCR Assay, when labeled consistently with the labeling authorized by FDA, entitled "CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised with written permission of FDA, is authorized to be distributed to and used by qualified laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

---

[6] This a WHO-recommended MERS-CoV primer and probe set. See Corman VM, et al. Detection of a novel human coronavirus by real-time reverse-transcription polymerase chain reaction. *Euro Surveill* 2012;17(39). Available online at: http://www.eurosurveillance.org/images/dynamic/EE/V17N39/art20285.pdf.

[7] This primer and probe set is not provided in the CDC Novel Coronavirus 2012 rRT-PCR Assay Kit, but it is required for test performance. Laboratories will utilize the Laboratory Response Network (LRN) RNase P Real-time PCR Primer and Probe Set.

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**The above described CDC Novel Coronavirus 2012 Real-time RT-PCR Assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to health care professionals and patients:**

- **Fact Sheet for Health Care Professionals: Interpreting CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Test Results**
- **Fact Sheet for Patients: Understanding Results from the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay**
- **Fact Sheet for Contacts of MERS Cases: Understanding Results from the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay**

As described in section IV below, CDC is also authorized to make available additional information relating to the emergency use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay in the specified population, when used for presumptive detection of MERS-CoV, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay may be effective in the diagnosis of MERS-CoV infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay, when used to diagnose MERS-CoV infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay described above is authorized to diagnose MERS-CoV infection in individuals meeting MERS-CoV clinical and/or epidemiological criteria (e.g., clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation).

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

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**III. Waiver of Certain Requirements**

I am waiving the following requirements for the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

**IV. Conditions of Authorization**

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

**CDC**

A. CDC will distribute the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay with the authorized labeling, as may be revised with written permission of FDA, only to qualified laboratories.

B. CDC will provide to the qualified laboratories the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Health Care Professionals, the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Patients, and the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Contacts of MERS Cases.

C. CDC will make available on its website the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Health Care Professionals, the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Patients, and the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Contacts of MERS Cases.

D. CDC will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. CDC will ensure that qualified laboratories using the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay have a process in place for reporting test results to health care professionals and federal, state, and/or local public health authorities, as appropriate.

F. CDC will track adverse events and report to FDA as required under 21 CFR Part 803.

G. Through a process of inventory control, CDC will maintain records of device usage.

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H. CDC will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which CDC becomes aware.

I. CDC is authorized to make available additional information relating to the emergency use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

J. Only CDC may request changes to the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Health Care Professionals, the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Patients, or the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Contacts of MERS Cases. Such requests will be made by contacting FDA concerning FDA review and approval.

**Qualified Laboratories**

K. Qualified laboratories will make available the authorized Fact Sheet for Health Care Professionals, the authorized Fact Sheet for Patients, and the authorized Fact Sheet for Contacts of MERS Cases.

L. Qualified laboratories will perform the assay on an Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with the appropriate software.

M. Qualified laboratories will have a process in place for reporting test results to health care professionals and federal, state, and/or local public health authorities, as appropriate.

N. Qualified laboratories will collect information on the performance of the assay, and report to CDC any suspected occurrence of false positive or false negative results of which qualified laboratories become aware.

**CDC and Qualified Laboratories**

O. CDC and qualified laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

**Conditions Related to Advertising and Promotion**

P. All advertising and promotional descriptive printed matter relating to the use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

Q. All advertising and promotional descriptive printed matter relating to the use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;

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- This test has been authorized by FDA under an Emergency Use Authorization for use by qualified laboratories;
- This test has been authorized only for the detection of MERS-CoV and not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of MERS-CoV under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1).

No advertising or promotional descriptive printed matter relating to the use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay may represent or suggest that this test is safe or effective for the diagnosis of MERS-CoV.

The emergency use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of MERS-CoV is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Enclosures

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/25/2020 8:06:15 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Co-Diagnostics SARS-CoV-2 Assay Garners CE Mark | GenomeWeb
**Attachments:** IVD Test Developers Commercial status 02242020.xlsx

Tim,

Here is the list, they have requested the EUA template but have not submitted anything yet.

Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 7:20 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Fwd: Co-Diagnostics SARS-CoV-2 Assay Garners CE Mark | GenomeWeb

Hi Uwe,

Has this firm requested the EUA template and/or reached out to you?

Sorry if you sent me a link already to all the companies.

Thanks in advance! :)

Best,
Tim

---

**From:** Tim Stenzel <ttstenzel@gmail.com>
**Date:** February 25, 2020 at 6:48:52 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Co-Diagnostics SARS-CoV-2 Assay Garners CE Mark | GenomeWeb

https://www.genomeweb.com/pcr/co-diagnostics-sars-cov-2-assay-garners-ce-mark

Sent from my iPad

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(b) (4)

| IVD Developer | POC | Technology | Email Received | Response provided - details | Column3 | Column4 | Column5 | Column6 | Column7 |
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| IVD Developer | POC | Technology | EUA Template Request | Pre-EUA Sub Submitted | EUA Submitted | Status | Pre-EUA | GEN Doc# | EUA |
|---|---|---|---|---|---|---|---|---|---|
| (b) (4) | | | | | | | | | |
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AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/20/2020 8:09:23 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: 2/20/20 6 AM update

Jeff,

This is important for CDC's effort to contract out manufacturing of the primer & probes to a commercial manufacturer.

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:02 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: 2/20/20 6 AM update

Uwe,

Thank you. What's the relevance of the last item regarding the (b) (5) ?

Jeff

---

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

**Date:** February 20, 2020 at 6:53:50 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** 2/20/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/20/20 6 AM update:

**Status of activities on diagnostics:**

CDC provided draft protocol for the community transmission surveillance plan and requested feedback on regulatory strategy options to ensure that the surveillance will be conducted in compliance with FDA law and regulation.

Community surveillance jurisdiction will be: New York City, Chicago, Seattle, San Francisco & Los Angeles

- Retrospective Community Transmission Surveillance:
- For de-identified specimens with no possibility to report SARS-CoV-2 test result back to individuals, the surveillance testing will start asap.
- Prospective Community Transmission Surveillance
- The specimens obtained will be collected as part of routine clinical care or as a result of enrollment in another study. Consent will be obtained or notification be given prior to sample collection to the patient to whom SARS-CoV-2 testing is being done.
- CDC plans to submit a request to conduct the surveillance activity this week.
- FDA will respond by issuing a new EUA.

Information on manufacturing of primer/probes at CDC for lots being used at CDC headquarters and for the EUA:

(b) (5)

CDC submitted protocol to FDA to qualify alternative fluorescent hydrolysis probe quencher chemistry for the CDC test panel. CDC Influenza PCR Diagnostic Panels have been 510(k)-cleared using both probe chemistries which perform equivalently. The proposed study protocol is sufficient to generate the required data to determine equivalency.

DMD provided responses to pre-EUA submission for BioFire Defense, Vela Diagnostics, Novacyte and (b) (4)

AMERICAN OVERSIGHT

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/18/2020 10:19:02 AM
**To:** Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** FW: RE: 2019-nCoV EUA Template

Tim,

Here the response from LabCorp regarding their testing plan. Will really need clarity from CDC on whether a commercial entity can use the CDC primers.

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Tuesday, February 18, 2020 9:56 AM
**To:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: 2019-nCoV EUA Template

Hey Himani,

(b) (4)

Thanks!

Brian Krueger, PhD
Associate Vice President
Technical Director, Research and Development
Laboratory Corporation of America

1912 TW Alexander Dr.
Research Triangle Park, NC 27703

Email: (b) (6) @LabCorp.com
Office: (b) (6)
Cell: (b) (6)

---

**From:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 9:20 AM
**To:** Krueger, Brian (b) (6) @LabCorp.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E

AMERICAN OVERSIGHT

<Kim.Sapsford@fda.hhs.gov>
**Subject:** [External] RE: 2019-nCoV EUA Template

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Dear Brian,

(b) (4)

Sincerely,
Himani

**Himani Bisht, Ph.D.**
*Interdisciplinary Scientist*

Viral Respiratory and HPV Branch
Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3202 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6189| Fax: (301)-847-8512
Himani.Bisht@fda.hhs.gov

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---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Monday, February 17, 2020 2:30 PM
**To:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Re: 2019-nCoV EUA Template

Hey Himani,

Thanks for the rapid review of the draft! I'll revise and get an updated draft to you tomorrow.

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(b) (4)

[redacted]

Thanks,

Brian Krueger, PhD
Associate Vice President
Technical Director, Research and Development
Laboratory Corporation of America

1912 TW Alexander Dr.
Research Triangle Park, NC 27703

Email (b) (6) @LabCorp.com
Office: (b) (6)
Cell: (b) (6)

---

**From:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 2:05 PM
**To:** Krueger, Brian (b) (6) @LabCorp.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** [External] 2019-nCoV EUA Template

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Dear Brian,

Thanks for sending us your preliminary EUA study design for our review. We have a few follow-up questions; please see below.

1. Controls:

(b) (4)

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2. Results interpretation:

(b) (4)

3. Components required but not included with the test:

(b) (4)

4. Limit of detection:

(b) (4)

5. Other Analytical studies:

(b) (4)

6. Clinical Evaluation:

(b) (4)

Sincerely,
Himani

**Himani Bisht, Ph.D.**
*Interdisciplinary Scientist*

Viral Respiratory and HPV Branch
Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3202 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6189| Fax: (301)-847-8512
Himani.Bisht@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/18/2020 11:54:36 AM
**To**: Needham, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f74f493e6c584b159560c932efe2734d-Mark.Needha]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]
**CC**: Carr, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c6df5ab0cc6f4f00b90a73a97ae81f0d-CARRP]; Corbin, Rhonda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e0963ce5594ce59eb7ab7da787f639-CorbinR]; Sauer, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce3d961aa3ed48fb856a56a618f1f3c1-Jonathan.Sa]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: PRIORITY DUE AT NOON TODAY: FY20-24 Coronavirus Resource Estimates

Mark,

For the review division we put a proposal in for 5 FTE permanent going forward, and 5 FTE (surge) to be fully prepared for an outbreak like this in the future.

Uwe

---

**From:** Needham, Mark <Mark.Needham@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 11:51 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Cc:** Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>; Sauer, Jonathan <Jonathan.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: PRIORITY DUE AT NOON TODAY: FY20-24 Coronavirus Resource Estimates

Thank you, this is very helpful. I know it is very difficult to project forward for future years, but would you estimate a similar effort in future years?

Mark

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 11:39 AM
**To:** Needham, Mark <Mark.Needham@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Cc:** Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>; Sauer, Jonathan <Jonathan.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: PRIORITY DUE AT NOON TODAY: FY20-24 Coronavirus Resource Estimates

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Mark,

My rough estimate is that we will be investing around 200 hours weekly going forward until a good number of well performing test have been issued under an EUA. This might be for the next 2-3 month. I hope this helps.

Uwe

---

**From:** Needham, Mark <Mark.Needham@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 11:30 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Cc:** Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>; Sauer, Jonathan <Jonathan.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: PRIORITY DUE AT NOON TODAY: FY20-24 Coronavirus Resource Estimates

Thank you, Uwe. This is actually for the other weekly data call. Do you have the FY20-24 estimates as well?
Thanks,
Mark

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 9:37 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; CDRH Leadership Team <CDRHLeadershipTeam@fda.hhs.gov>
**Cc:** Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>; Needham, Mark <Mark.Needham@fda.hhs.gov>; Sauer, Jonathan <Jonathan.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: PRIORITY DUE AT NOON TODAY: FY20-24 Coronavirus Resource Estimates

Tim, Denise,

Attached please find the updated numbers for last week and the previously reported numbers.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 9:32 AM
**To:** Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; CDRH Leadership Team <CDRHLeadershipTeam@fda.hhs.gov>
**Cc:** Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>; Needham, Mark

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<Mark.Needham@fda.hhs.gov>; Sauer, Jonathan <Jonathan.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: PRIORITY DUE AT NOON TODAY: FY20-24 Coronavirus Resource Estimates

Hi Denise,

Copying Uwe and Kim as they are finalizing the numbers for our Office.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 8:43 AM
**To:** CDRH Leadership Team <CDRHLeadershipTeam@fda.hhs.gov>
**Cc:** Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>; Needham, Mark <Mark.Needham@fda.hhs.gov>; Sauer, Jonathan <Jonathan.Sauer@fda.hhs.gov>
**Subject:** PRIORITY DUE AT NOON TODAY: FY20-24 Coronavirus Resource Estimates

LT,

Late Thursday afternoon, FDA's Office of Budget sent out a data call to all Centers, ORA and HQ Offices requesting updated estimates of FDA's total anticipated costs related to the Coronavirus outbreak for FY 2020 through FY 2024.

This weekend, we were told that FDA data must be submitted to HHS and OMB no later than Tuesday which means we are required to submit our responses by NOON TODAY. OM is working with your teams to update the previously provided FY 2020 estimates as well as collecting outyear estimates for FY 2021 through FY 2024 on the level of effort associated with the Coronavirus outbreak response, including:

- Estimated Spending for the Remainder of FY 2020 in support of the Coronavirus response
- FY 2021 to FY 2024 Cost Estimates
- Estimated FY 2020 to FY 2024 Costs Related to Efforts to Address Shortages
- Incident Management Group (IMG) - costs associated with our Center's participation in the IMG. This group is currently very active so we want to capture these costs.

AMERICAN OVERSIGHT

**Please ensure that OM receives Office responses this morning so we may meet the NOON deadline.**

Thank you,

**Denise J. Huttenlocker**
*Executive Officer and Director, Office of Management*

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-6435
Denise.Huttenlocker@fda.hhs.gov






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Assessment of Benefits and Risks:

(b) (5)



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(b) (5)



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/18/2020 6:42:41 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**Subject**: RE: Contract Manufacturer

Ellen,

Thanks, I will await Marcy's comments and will get it out tomorrow. Uwe

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 6:40 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: Contract Manufacturer

Predecisional/Deliberative

See suggested edits below.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 6:07 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Contract Manufacturer

Ellen and Marcy,

Here the draft for the response to CDC regarding their wish to contract out the manufacturing. I tried to capture as much from our conversation as I could. Please provide any edits you have. Uwe

Predecisional/Deliberative:

(b) (5)



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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/25/2020 4:42:30 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Availability of CDC Designed Kits

Tim,

This is the contact information for IDT: **Claire Behrends**
Best number to reach her: (b) (6)

**Claire Behrends**
Product Manager, qPCR

Integrated DNA Technologies, Inc.
o: (b) (6) | m: +(b) (6)

INTEGRATED DNA TECHNOLOGIES

www.idtdna.com

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:26 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Availability of CDC Designed Kits

Dan really likes the IDT and Co-Diagnostics kit plans! And Dan asked me to go to the lab task force group. I am in the lab task force office now, they are on a conference call. Will bring it up as soon as conf call is over.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 25, 2020 at 4:16:10 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Availability of CDC Designed Kits

FYI. Going to talk to who I can find now.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:15 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Pallansch, Mark (CDC) <map1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>
**Cc:** Thomas, Jennifer (CDC) <fsu8@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** Availability of CDC Designed Kits

Hi,

We just got off the phone with IDT. The have the following kits available for sale today of the CDC designed kits.

(b) (4)

The CDC Test Panel includes fluorescently labeled hydrolysis probes that contain Black Hole Quencher® (BHQ®), a proprietary chemistry owned by Biosearch Technologies.
IDTDNA has an alternative fluorescent hydrolysis probe quencher chemistry (ZEN™ Double-Quenched Probe technology) being used in their kits.

Can we?

1. Sequester lots of these kits first for PHL
2. Order today and receive kits at the CDC to conduct a bridging study here at the CDC, bridging to the current kits.

Note:
1. The IDT kits also have N3 (which can be pulled out of the kits as needed)
2. I have not heard why (b) (5) . Who can fill me in on the reasons for this decision?

Also:
1. Co-Diagnostics has announced sale of a CE Marked kit. They are on the list of manufacturers who have requested EUA information from the FDA. Can we work with them (b) (5)

https://www.genomeweb.com/pcr/co-diagnostics-sars-cov-2-assay-garners-ce-mark

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Best,

*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 6:08:55 PM
**To**: Proctor, Tremyl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35056b97ee224343b77af6a0973d5d61-Tremyl.Proc]
**Subject**: 2019 nCoV DMD EUA MCM Hours_February 16 thru 22_2020 (2-21-20).xlsx
**Attachments**: 2019 nCoV DMD EUA MCM Hours_February 16 thru 22_2020 (2-21-20).xlsx

Tremyl,

Please find one updated from me, added 4 hrs for last Sunday.

Uwe

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 22-Dec | 23-Dec | 24-Dec | 25-Dec | 26-Dec | 27-Dec | 28-Dec | Week Total 1 | 29-Dec | 30-Dec | 31-Dec | 1-Jan | 2-Jan | 3-Jan | 4-Jan | Week Total 2 | 5-Jan | 6-Jan | 7-Jan | 8-Jan | 9-Jan | 10-Jan | 11-Jan | Week Total 3 | 12-Jan | 13-Jan | 14-Jan | 15-Jan | 16-Jan | 17-Jan | 18-Jan | Week Total 4 | Period Total |
| **2019-nCoV HOURS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Scherf, Uwe** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Feldblyum, Tamara** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Roth, Kris** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Sapsford, Kim** | | | | | | | | 0 | | | | | | | | 0 | | | | | 3 | 3 | | 6 | | 0.5 | 2.5 | 2.5 | 3 | 4 | 4 | 16.5 | 22.5 |
| **Li, Li** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Garcia, Mayra** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Total** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **6** | | | | | | | | **16.5** | **22.5** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 19-Jan | 20-Jan | 21-Jan | 22-Jan | 23-Jan | 24-Jan | 25-Jan | Week Total 1 | 26-Jan | 27-Jan | 28-Jan | 29-Jan | 30-Jan | 31-Jan | 1-Feb | Week Total 2 | 2-Feb | 3-Feb | 4-Feb | 5-Feb | 6-Feb | 7-Feb | 8-Feb | Week Total 3 | 9-Feb | 10-Feb | 11-Feb | 12-Feb | 13-Feb | 14-Feb | 15-Feb | Week Total 4 | Period Total |
| **2019-nCoV HOURS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Scherf, Uwe** | | Hol. | 8 | 6 | 6 | 6 | | 26 | | 6 | 8 | 8 | 6 | 6 | | 34 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 39 | | 6 | 6 | 6 | 6 | 6 | 6 | 36 | 135 |
| **Feldblyum, Tamara** | | Hol. | | 1 | 1 | | 3 | 5 | 1 | 3.5 | 2.5 | 1 | 2 | 2 | 2.5 | 14.5 | 3 | 3 | 3 | 2 | 2 | 2 | 1.5 | 16.5 | 0.5 | 2.5 | 1.5 | 2.5 | 1 | 3 | | 11 | 47 |
| **Roth, Kris** | | Hol. | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Sapsford, Kim** | 6.5 | Hol. | 8 | 8 | 9 | 10 | 4 | 45.5 | 2 | 8 | 8 | 8 | 8 | 8 | | 42 | 6 | 4 | 7.75 | 9.5 | 8 | 8 | | 43.25 | | 9 | 8 | 8 | 8 | | | 33 | 163.75 |
| **Li, Li** | | Hol. | | 3 | 4 | 4 | 3 | 14 | 3 | 4 | 5 | 5 | 6 | 6 | 3 | 32 | 3 | 6 | 5 | 5 | 1 | 3 | | 23 | 1 | 5 | 6 | 6 | 7 | 7 | | 32 | 101 |
| **Garcia, Mayra** | | Hol. | 2 | 1 | 5 | 8 | 2 | 18 | 1 | 5 | 2.5 | 5.5 | 4 | 1 | | 19 | 1 | 8 | 1 | 1 | 1 | 2 | | 14 | 0.5 | 0.5 | 0.5 | 1 | | 1 | | 3.5 | 54.5 |
| **Thornton, Keith** | | Hol. | | | | | | 0 | | | | 1 | | | | 1 | 0.5 | | | 0.5 | | 1 | | 2 | | 1.5 | 2 | 4 | 6 | 4 | | 17.5 | 20.5 |
| **Post, Justin** | | Hol. | | | | | | 0 | | | | 1 | | | | 1 | | | | | | | | 0 | | | | | | | | 0 | 1 |
| **White, Michael** | | Hol. | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | 2 | | 2 | 2 |
| **Himani Bisht** | | Hol. | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | 3 | 3 | 3 |
| **Anna Mielech** | | Hol. | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | 2 | 2 | 4 | 4 |
| **Hwang, Leroy** | | Hol. | | | | | | 0 | | | | | | | | 0 | | | | | 0.5 | 1 | | 1.5 | | 1 | 6.5 | 1 | 1.5 | 1.5 | | 11.5 | 13 |
| **Total** | | | | | | | | **108.5** | | | | | | | | **143.5** | | | | | | | | **139.25** | | | | | | | | **153.5** | **544.75** |

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# *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 16-Feb | 17-Feb | 18-Feb | 19-Feb | 20-Feb | 21-Feb | 22-Feb | Week Total 1 | 23-Feb | 24-Feb | 25-Feb | 26-Feb | 27-Feb | 28-Feb | 29-Feb | Week Total 2 | 1-Mar | 2-Mar | 3-Mar | 4-Mar | 5-Mar | 6-Mar | 7-Mar | Week Total 3 | 8-Mar | 9-Mar | 10-Mar | 11-Mar | 12-Mar | 13-Mar | 14-Mar | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | 4 | 6 | 8 | 8 | 6 | 8 | 7 | 47 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 47 |
| Feldblyum, Tamara | 2.5 | | 4.5 | 6 | 4 | 4 | | 21 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 21 |
| Roth, Kris | | | 3 | 1 | 1 | 2 | | 7 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 7 |
| Sapsford, Kim | | | | | 10 | 10 | | 20 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 20 |
| Li, Li | 4 | 8 | 8 | 6 | 7 | 6 | | 39 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 39 |
| Garcia, Mayra | | 1 | 6 | 5.5 | 0.5 | | | 13 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 13 |
| Thornton, Keith | | | 2 | 2 | 6 | 4 | | 14 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 14 |
| Post, Justin | | | 6 | | | | | 6 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 6 |
| White, Michael | | | | 1 | | 2 | | 3 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 3 |
| Hwang, Leroy | | | 2 | 2 | 0.5 | 2 | | 6.5 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 6.5 |
| Joe Briggs | | | | 3 | 8 | 7 | | 18 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | |
| Himani Bisht | 7.5 | 3.75 | 1.5 | | 2.5 | 7.5 | 3 | 25.75 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | |
| Anna Mielech | 3 | 2 | 6 | 5 | 1 | 3 | | 20 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Total** | | | | | | | | **240.25** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **176.5** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 15-Mar | 16-Mar | 17-Mar | 18-Mar | 19-Mar | 20-Mar | 21-Mar | Week Total 1 | 22-Mar | 23-Mar | 24-Mar | 25-Mar | 26-Mar | 27-Mar | 28-Mar | Week Total 2 | 29-Mar | 30-Mar | 31-Mar | 1-Apr | 2-Apr | 3-Apr | 4-Apr | Week Total 3 | 5-Apr | 6-Apr | 7-Apr | 8-Apr | 9-Apr | 10-Apr | 11-Apr | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 12-Apr | 13-Apr | 14-Apr | 15-Apr | 16-Apr | 17-Apr | 18-Apr | Week Total 1 | 19-Apr | 20-Apr | 21-Apr | 22-Apr | 23-Apr | 24-Apr | 25-Apr | Week Total 2 | 26-Apr | 27-Apr | 28-Apr | 29-Apr | 30-Apr | 1-May | 2-May | Week Total 3 | 3-May | 4-May | 5-May | 6-May | 7-May | 8-May | 9-May | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 10-May | 11-May | 12-May | 13-May | 14-May | 15-May | 16-May | Week Total 1 | 17-May | 18-May | 19-May | 20-May | 21-May | 22-May | 23-May | Week Total 2 | 24-May | 25-May | 26-May | 27-May | 28-May | 29-May | 30-May | Week Total 3 | 31-May | 1-Jun | 2-Jun | 3-Jun | 4-Jun | 5-Jun | 6-Jun | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 7-Jun | 8-Jun | 9-Jun | 10-Jun | 11-Jun | 12-Jun | 13-Jun | Week Total 1 | 14-Jun | 15-Jun | 16-Jun | 17-Jun | 18-Jun | 19-Jun | 20-Jun | Week Total 2 | 21-Jun | 22-Jun | 23-Jun | 24-Jun | 25-Jun | 26-Jun | 27-Jun | Week Total 3 | 28-Jun | 29-Jun | 30-Jun | 1-Jul | 2-Jul | 3-Jul | 4-Jul | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 5-Jul | 6-Jul | 7-Jul | 8-Jul | 9-Jul | 10-Jul | 11-Jul | Week Total 1 | 12-Jul | 13-Jul | 14-Jul | 15-Jul | 16-Jul | 17-Jul | 18-Jul | Week Total 2 | 19-Jul | 20-Jul | 21-Jul | 22-Jul | 23-Jul | 24-Jul | 25-Jul | Week Total 3 | 26-Jul | 27-Jul | 28-Jul | 29-Jul | 30-Jul | 31-Jul | 1-Aug | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 2-Aug | 3-Aug | 4-Aug | 5-Aug | 6-Aug | 7-Aug | 8-Aug | Week Total 1 | 9-Aug | 10-Aug | 11-Aug | 12-Aug | 13-Aug | 14-Aug | 15-Aug | Week Total 2 | 16-Aug | 17-Aug | 18-Aug | 19-Aug | 20-Aug | 21-Aug | 22-Aug | Week Total 3 | 23-Aug | 24-Aug | 25-Aug | 26-Aug | 27-Aug | 28-Aug | 29-Aug | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 30-Aug | 31-Aug | 1-Sep | 2-Sep | 3-Sep | 4-Sep | 5-Sep | Week Total 1 | 6-Sep | 7-Sep | 8-Sep | 9-Sep | 10-Sep | 11-Sep | 12-Sep | Week Total 2 | 13-Sep | 14-Sep | 15-Sep | 16-Sep | 17-Sep | 18-Sep | 19-Sep | Week Total 3 | 20-Sep | 21-Sep | 22-Sep | 23-Sep | 24-Sep | 25-Sep | 26-Sep | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 27-Sep | 28-Sep | 29-Sep | 30-Sep | 1-Oct | 2-Oct | 3-Oct | Week Total 1 | 4-Oct | 5-Oct | 6-Oct | 7-Oct | 8-Oct | 9-Oct | 10-Oct | Week Total 2 | 11-Oct | 12-Oct | 13-Oct | 14-Oct | 15-Oct | 16-Oct | 17-Oct | Week Total 3 | 18-Oct | 19-Oct | 20-Oct | 21-Oct | 22-Oct | 23-Oct | 24-Oct | Week Total 4 | Period Total |
| **2019-nCoV HOURS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Total** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 25-Oct | 26-Oct | 27-Oct | 28-Oct | 29-Oct | 30-Oct | 28-Dec | Week Total 1 | 29-Oct2 | 30-Oct2 | 31-Oct | 1-Nov | 2-Nov | 3-Nov | 4-Nov | Week Total 2 | 5-Nov | 6-Nov | 7-Nov | 8-Nov | 9-Nov | 10-Nov | 11-Nov | Week Total 3 | 12-Nov | 13-Nov | 14-Nov | 15-Nov | 16-Nov | 17-Nov | 18-Nov | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 22-Nov | 23-Nov | 24-Nov | 25-Nov | 26-Nov | 27-Nov | 28-Nov | Week Total 1 | 29-Nov | 30-Nov | 1-Dec | 2-Dec | 3-Dec | 4-Dec | 5-Dec | Week Total 2 | 6-Dec | 7-Dec | 8-Dec | 9-Dec | 10-Dec | 11-Dec | 12-Dec | Week Total 3 | 13-Dec | 14-Dec | 15-Dec | 16-Dec | 17-Dec | 18-Dec | 19-Dec | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/26/2020 7:29:27 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** FW: PEUA200003 BioFire 2019-nCoV Test

**Need to discuss this tomorrow. Uwe**

---

**From:** Cynthia Phillips, PhD <Cynthia.Phillips@BioFireDefense.com>
**Sent:** Wednesday, February 26, 2020 1:53 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Maher, Carmen T CIV USARMY DOD JPEO CBRND (USA) <carmen.t.maher.civ@mail.mil>
**Subject:** RE: PEUA200003 BioFire 2019-nCoV Test

Hi Li,
As we work to create a CDC-like assay for head to head testing with our BioFire COVID-19 test, we would like to know:

(b) (4)

Thank you,
Cynthia

---

**Cynthia Phillips, PhD**
*VP of Regulatory, Quality and Clinical Affairs*
**BioFire Defense**
Phone: 801-262-3592 x1370

---

**From:** Cynthia Phillips, PhD
**Sent:** Wednesday, February 26, 2020 9:30 AM
**To:** 'Li, Li (CDRH)' <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Maher, Carmen T CIV USARMY DOD JPEO CBRND (USA) <carmen.t.maher.civ@mail.mil>
**Subject:** RE: PEUA200003 BioFire 2019-nCoV Test

Hi Li,
Thank you for the quick and clear responses. (b) (4)

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(b) (4)

Thank you,
Cynthia

**Cynthia Phillips, PhD**
*VP of Regulatory, Quality and Clinical Affairs*
**BioFire Defense**
Phone: 801-262-3592 x1370

**From:** Li, Li (CDRH) [mailto:Li.Li2@fda.hhs.gov]
**Sent:** Wednesday, February 26, 2020 6:43 AM
**To:** Cynthia Phillips, PhD <Cynthia.Phillips@BioFireDefense.com>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Maher, Carmen T CIV USARMY DOD JPEO CBRND (USA) <carmen.t.maher.civ@mail.mil>
**Subject:** RE: PEUA200003 BioFire 2019-nCoV Test

Hi Cynthia,

My responses to your additional questions and clarifications are provided in the attached.

The pre-EUA review is interactive, I prefer to see updates to the submission as soon as they are available, so that I can review and provide feedback in a timely fashion. You can also ask questions any time by phone or e-mail. I will also update you with any new pertinent FDA recommendations as soon as possible.

Best Regards,
Li

**From:** Cynthia Phillips, PhD <Cynthia.Phillips@BioFireDefense.com>
**Sent:** Tuesday, February 25, 2020 8:15 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Maher, Carmen T CIV USARMY DOD JPEO CBRND (USA) <carmen.t.maher.civ@mail.mil>
**Subject:** RE: PEUA200003 BioFire 2019-nCoV Test

RE: A few additional questions on the PEUA200003 BioFire 2019-nCoV Test

Hi Li,
Attached are a few additional questions and clarifications embedded within the document you worked on. We are busy designing and testing assays, locating adequate virus sources, and preparing testing plans. Please let me know if there is an updated EUA Template and at what points you would like to see updates to the submission to ensure that the review is interactive (e.g. when it is half complete, when we have software report examples, when we have completed LoD and Exclusivity testing?).

I believe the new name of the test is : BioFire COVID-19 Test.

Thank you,
Cynthia

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**Cynthia Phillips, PhD**
*VP of Regulatory, Quality and Clinical Affairs*
**BioFire Defense**
Phone: 801-262-3592 x1370

**From:** Li, Li (CDRH) [mailto:Li.Li2@fda.hhs.gov]
**Sent:** Wednesday, February 19, 2020 8:06 AM
**To:** Cynthia Phillips, PhD <Cynthia.Phillips@BioFireDefense.com>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** PEUA200003 BioFire 2019-nCoV Test

Hi Cynthia,

I was assigned as the lead reviewer for PEUA200003 for the BioFire FilmArray 2019-nCoV Test. Attached please find our comments to the draft Pre EUA template you submitted for FDA review.

Please let me know if you have any questions or concerns regarding the FDA review comments.

Best Regards,
Li

**Li Li**
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 762-6200 | Fax: (301) 847-8512
li.li2@fda.hhs.gov






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distribution, or use of this email or any attachment is prohibited. If you have received this email in error, please notify us immediately by returning it to the sender and delete this copy from your system. Thank you for your cooperation.

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/25/2020 10:12:51 AM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Mielech, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]; Bialas, Kristy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43218ad182d74b3180b50e906723dd84-Kristy.Bial]
**Subject**: RE: CDC kits for manufacturers

Agree, this could be a faster way. Uwe

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 10:00 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bialas, Kristy <Kristy.Bialas@fda.hhs.gov>
**Subject:** RE: CDC kits for manufacturers

Agree, some validation is needed and your suggested approach should work

Tamara

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 9:58 AM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bialas, Kristy <Kristy.Bialas@fda.hhs.gov>
**Subject:** RE: CDC kits for manufacturers

One thought is to (b) (5)
[redacted]
Li

---

**From:** Li, Li (CDRH)
**Sent:** Tuesday, February 25, 2020 9:52 AM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bialas, Kristy

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<Kristy.Bialas@fda.hhs.gov>
**Subject:** RE: CDC kits for manufacturers

I think (b) (5)

Thanks,
Li

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 9:06 AM
**To:** Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bialas, Kristy <Kristy.Bialas@fda.hhs.gov>
**Subject:** RE: CDC kits for manufacturers

I don't see any issues with (b) (4) approaching CDC directly but I don't think (b) (5)

Would we consider an option of (b) (4), (b) (5)

Any other suggestions?

Thanks,

Tamara

---

**From:** Mielech, Anna <Anna.Mielech@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 7:47 AM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bialas, Kristy <Kristy.Bialas@fda.hhs.gov>
**Subject:** CDC kits for manufacturers

All,

Please see email from (b) (4) below. Is there a process to request the CDC kits? Are there any issues with their approach?

Thank you,

(b) (4)

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Anna

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 7:01:35 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/21/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/21/20 6 AM update:

**Status of activities on diagnostics:**

Association of Public Health Laboratories announced yesterday that only three of the more than 100 public health labs across the country have verified the CDC test for use.

- Screening retrospective samples, negative for the flu and other common respiratory viruses, for the coronavirus is delayed.

- Prospective Community Transmission Surveillance:
- CDC plans to submit a request to conduct the surveillance activity this week.
- New EUA will be issued.
- Draft Letter of Authorization has been provided to OCET/OCC.
- Fact sheet for patients participating in the study being drafted.

DMD has received a and is reviewing 4 new pre-EUA submission: (b) (4) 3 are from small companies, several abroad.

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Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/26/2020 7:19:13 PM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Gitterman, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4747486679444f24aa8d1086cca27390-SRG]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: COVID-19 diagnostics

Elizabeth,
Can you help with this delicate request? Thanks, uwe

**From:** Fink, Doran <Doran.Fink@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 3:34 PM
**To:** Gitterman, Steven <Steven.Gitterman@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** COVID-19 diagnostics

Hi,

I am at the Advisory Committee for Immunization Practices (ACIP) meeting and getting lots of questions about use of investigational diagnostics at hospital labs. There is great interest in using laboratory developed tests to complement CDC and state health department efforts. However, people's understanding is that all tests for SARS-CoV-2, including laboratory developed tests (LDTs), must be reviewed and cleared or authorized by the FDA for emergency use, or they cannot be used for diagnostic testing, and therefore at this time only the CDC RT-PCR covered by the EUA can be used, and only in authorized labs. This is articulated on the CDC website:
https://www.cdc.gov/csels/dls/locs/2020/reminder_covid-19_diagnostic_testing.html

However, I am told that this directive conflicts with prior experience at CLIA-certified hospital labs where investigational diagnostics have frequently been used without FDA authorization. Can you provide any clarification that I can pass along regarding this directive and the intentions behind it?

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/20/2020 1:50:17 PM
**To:** Melissa Mahall - QIAGEN [Melissa.Mahall@qiagen.com]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Request for 2019-CoV EUA Template

**Importance:** High

Dear Melissa,

We are accepting multiplex approaches for the 2019-nCoV for devices that had previously cleared respiratory pathogens.

The wording for the final intended use is still being worked out, but please go ahead and submit your pre-EUA to us, so we can give you feedback regarding your planned studies asap.

Kind regards,

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Melissa Mahall - QIAGEN <Melissa.Mahall@qiagen.com>
**Sent:** Thursday, February 20, 2020 12:50 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Request for 2019-CoV EUA Template

Dear Kim,

I just wanted to check if you need any additional information for your discussions.

Thanks and best regards,
Melissa

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 3:37 PM
**To:** Melissa Mahall - QIAGEN <Melissa.Mahall@qiagen.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E

AMERICAN OVERSIGHT

<Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Request for 2019-CoV EUA Template

Dear Melissa,

Thank you for your email, we will need to discuss and get back to you.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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---

**From:** Melissa Mahall - QIAGEN <Melissa.Mahall@qiagen.com>
**Sent:** Thursday, February 13, 2020 3:32 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Request for 2019-CoV EUA Template

Dear Kim,

(b) (4)

[redacted]

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(b) (4)

[redacted]

Best regards,
Melissa

Melissa Mahall
Senior Directory, Regulatory Affairs

QIAGEN - Sample to Insight

QIAGEN | 19300 Germantown Road | Germantown, MD 20874 | USA
Phone +1-301-944-7768 | Fax +1-240-686-7559

melissa.mahall@qiagen.com
www.qiagen.com

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**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 6:55 AM
**To:** Melissa Mahall - QIAGEN <Melissa.Mahall@qiagen.com>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Request for 2019-CoV EUA Template

Dear Melissa,

Thank you for your email. Please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of 2019-novel coronavirus (2019-nCoV). I suggest when you are ready, the first step is to populate this draft template with the information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center). The Pre-EUA review is an interactive process, so we will provide feedback after receiving and reviewing the information provided. The draft review template is a shared "work-in-progress" document which you will populate with information and data as obtained and which we will review and provide feedback to you.

I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of 2019-nCoV to FDA (it includes the address for the Document Control Center). Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under type of submission please check "other" and specify Pre-EUA.

One hard copy of the signed EUA Cover Letter and one electronic copy of you Pre-EUA submission package (including the EUA Review Template - MS word document) should be enclosed in your Pre-EUA submission to FDA, and we also request that you submit the information requested via electronic mail to myself Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

AMERICAN OVERSIGHT

- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;

- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please be reminded that ***in the U.S. a test*** for the detection of 2019-nCoV or to diagnoses 2019-nCoV infection must not be distributed and/or used for clinical diagnosis without premarket clearance, approval, or EUA by the FDA.
NOTE: The EUA Interactive Review Template from the FDA is considered an internal working document and must not be distributed outside of your organization.

Please let me know if you have any questions, we look forward to working with you,
Best regards,
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Melissa Mahall - QIAGEN <Melissa.Mahall@qiagen.com>
**Sent:** Monday, January 27, 2020 1:53 PM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Subject:** Request for 2019-CoV EUA Template

Hello,

QIAGEN is requesting a copy of the 2019-CoV EUA template. The template should be sent to me at melissa.mahall@qiagen.com.

Best regards,
Melissa Mahall

Melissa Mahall
Senior Directory, Regulatory Affairs

QIAGEN - Sample to Insight

QIAGEN | 19300 Germantown Road | Germantown, MD 20874 | USA
Phone +1-301-944-7768 | Fax +1-240-686-7559

melissa.mahall@qiagen.com
www.qiagen.com

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/18/2020 8:00:41 AM
**To:** Hwang, Leroy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5da97657ec944cebf943616bd848105-Leroy.Hwang]
**Subject:** RE: CDC & EUA lot testing

Here another way.

As a part of your efforts in investigating this reagent issue, please provide information regarding the reagent lot release testing criteria and **results at the CDC for the original reagent lot, as well as the new replacement reagent lot for the N3 assay**. We are particularly interested in learning (b) (5) [redacted]

Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01** (b) (5) **Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| 2019-nCoV_N1 | (b) (5) [redacted] | | | |
| 2019-nCoV_N2 | | | | |
| 2019-nCoV_N3 | | | | |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

Hi Uwe,
For clarification the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel consists of two separate boxes. Box #1 contains the primers and probes as described below:

**2019-nCoVEUA-01 Box #1: Primers and Probes**

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
|---|---|---|---|---|
| 2019-nCoV_N1 | (b) (5) [redacted] | | | |
| 2019-nCoV_N2 | | | | |
| 2019-nCoV_N3 | | | | |
| RP | | | | |

**Primer and probes from three individual boxes that were randomly selected after kit assembly were tested as presented in the powerpoint file provided earlier.**

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Also as requested, please find attached the QC testing process of primer/probe reagents at bulk and post-fill analysis.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 7:59 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC & EUA lot testing

Uwe,

The .mht file doesn't seem like it opens anything. I get a message that I "Can't reach this page".

Do you have anything else that can access this information?

Leroy

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 7:57 AM
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Subject:** CDC & EUA lot testing

Click the .mht attachment to view the notes as a Web page.

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/26/2020 7:12:19 PM
**To:** Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]
**Subject:** RE: Co-Diagnostics

Linda,

They requested a pre-EUA template, following up when they are already in now. Thanks, Uwe

---

**From:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 6:43 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Co-Diagnostics

Hi Uwe,

In a meeting with Jeff today, he inquired about an announcement that came from fiercebiotech. Have you all received anything from a company called Co-Diagnostics? They announced yesterday that they received EU approval for a Logix Smart Coronavirus COVID-19 Test. They are based in Salt Lake City.

I understand that you all are swamped right now. If Co-Diagnostics is not already on your radar, we are happy to reach out to them if that would be helpful. Also, please let me know how we can support your activities.

https://www.fiercebiotech.com/medtech/co-diagnostics-nets-european-approval-for-its-coronavirus-pcr-test

Thanks
--Linda

Linda Ricci, MME MPH
*Director*

**Division of All Hazard Response, Science and Strategic Partnerships (DARSS)**
**Office of Strategic Partnerships and Technology Innovation (OST)**
**CDRH | Food and Drug Administration**
Tel: 301-796-6325
Cell: 240-506-4356
Linda.Ricci@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=7010&S=E

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/24/2020 3:00:22 PM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; uxs; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: draft language

Excellent, can you please look out for the updated data set to come and perform the final analysis.

Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 2:49 PM
**To:** uxs; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** draft language

(b) (5)



**Li Li**
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6200 | Fax: (301) 847-8512
li.li2@fda.hhs.gov

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**Sent:** 2/26/2020 7:11:28 PM
**To:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** FW: Co-Diagnostics

Tamara,

Do we have an update on this company? We send them a template. Get we get a pre-EUA?

---

**From:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 6:43 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Co-Diagnostics

Hi Uwe,

In a meeting with Jeff today, he inquired about an announcement that came from fiercebiotech. Have you all received anything from a company called Co-Diagnostics? They announced yesterday that they received EU approval for a Logix Smart Coronavirus COVID-19 Test. They are based in Salt Lake City.

I understand that you all are swamped right now. If Co-Diagnostics is not already on your radar, we are happy to reach out to them if that would be helpful. Also, please let me know how we can support your activities.

https://www.fiercebiotech.com/medtech/co-diagnostics-nets-european-approval-for-its-coronavirus-pcr-test

Thanks
--Linda

Linda Ricci, MME MPH
*Director*

**Division of All Hazard Response, Science and Strategic Partnerships (DARSS)**
**Office of Strategic Partnerships and Technology Innovation (OST)**
**CDRH | Food and Drug Administration**
Tel: 301-796-6325
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Linda.Ricci@fda.hhs.gov
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# COVID19 Diagnostics Key Points

(b) (5)





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**Interagency Strategy Recommendation from** (b) (5)

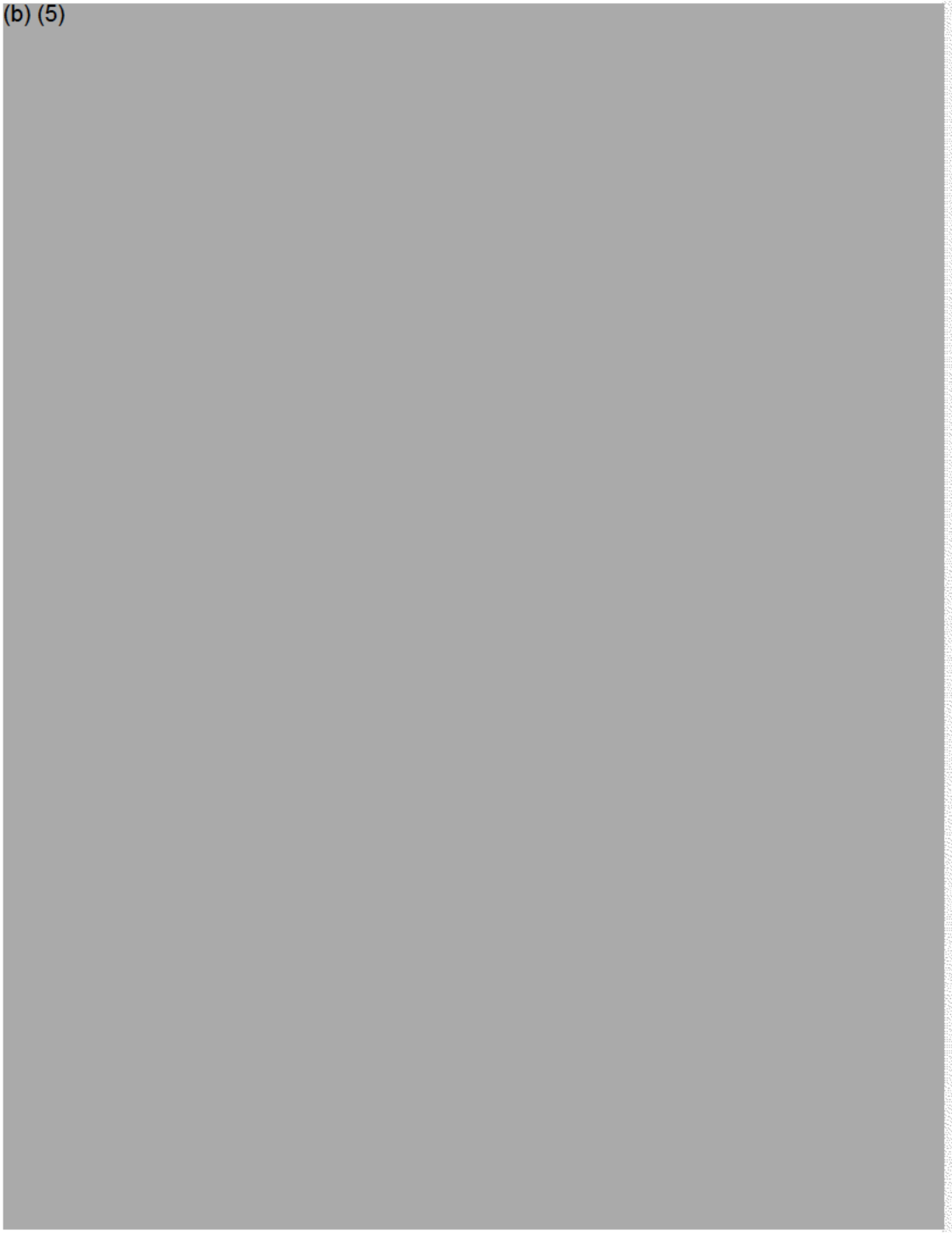
(b) (5)

[redacted]



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(b) (5)





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(b) (5)





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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/20/2020 6:53:49 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/20/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/20/20 6 AM update:

**Status of activities on diagnostics:**

CDC provided draft protocol for the community transmission surveillance plan and requested feedback on regulatory strategy options to ensure that the surveillance will be conducted in compliance with FDA law and regulation.

Community surveillance jurisdiction will be: (b) (5)

- Retrospective Community Transmission Surveillance:

(b) (5)

- Prospective Community Transmission Surveillance

(b) (5)

- CDC plans to submit a request to conduct the surveillance activity this week.
- FDA will respond by issuing a new EUA.

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Information on manufacturing of primer/probes at CDC for lots being used at CDC headquarters and for the EUA:

(b) (5)

CDC submitted protocol to FDA to qualify alternative fluorescent hydrolysis probe quencher chemistry for the CDC test panel. CDC Influenza PCR Diagnostic Panels have been 510(k)-cleared using both probe chemistries which perform equivalently. The proposed study protocol is sufficient to generate the required data to determine equivalency.

DMD provided responses to pre-EUA submission for (b) (4) .

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/25/2020 4:24:45 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Exclusion of N3

One minor correct, CDC just corrected a number and we verified. Instead of (b) (5) unique respiratory tract specimens is was only **2079**.

This does not change the previously final conclusion but is relevant for the record.

The team concludes: (b) (5)
(b) (5)

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:53 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

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**Subject:** Exclusion of N3
**Importance:** High

My team analyzed the revised data set from CDC concerning excluding the N3 from the panel.

The team concludes: (b) (5)
(b) (5)

Best,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/16/2020 1:50:26 PM
**To**: Proctor, Tremyl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35056b97ee224343b77af6a0973d5d61-Tremyl.Proc]
**Subject**: 2019 nCoV DMD EUA MCM Hours_January thru February 15_2020.xlsx
**Attachments**: 2019 nCoV DMD EUA MCM Hours_January thru February 15_2020.xlsx

Tremyl,

Thanks for keeping us organized. I added my hours to the sheet.
Best, Uwe

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 19-Jan | 20-Jan | 21-Jan | 22-Jan | 23-Jan | 24-Jan | 25-Jan | Week Total 1 | 26-Jan | 27-Jan | 28-Jan | 29-Jan | 30-Jan | 31-Jan | 1-Feb | Week Total 2 | 2-Feb | 3-Feb | 4-Feb | 5-Feb | 6-Feb | 7-Feb | 8-Feb | Week Total 3 | 9-Feb | 10-Feb | 11-Feb | 12-Feb | 13-Feb | 14-Feb | 15-Feb | Week Total 4 | Period Total |
| **2019-nCoV HOURS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Scherf, Uwe** | | Hol. | 8 | 6 | 6 | 6 | | 26 | | 6 | 8 | 8 | 6 | 6 | | 34 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 39 | | 6 | 6 | 6 | 6 | 6 | 6 | 36 | 135 |
| **Feldblyum, Tamara** | | Hol. | | 1 | 1 | | 3 | 5 | 1 | 3.5 | 2.5 | 1 | 2 | 2 | 2.5 | 14.5 | 3 | 3 | 3 | 2 | 2 | 2 | 1.5 | 16.5 | 0.5 | 2.5 | 1.5 | 2.5 | 1 | 3 | | 11 | 47 |
| **Roth, Kris** | | Hol. | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Sapsford, Kim** | 6.5 | Hol. | 8 | 8 | 9 | 10 | 4 | 45.5 | 2 | 8 | 8 | 8 | 8 | 8 | | 42 | 6 | 4 | 7.75 | 9.5 | 8 | 8 | | 43.25 | | 9 | 8 | 8 | 8 | | | 33 | 163.75 |
| **Li, Li** | | Hol. | | 3 | 4 | 4 | 3 | 14 | 3 | 4 | 5 | 5 | 6 | 6 | 3 | 32 | 3 | 6 | 5 | 5 | 1 | 3 | | 23 | 1 | 5 | 6 | 6 | 7 | 7 | | 32 | 101 |
| **Garcia, Mayra** | | Hol. | 2 | 1 | 5 | 8 | 2 | 18 | 1 | 5 | 2.5 | 5.5 | 4 | 1 | | 19 | 1 | 8 | 1 | 1 | 1 | 2 | | 14 | 0.5 | 0.5 | 0.5 | 1 | | 1 | | 3.5 | 54.5 |
| **Thornton, Keith** | | Hol. | | | | | | 0 | | | | 1 | | | | 1 | 0.5 | | | 0.5 | | 1 | | 2 | | 1.5 | 2 | 4 | 6 | 4 | | 17.5 | 20.5 |
| **Post, Justin** | | Hol. | | | | | | 0 | | | | 1 | | | | 1 | | | | | | | | 0 | | | | | | | | 0 | 1 |
| **White, Michael** | | Hol. | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | 2 | | 2 | 2 |
| **Hwang, Leroy** | | Hol. | | | | | | 0 | | | | | | | | 0 | | | | | 0.5 | 1 | | 1.5 | | 1 | 6.5 | 1 | 1.5 | 1.5 | | 11.5 | 13 |
| **Total** | | | | | | | | **108.5** | | | | | | | | **143.5** | | | | | | | | **139.25** | | | | | | | | **146.5** | **537.75** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 22-Dec | 23-Dec | 24-Dec | 25-Dec | 26-Dec | 27-Dec | 28-Dec | Week Total 1 | 29-Dec | 30-Dec | 31-Dec | 1-Jan | 2-Jan | 3-Jan | 4-Jan | Week Total 2 | 5-Jan | 6-Jan | 7-Jan | 8-Jan | 9-Jan | 10-Jan | 11-Jan | Week Total 3 | 12-Jan | 13-Jan | 14-Jan | 15-Jan | 16-Jan | 17-Jan | 18-Jan | Week Total 4 | Period Total |
| **2019-nCoV HOURS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Scherf, Uwe** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Feldblyum, Tamara** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Roth, Kris** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Sapsford, Kim** | | | | | | | | 0 | | | | | | | | 0 | | | | | 3 | 3 | | 6 | | 0.5 | 2.5 | 2.5 | 3 | 4 | 4 | 16.5 | 22.5 |
| **Li, Li** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Garcia, Mayra** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Total** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **6** | | | | | | | | **16.5** | **22.5** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 16-Feb | 17-Feb | 18-Feb | 19-Feb | 20-Feb | 21-Feb | 22-Feb | Week Total 1 | 23-Feb | 24-Feb | 25-Feb | 26-Feb | 27-Feb | 28-Feb | 29-Feb | Week Total 2 | 1-Mar | 2-Mar | 3-Mar | 4-Mar | 5-Mar | 6-Mar | 7-Mar | Week Total 3 | 8-Mar | 9-Mar | 10-Mar | 11-Mar | 12-Mar | 13-Mar | 14-Mar | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
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| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 15-Mar | 16-Mar | 17-Mar | 18-Mar | 19-Mar | 20-Mar | 21-Mar | Week Total 1 | 22-Mar | 23-Mar | 24-Mar | 25-Mar | 26-Mar | 27-Mar | 28-Mar | Week Total 2 | 29-Mar | 30-Mar | 31-Mar | 1-Apr | 2-Apr | 3-Apr | 4-Apr | Week Total 3 | 5-Apr | 6-Apr | 7-Apr | 8-Apr | 9-Apr | 10-Apr | 11-Apr | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
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| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 12-Apr | 13-Apr | 14-Apr | 15-Apr | 16-Apr | 17-Apr | 18-Apr | Week Total 1 | 19-Apr | 20-Apr | 21-Apr | 22-Apr | 23-Apr | 24-Apr | 25-Apr | Week Total 2 | 26-Apr | 27-Apr | 28-Apr | 29-Apr | 30-Apr | 1-May | 2-May | Week Total 3 | 3-May | 4-May | 5-May | 6-May | 7-May | 8-May | 9-May | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 10-May | 11-May | 12-May | 13-May | 14-May | 15-May | 16-May | Week Total 1 | 17-May | 18-May | 19-May | 20-May | 21-May | 22-May | 23-May | Week Total 2 | 24-May | 25-May | 26-May | 27-May | 28-May | 29-May | 30-May | Week Total 3 | 31-May | 1-Jun | 2-Jun | 3-Jun | 4-Jun | 5-Jun | 6-Jun | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
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| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 7-Jun | 8-Jun | 9-Jun | 10-Jun | 11-Jun | 12-Jun | 13-Jun | Week Total 1 | 14-Jun | 15-Jun | 16-Jun | 17-Jun | 18-Jun | 19-Jun | 20-Jun | Week Total 2 | 21-Jun | 22-Jun | 23-Jun | 24-Jun | 25-Jun | 26-Jun | 27-Jun | Week Total 3 | 28-Jun | 29-Jun | 30-Jun | 1-Jul | 2-Jul | 3-Jul | 4-Jul | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 5-Jul | 6-Jul | 7-Jul | 8-Jul | 9-Jul | 10-Jul | 11-Jul | Week Total 1 | 12-Jul | 13-Jul | 14-Jul | 15-Jul | 16-Jul | 17-Jul | 18-Jul | Week Total 2 | 19-Jul | 20-Jul | 21-Jul | 22-Jul | 23-Jul | 24-Jul | 25-Jul | Week Total 3 | 26-Jul | 27-Jul | 28-Jul | 29-Jul | 30-Jul | 31-Jul | 1-Aug | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 2-Aug | 3-Aug | 4-Aug | 5-Aug | 6-Aug | 7-Aug | 8-Aug | Week Total 1 | 9-Aug | 10-Aug | 11-Aug | 12-Aug | 13-Aug | 14-Aug | 15-Aug | Week Total 2 | 16-Aug | 17-Aug | 18-Aug | 19-Aug | 20-Aug | 21-Aug | 22-Aug | Week Total 3 | 23-Aug | 24-Aug | 25-Aug | 26-Aug | 27-Aug | 28-Aug | 29-Aug | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 30-Aug | 31-Aug | 1-Sep | 2-Sep | 3-Sep | 4-Sep | 5-Sep | Week Total 1 | 6-Sep | 7-Sep | 8-Sep | 9-Sep | 10-Sep | 11-Sep | 12-Sep | Week Total 2 | 13-Sep | 14-Sep | 15-Sep | 16-Sep | 17-Sep | 18-Sep | 19-Sep | Week Total 3 | 20-Sep | 21-Sep | 22-Sep | 23-Sep | 24-Sep | 25-Sep | 26-Sep | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 27-Sep | 28-Sep | 29-Sep | 30-Sep | 1-Oct | 2-Oct | 3-Oct | Week Total 1 | 4-Oct | 5-Oct | 6-Oct | 7-Oct | 8-Oct | 9-Oct | 10-Oct | Week Total 2 | 11-Oct | 12-Oct | 13-Oct | 14-Oct | 15-Oct | 16-Oct | 17-Oct | Week Total 3 | 18-Oct | 19-Oct | 20-Oct | 21-Oct | 22-Oct | 23-Oct | 24-Oct | Week Total 4 | Period Total |
| **2019-nCoV HOURS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Total** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 25-Oct | 26-Oct | 27-Oct | 28-Oct | 29-Oct | 30-Oct | 28-Dec | Week Total 1 | 29-Oct2 | 30-Oct2 | 31-Oct | 1-Nov | 2-Nov | 3-Nov | 4-Nov | Week Total 2 | 5-Nov | 6-Nov | 7-Nov | 8-Nov | 9-Nov | 10-Nov | 11-Nov | Week Total 3 | 12-Nov | 13-Nov | 14-Nov | 15-Nov | 16-Nov | 17-Nov | 18-Nov | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 22-Nov | 23-Nov | 24-Nov | 25-Nov | 26-Nov | 27-Nov | 28-Nov | Week Total 1 | 29-Nov | 30-Nov | 1-Dec | 2-Dec | 3-Dec | 4-Dec | 5-Dec | Week Total 2 | 6-Dec | 7-Dec | 8-Dec | 9-Dec | 10-Dec | 11-Dec | 12-Dec | Week Total 3 | 13-Dec | 14-Dec | 15-Dec | 16-Dec | 17-Dec | 18-Dec | 19-Dec | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 11:22:36 AM
**To:** Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Due by NOON - Review of EUA Text in Response to Sen. Markey re COVID-19

(b) (5)

**From:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 11:19 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Due by NOON - Review of EUA Text in Response to Sen. Markey re COVID-19

Maybe this?

(b) (5)

**Toby Lowe**
*CDRH/OIR*
Tel: 301-796-6512

***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:*** *https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E*

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 11:11 AM
**To:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Due by NOON - Review of EUA Text in Response to Sen. Markey re COVID-19

(b) (5)

**From:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 11:01 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>

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**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Due by NOON - Review of EUA Text in Response to Sen. Markey re COVID-19

Should we comment on the (b) (5) ?

**Toby Lowe**
*CDRH/OIR*
Tel: 301-796-6512

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**From:** Lowe, Toby A
**Sent:** Monday, February 24, 2020 11:00 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Due by NOON - Review of EUA Text in Response to Sen. Markey re COVID-19

Thanks, Uwe. I agree on the CLIA language and had previously talked to JT about that. (b) (5)

-T

**Toby Lowe**
*CDRH/OIR*
Tel: 301-796-6512

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 10:59 AM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Due by NOON - Review of EUA Text in Response to Sen. Markey re COVID-19

Jennifer,

sorry cannot confirm the appropriate wording with CMS. Please strike the blue text. Added red text for clarification.

Uwe

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 10:48 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Due by NOON - Review of EUA Text in Response to Sen. Markey re COVID-19
**Importance:** High

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Kim and Uwe,

HHS has asked us to review a response to Senator Markey re COVID, and most of it looks fine but they have a section on EUAs with some wording that I was not sure of. Below is the text; in particular, (b) (5) [redacted] Most of the rest of it is the same as the testimony you reviewed last week. Can you let me know if you have edits/feedback on this? Sorry for the short turnaround (once again). I might suggest just striking the text in blue if that is easiest.

I already made the changes Kim had suggested to the testimony (in yellow highlight).

Best,

Jennifer

(b) (5) [redacted] On February 4, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to enable emergency use of CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel.. This authorization allows the use of the test at any CDC-qualified lab across the country. CDC is working closely with FDA and public health partners, including the American Public Health Laboratories, to rapidly share these tests domestically and internationally through CDC's International Reagent Resource (www.internationalreagentresource.org). In addition, CDC uploaded the genome of the virus from the first reported cases in the United States to GenBank, the National Institutes of Health genetic sequence database of publicly available DNA sequences (www.ncbi.nlm.nih.gov/genbank). CDC also is growing the virus in cell culture, which is necessary for further studies, including for additional genetic characterization. Once isolated, the virus will be made available through Biodefense and Emerging Infections Research Resources Repository (www.beiresources.org) to assist research efforts. CDC has also sequenced the novel virus and shared it with the National Institutes of Health for use by the research community.

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On Monday, February 3, 2020, CDC submitted an EUA package to the FDA in order to expedite FDA permitted use of the CDC-developed laboratory test kit, called the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. FDA approved the EUA on February 4, 2020, and the test kit began shipping on February 5, 2020 to select qualified U.S. and international laboratories. Distribution of the tests will help improve the global capacity to detect and respond to the 2019 novel coronavirus.

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/19/2020 9:24:02 AM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: (b) (4) pre-EUA submission

Thanh you Li to take on another one. Uwe

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 9:19 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: (b) (4) pre-EUA submission

Li will be the lead reviewer for this submission.

Thank you,

Tamara

---

**From:** (b) (4)
**Sent:** Wednesday, February 19, 2020 3:09 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** (b) (4) pre-EUA submission

Hi Dr. Sapsford,

Attached is our current Pre-EUA submission. We look forward to working with you on this assay.

(b) (4)

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/22/2020 4:52:20 PM
**To:** Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]
**Subject:** FW: Pre-EUA Submission for COVID-19 RT-PCR Test
**Attachments:** LCAPreEUASubmissionCOVID19RTPCR.pdf

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Thursday, February 20, 2020 1:33 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** Pre-EUA Submission for COVID-19 RT-PCR Test

Dear Dr. Sapsford,

Please find attached our Pre-EUA submission for our COVID-19 RT-PCR Test. I have also sent you signed hard copies via FedEx.

Thank you again for all of your help with this! We really appreciate your rapid attention to this submission.

Sincerely,

Brian Krueger, PhD
Associate Vice President
Technical Director, Research and Development
Laboratory Corporation of America

1912 TW Alexander Dr.
Research Triangle Park, NC 27703

Email (b) (6) @LabCorp.com
Office: (b) (6)
Cell: (b) (6)
-This e-mail and any attachments may contain CONFIDENTIAL information, including PROTECTED HEALTH INFORMATION. If you are not the intended recipient, any use or disclosure of this information is STRICTLY PROHIBITED;

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you are requested to delete this e-mail and any attachments, notify the sender immediately, and notify the LabCorp Privacy Officer at privacyofficer@labcorp.com or call (877) 23-HIPAA / (877) 234-4722

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**2/20/2020**

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**ATTN:** Division Director: Dr. Uwe Scherf**,** OHT7-OIR/OPEQ/CDRH/FDA

**RE:** Request for Pre-Emergency Use Authorization (Pre-EUA) of the COVID-2019 RT-PCR Test

**Dear Dr. Scherf,**

Laboratory Corporation of America is submitting a Pre-Emergency Use (Pre-EUA) for the COVID-2019 RT-PCR Test so we can obtain feedback from FDA concerning the studies and/or testing outlined in our Pre-Emergency Use Authorization (Pre-EUA) submission package.

The Molecular Research and Development Department of Laboratory Corporation of America in Burlington, NC will perform a validation study for the detection of the 2019-Novel Coronavirus. In response to the rapid emergence of the 2019 novel Coronavirus, the CDC published a protocol for the detection of this virus by RT-PCR and was issued an Emergency Use Authorization to perform this testing (Feb 4, 2020). The test validation plan described here utilizes high throughput sample processing automation coupled to qualitative real time PCR on the Applied Biosystems QuantStudio 7 to detect the presence of 2019-Novel Coronavirus.

Attached to this letter is the first draft of our device EUA Interactive Review Template for FDA review as a Pre-EUA. One hard copy of the signed EUA Cover Letter and one electronic copy are enclosed. Also, these documents have been sent to you via email.

In case you should have any questions regarding the information provided and/or need additional information/data from us please contact me immediately either via email Brian.Krueger@LabCorp.com or phone (919) 536-2604.

Sincerely,

Brian Krueger, PhD
Associate Vice President
Technical Director, Research and Development
Laboratory Corporation of America

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
**FOOD AND DRUG ADMINISTRATION**

# CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: June 30, 2020
See PRA Statement on page 5.

| Date of Submission | User Fee Payment ID Number | FDA Submission Document Number *(if known)* |
|---|---|---|
| | | |

## SECTION A TYPE OF SUBMISSION

| PMA | PMA & HDE Supplement | PDP | 510(k) | Request for Feedback |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Regular (180 day) | ☐ Original PDP | ☐ Original Submission: | ☐ Pre-Submission |
| ☐ Premarket Report | ☐ Special | ☐ Notice of Completion | ☐ Traditional | ☐ Informational Meeting |
| ☐ Modular Submission | ☐ Panel Track (PMA Only) | ☐ Amendment to PDP | ☐ Special | ☐ Submision Issue Meeting |
| ☐ Amendment | ☐ 30-day Supplement | | ☐ Abbreviated (Complete section I, Page 5) | ☐ Day 100 Meeting |
| ☐ Report | ☐ 30-day Notice | | ☐ Additional Information | ☐ Agreement Meeting |
| ☐ Report Amendment | ☐ 135-day Supplement | | ☐ Third Party | ☐ Determination Meeting |
| ☐ Licensing Agreement | ☐ Real-time Review | | | ☐ Study Risk Determination |
| | ☐ Amendment to PMA & HDE Supplement | | | ☐ Other *(specify)*: |
| | ☐ Other | | | |

| IDE | Humanitarian Device Exemption (HDE) | Class II Exemption Petition | Evaluation of Automatic Class III Designation (De Novo) | Other Submission |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ 513(g) |
| ☐ Amendment | ☐ Amendment | ☐ Additional Information | ☐ Additional Information | ☒ Other *(describe submission)*: |
| ☐ Supplement | ☐ Supplement | | | Pre-EUA |
| | ☐ Report | | | |
| | ☐ Report Amendment | | | |

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

## SECTION B SUBMITTER, APPLICANT OR SPONSOR

| Company / Institution Name | Establishment Registration Number *(if known)* | | |
|---|---|---|---|
| Laboratory Corporation of America | | | |
| **Division Name *(if applicable)*** | **Phone Number *(including area code)*** | | |
| Research and Development | (b) (6) | | |
| **Street Address** | **FAX Number *(including area code)*** | | |
| 1912 TW Alexander Drive | | | |
| **City** | **State / Province** | **ZIP/Postal Code** | **Country** |
| Research Triangle Park | NC | 27703 | US |
| **Contact Name** | | | |
| Brian Krueger, PhD | | | |
| **Contact Title** | **Contact E-mail Address** | | |
| Technical Director, AVP | (b) (6)@labcorp.com | | |

## SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

| Company / Institution Name | | | |
|---|---|---|---|
| Laboratory Corporation of America | | | |
| **Division Name *(if applicable)*** | **Phone Number *(including area code)*** | | |
| Research and Development | (b) (6) | | |
| **Street Address** | **FAX Number *(including area code)*** | | |
| 1447 York Court | | | |
| **City** | **State / Province** | **ZIP Code** | **Country** |
| Burlington | NC | 27215 | US |
| **Contact Name** | | | |
| (b) (6) | | | |
| **Contact Title** | **Contact E-mail Address** | | |
| Researcher | (b) (6)@labcorp.com | | |

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PSC Publishing Services (301) 443-6740 EF

FDACDRH-p5-AO-001913

MULTI-HHS-20-0522-B, 20-0523-A-001369

## SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

## SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

## SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

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## SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

| | | | |
|---|---|---|---|
| 1 | 2 | 3 | 4 |
| 5 | 6 | 7 | 8 |

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

| | *510(k) Number* | *Trade or Proprietary or Model Name* | *Manufacturer* |
|---|---|---|---|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |

## SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

COVID-19 RT-PCR Test

| | Trade or Proprietary or Model Name for This Device | Model Number |
|---|---|---|
| 1 | COVID-19 RT-PCR Test | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

FDA document numbers of all prior related submissions *(regardless of outcome)*

| | | | | | |
|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 |

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

## SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: QJR

C.F.R. Section *(if applicable)*:

Device Class

☐ Class I ☐ Class II ☐ Class III ☒ Unclassified

Classification Panel: Microbiology

Indications *(from labeling)*

COVID-19 RT-PCR Test for the in vitro qualitative detection of RNA from the COVID-19 in nasopharyngeal (NP) or oropharyngeal (OP) aspirates or washes, NP or OP swabs, and broncheoalveolar lavage (BAL) from patients (b) (4) (b) (4) (b) (4) to aid in the diagnosis of COVID-19 infection.

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| ***Note:*** Submission of the information entered in Section H does not affect the need to submit device establishment registration. | FDA Document Number *(if known)* |
|---|---|

**SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

| ☐ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number | ☐ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ Repackager / Relabeler |
|---|---|---|---|
| Company / Institution Name | | Establishment Registration Number | |
| Division Name *(if applicable)* | | Phone Number *(including area code)* | |
| Street Address | | FAX Number *(including area code)* | |
| City | State / Province | ZIP Code | Country |
| Contact Name | Contact Title | Contact E-mail Address | |

| ☐ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number | ☐ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ Repackager / Relabeler |
|---|---|---|---|
| Company / Institution Name | | Establishment Registration Number | |
| Division Name *(if applicable)* | | Phone Number *(including area code)* | |
| Street Address | | FAX Number *(including area code)* | |
| City | State / Province | ZIP Code | Country |
| Contact Name | Contact Title | Contact E-mail Address | |

| ☐ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number | ☐ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ Repackager / Relabeler |
|---|---|---|---|
| Company / Institution Name | | Establishment Registration Number | |
| Division Name *(if applicable)* | | Phone Number *(including area code)* | |
| Street Address | | FAX Number *(including area code)* | |
| City | State / Province | ZIP Code | Country |
| Contact Name | Contact Title | Contact E-mail Address | |

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| SECTION I | UTILIZATION OF STANDARDS | | | | |
|---|---|---|---|---|---|
| **Note:** Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement. | | | | | |
| 1 | Standards No. | Standards Organization | Standards Title | Version | Date |
| 2 | Standards No. | Standards Organization | Standards Title | Version | Date |
| 3 | Standards No. | Standards Organization | Standards Title | Version | Date |
| 4 | Standards No. | Standards Organization | Standards Title | Version | Date |
| 5 | Standards No. | Standards Organization | Standards Title | Version | Date |
| 6 | Standards No. | Standards Organization | Standards Title | Version | Date |
| 7 | Standards No. | Standards Organization | Standards Title | Version | Date |

**Please include any additional standards to be cited on a separate page.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*

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(b) (4)

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(b) (4)

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 8:26:22 AM
**To:** Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: For Data Population and Review by 1pm Monday

Heather,

The number of EUA authorized and the templates send are current. I added this additional data point:

- **13** developers have submitted pre-EUA documents for FDA feedback as of 2/21/20

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 7:22 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: For Data Population and Review by 1pm Monday

Hi Kim and Uwe,

I just wanted to reach out to make sure you saw the ask below that is due at 1 pm today. If you need anything, let us know. I know the Commissioner really wants to have solid numbers and specifics.

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: 240-507-3139
Email: Heather.Agler@fda.hhs.gov

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**From:** Shuren, Jeff
**Sent:** Monday, February 24, 2020 7:16 AM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Cc:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Subject:** FW: For Data Population and Review by 1pm Monday

Flagging as an FYI — I know you are working on it and need to include our IVD efforts, as well.

Jeff

---

**From:** Gross, Karas <Karas.Gross@fda.hhs.gov>
**Date:** February 24, 2020 at 7:02:19 AM EST
**To:** Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Solomon, Steven M <Steven.Solomon@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
**Subject:** FW: For Data Population and Review by 1pm Monday

Good morning-

Making sure the below effort to obtain more granular information for the Commissioner (as requested by the Secretary) is on your radar screens as well—particularly number of manufacturers contacted and what information we're learning. I know this request has come through different channels, but making you know that the Commissioner is briefing senators tomorrow at 8am where we've been told he'll get these types of questions.

We're working directly with your teams, but I have Keagan cc'd here, so let us know if you have questions or concerns. We've also made clear in the request to let us know if certain information can't be shared for a particular reason (legal, cci, etc).

Thanks to you and your teams for all of the support.

Karas

**From:** Gross, Karas
**Sent:** Sunday, February 23, 2020 8:33 PM
**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
**Subject:** RE: For Data Population and Review by 1pm Monday

Reminder that the deadline for this is tomorrow at 1pm. And highlighting the information that Michael flagged below should, indeed, be the immediate priority. If you are providing that information to the commissioner through other requests or channels, please cc OL or add it hear as well. Thank you!

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Karas

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 10:28 AM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
**Subject:** For Data Population and Review by 1pm Monday

Thanks Michael! And I'm sorry to do this, but since the Commissioner needs this for an 8am Tuesday morning, the paper will have to be populated by **1pm Monday** so that we can run it through OCC with enough time for him to offer feedback.

+OCC so they can see what is coming.

Thank you again.

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 8:46 AM
**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
**Subject:** RE: For Data Population and Review by COB Monday

Adding Brooke. While it will be really useful to compile an maintain quantifiable info that speaks to our response efforts across the full range of our activities for many uses – what the Secretary is specifically requesting is more specific/granular information regarding supply chain efforts (b) (5)

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 10:03 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
**Subject:** RE: For Data Population and Review by COB Monday

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Should also note that if there are other, more preferable ways to quantify or give specifics please feel free to suggest them in the document. That said, we expect the Commissioner may be asked questions along these lines as early as Tuesday, so the information or the rationale he can convey as to why he cannot disclose it will be very helpful.

Thank you all!

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 9:59 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
**Subject:** For Data Population and Review by COB Monday

IMG, CDER, CBER, CDRH, and ORA:

OL has developed a document to respond to the following directive from Leadership:

*Sec. Azar wants more specific and precise answers around our response efforts. Dr. Hahn wants to be as specific as we possibly can with regard to our response efforts, and if there is a legal reason we can't, he wants to know why. By COB Monday 2/24, JIC needs to provide these type of specifics throughout the remarks/materials prepared for Tuesday briefings, + in any press materials. The specifics don't have to be product-specific, but they want numbers, e.g., we have contacted ## manufacturing facilities in China as of DATE, and ## are still shipping product without delay.*

The document is linked below for your respective Centers/Office to populate data and review by **COB Monday, Feb. 24.** We anticipate that some of this information is not able to be shared publicly. If you believe that to be the case please so indicate in a comment bubble.

Also please note that the document may contain nonpublic and/or confidential commercial information. Please do not distribute it beyond FDA and limit its internal distribution as much as is possible.

Thank you for your efforts on this project. Please let us know if you have any questions or need additional information.

http://sharepoint.fda.gov/orgs/OC-OL/corona/For%20Clearance/Response%20By%20the%20Numbers901.docx

**Andrew Tantillo**
*Deputy Director*

**Office of Legislation**
**U.S. Food and Drug Administration**
O: 301-796-8919 M: 202-809-2989
andrew.tantillo@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/18/2020 6:06:55 PM
**To**: Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Ellen Flannery (Ellen.Flannery@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Contract Manufacturer

Ellen and Marcy,

Here the draft for the response to CDC regarding their wish to contract out the manufacturing. I tried to capture as much from our conversation as I could. Please provide any edits you have. Uwe

Predecisional/Deliberative:

(b) (5)



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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/21/2020 10:27:18 AM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: RMS PEUA questions and responses

See my comments: I needed to delete the (b) (5), (b) (4) because it is very limited material, and Roche will be informed separately by BARDA of the availability of this material by (b) (5), (b) (4)
For the (b) (5)

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 9:25 AM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RMS PEUA questions and responses

If RMS will use (b) (4), (b) (5) . They may have to use whole viral RNA or inactivated virus if the testing will not be in house (BSL-3 space)? Just another potential wrinkle.
Thanks,
LI

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 9:19 AM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RMS PEUA questions and responses

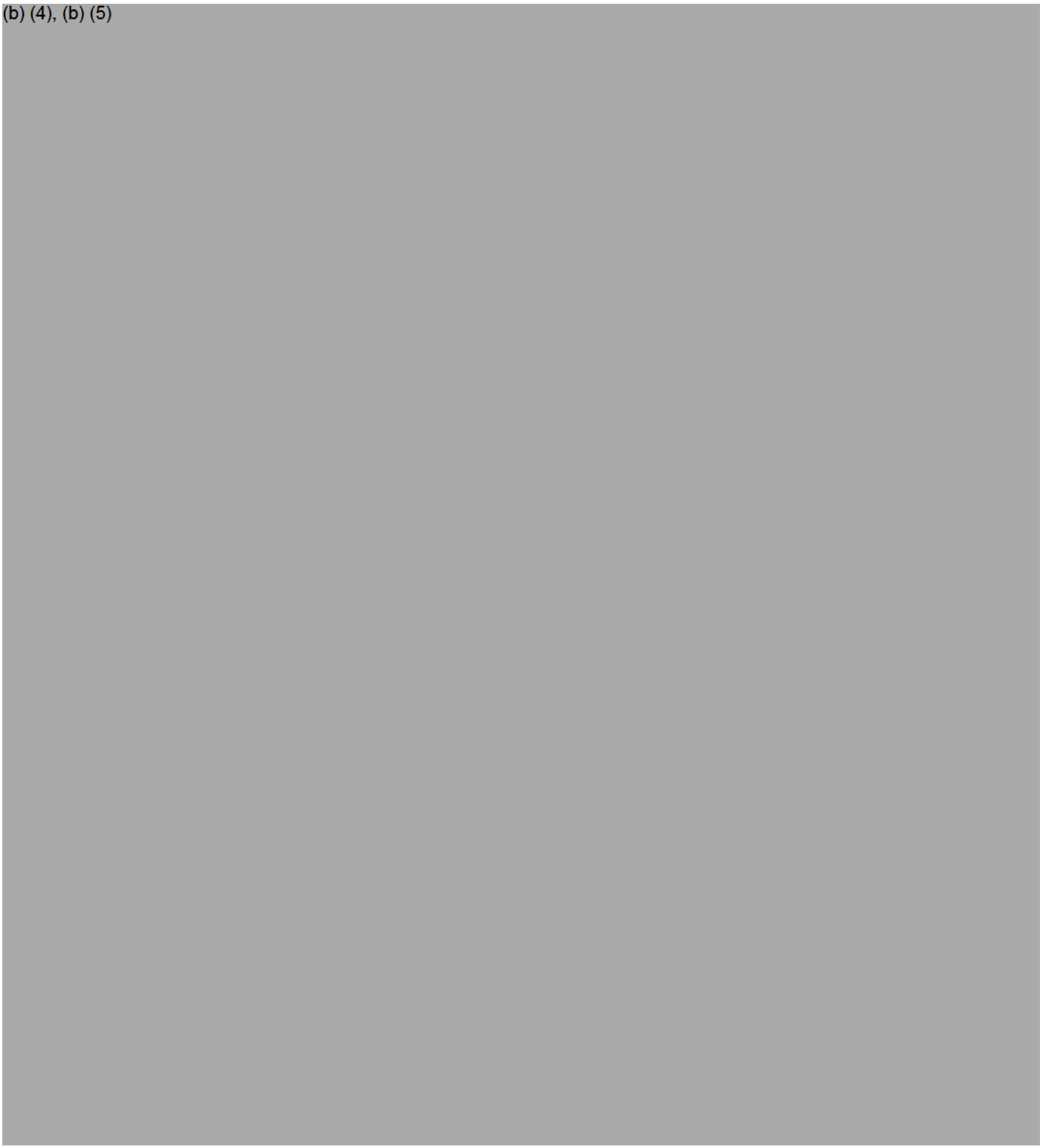
Hi all,

As discussed briefly this morning, attached please find my draft response to RMS's questions for your review. I extracted the following questions from the template and my proposed responses (in red) that I would like to get your feedback on particularly:

(b) (4), (b) (5)

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(b) (4), (b) (5)



Thanks,
Li

**Li Li**
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)

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Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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li.li2@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/18/2020 2:30:21 PM
**To**: Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Info

Mary,

This is the section in the submission stating who is the manufacturer of the CDC assay:

(b) (5)

[redacted]

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 2:24 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Info

Mary,

(b) (5)

[redacted]

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/23/2020 1:58:29 PM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

If CDC accepts our edits, yes.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 1:27 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

So everything is on the FDA as long as the CDC is ok with our edits?

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 23, 2020 at 12:03:46 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Tim,

Getting the authorization letter done, need to touch base where we are on this.

Drafting the review memo, Kim will do that this afternoon.

Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:59 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hi Uwe,

What is the next step on this EUA?

Thanks!

Best,
Tim

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 23, 2020 at 11:53:55 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>

AMERICAN OVERSIGHT

**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Importance:** High

Jeff,

The draft edits for the document for the surveillance study just went out to CDC.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:13 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

The following email just went out to CDC. Thank you all for the fast turnabout to get this done.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:09 AM
**To:** Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC)

AMERICAN OVERSIGHT

<wdk1@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear Laura,

Attached please find the following documents you submitted on February 21, 2020 to support the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in surveillance activities. These documents have been reviewed and edited by FDA's OCET and OCC.

1. Draft COVID-19 sentinel surveillance
2. Draft SARS-CoV-2 surveillance risk benefit
3. Draft CDC Surveillance EUA Request Cover letter

Please do not hesitate to reach out to me with questions.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/22/2020 4:10:13 PM
**To:** Garcia, Mayra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7db05677732d4023bcdf772ee0474055-GarciaM]
**Subject:** RE: Coronavirus and MERS culturing

Mayra,

Can you please give me a call at (b) (6) . Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 9:01 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Coronavirus and MERS culturing

FYI

---

**From:** Garcia, Mayra
**Sent:** Saturday, February 22, 2020 8:59 AM
**To:** Wang, Tony <Tony.Wang@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; McGivern, David <David.McGivern@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Dear Tim,

As I mentioned to Uwe yesterday, the idea was to handle the COVID-19 materials for the CDRH devices as we did for Zika. CBER has the laboratories and knowledge to propagate the virus. DMD will be able to design the panel that will best challenge the sensitivity and specificity of the devices we are getting in house. Therefore, after Tony grows and inactivates the BSL-3 stocks, I would be preparing the dilutions of the viral stocks with David's help to formulate the final panel. In addition, I was also the one receiving at CDRH the orders, distributing the panels when available to the companies, as well as receiving the results of the testing. This strategy allowed DMD to have knowledge of the progress companies where doing with the panel testing and compile all the results for the EUA devices.

The preparation of the panel will take some time as the virus strains need still to be grown (and as Tony said the BSL-3 just got validated to work with COVID-19), inactivated, titrated, and the panel will have to be prepared with different dilutions that could satisfy the sensitivity observed in our devices.

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I proposed a meeting with CBER for next week, now that that the BSL-3 and the funds are available since 2/21/2020, to set up a timeline for the next steps.

Regards,

Mayra

---

**From:** Wang, Tony <Tony.Wang@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 8:27 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; McGivern, David <David.McGivern@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Dear Tim,

I am adding Drs. Carolyn Wilson, Mayra Garcia from CDRH and David McGivern to this email chain for communication purpose. Dr. Wilson is the director of office of research at CBER who oversees all 2019-nCoV activities. Dr. McGivern at the Office of Blood Research and Review at CBER will work with Mayra at CDRH to generate reference standards for industry to use.

My group is to propagate virus and then work with David's group to establish conditions for heat-inactivation of the virus. We have just received the approval to conduct the work, but there are a few house-keeping items that we need to take care of before we can start the work.

I would leave to Dr. Wilson, Mayra and Dr. McGivern to speak on the part regarding dialogues with industries.

Best,

Tony

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 3:14 PM
**To:** Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>; Wang, Tony <Tony.Wang@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Coronavirus and MERS culturing

Hi Tony, Shufeng and Christopher,

We are getting inquiries from IVD test developers who are ready to finish the validation of their molecular Coronavirus assays so they can submit them to CDRH for EUA authorization. I have heard that you are developing a source of Coronavirus and mers and was wondering if you are in dialogue with companies already and if we can introduce them to you so they can get in line to receive samples when they are ready.

Thanks so much in advance!

Best,
*Tim*

AMERICAN OVERSIGHT

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*

*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:42 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Hello Tim,
Likewise, I am delighted to meet you today. Please see attached for the IBC application we received from CBER for review and approval. We will have to contact the PI's at CBER to find out when they will have the materials ready. Based on the application, it seems like they are only preparing nConV19 (SARS CoV 2) and MERS CoV materials. (b) (5) [redacted] Take care.

Pillai

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:13 PM
**To:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Coronavirus and MERS culturing

Hi Pillai,

Great to meet you today! I wanted to reach out and have copied Jeff to find out more details about the coronavirus and mers cultures. We have a number of test developers who cannot complete validation of their EUA assays until they have at least mock samples made with virus to test.

How soon will virus be available?
Can we connect developers with someone here at the agency so they can coordinate access?

Thanks!

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Best,

*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/17/2020 10:42:25 AM
**To**: Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]
**CC**: Garcia, Mayra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7db05677732d4023bcdf772ee0474055-GarciaM]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject**: FW: RE: 2019-nCov EUA Template
**Attachments**: DRAFT EUA Review Template_NAT_Novel Coronavirus LCA 20200217.doc

Himani,

Can you start reviewing this information. Uwe

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Monday, February 17, 2020 10:39 AM
**To:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: RE: 2019-nCov EUA Template

Hi All,

I see Kim is out of the office.

Thank you for your help with this!

Brian Krueger, PhD
Associate Vice President
Technical Director, Research and Development
Laboratory Corporation of America

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Monday, February 17, 2020 10:30 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Subject:** Re: [External] RE: RE: 2019-nCov EUA Template

Hi Kim,

Please find attached our preliminary EUA Study design. We look forward to reviewing your comments.

Thank you again for all of your help!

Sincerely,

AMERICAN OVERSIGHT

Brian Krueger, PhD

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 9:54 AM
**To:** Krueger, Brian (b) (6) @LabCorp.com>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** [External] RE: RE: 2019-nCov EUA Template

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Dear Brian,

Apologize for the delayed response but we are currently working with various stakeholders around access to 2019-nCoV materials and clinical specimens. We appreciate that access to whole virus and/or purified whole genome RNA is limited at this present time and therefore we would consider use of representative IVTs for the initial limit of detection (LoD) evaluation. We do not anticipate access to clinical specimens in the near future and are currently discussing acceptable alternatives to that for the clinical evaluation of EUA tests. (b) (4)

Please note that live whole virus is now available through BEI Resources under catalog number NR-52281, however, this material is a BSL-3 pathogen requiring BEI Level 3 registration and a CDC permit for domestic shipments. It is our understanding that inactivated virus may be available in the next 1-2 months.

We recommend as the next step that you submit your Pre-EUA submission to FDA, as outlined in the initial email that was sent with the EUA Interactive Review Template, so we can assign you a Lead Reviewer and provide more detailed formal feedback going forward.
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Wednesday, February 05, 2020 10:15 AM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: 2019-nCov EUA Template

Hey Kim,

Thank you so much for your rapid response. (b) (4)

Sincerely,

Brian

---

**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Wednesday, February 5, 2020 9:53 AM
**To:** Krueger, Brian (b) (6) @LabCorp.com>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** [External] RE: 2019-nCov EUA Template

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Dear Brian,

Thank you for your email. Please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of 2019-novel coronavirus (2019-nCoV). I suggest when you are ready, the first step is to populate this draft template with the information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center). The Pre-EUA review is an interactive process, so we will provide feedback after receiving and reviewing the information provided. The draft review template is a shared "work-in-progress" document which you will populate with information and data as obtained and which we will review and provide feedback to you.

I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of 2019-nCoV to FDA (it includes the address for the Document Control Center). Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under type of submission please check "other" and specify Pre-EUA.

One hard copy of the signed EUA Cover Letter and one electronic copy of you Pre-EUA submission package (including the EUA Review Template - MS word document) should be enclosed in your Pre-EUA submission to FDA, and we also request that you submit the information requested via electronic mail to myself Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

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- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;
- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please be reminded that in the U.S. a test for the detection of 2019-nCoV or to diagnoses 2019-nCoV infection must not be distributed and/or used for clinical diagnosis without premarket clearance, approval, or EUA by the FDA.

NOTE: The EUA Interactive Review Template from the FDA is considered an internal working document and must not be distributed outside of your organization.

Please let me know if you have any questions, we look forward to working with you,
Best regards,
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Tuesday, February 04, 2020 5:49 PM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Subject:** 2019-nCov EUA Template

Hello,

I am inquiring to obtain the Pre-EUA template for 2019-nCov.

(b) (4)

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(b) (4)

[redacted]

Sincerely,

Brian Krueger, PhD
Associate Vice President, Technical Director, Research and Development
Laboratory Corporation of America
1447 York Court
Burlington, NC 27215

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**EMERGENCY USE AUTHORIZATION (EUA)**

**EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (~~2019-nCoV~~COVID-19)**

(b) (5) Draft



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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

(b) (5) Draft

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/25/2020 6:08:29 PM
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]
**CC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

Jennifer,

See updated numbers below. 75 developers and 16 submitted pre-EUAs.

**Thanks,**
**Uwe**

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:41 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** RE: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers
**Importance:** High

Good evening all,

Are there any updates to the numbers below? Jeff is briefing Senate HELP staff tomorrow so wanted to check in.

Best,

Jennifer

- FDA has granted 1 Emergency Use Authorization (EUA), to the CDC, as of 2/21/20.
- This test was developed and validated within about a month.
- CDC submitted validation data interactively throughout the process and the EUA package was submitted to FDA on 2/3/2020; on 2/4/2020, FDA issued an EUA.
- FDA has provided the EUA template to (b) (5) developers of diagnostics for this outbreak as of 2/21/20.
- (b) (5) developers have submitted pre-EUA documents for FDA feedback as of 2/21/20.

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*
**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**

AMERICAN OVERSIGHT

Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:18 AM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

Jennifer, see edits below.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 5:26 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers
**Importance:** High

Uwe, Kim, and Toby,

Good evening. Secretary Azar has requested a great deal of data from FDA (particularly regarding the supply chain, number of firms we have contacted, numbers of firms manufacturing certain products OUS and domestically, etc.). As part of this, we want to provide some of the notable information about diagnostic tests and EUAs. Can you review the four points below by 9 am on Monday morning? Feel free to add anything else you think is responsive and helpful.

Sorry for the quick turnaround (once again).

Thanks very much for your help.

Best,

Jennifer

## FDA Response to COVID-19 By-the-Numbers

Diagnostic Tests

- Granted 1 Emergency Use Authorization, to the CDC, as of 2/21/20
- This test was developed and validated within about a month.

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- CDC submitted validation data interactively throughout the process and the EUA package to FDA on 2/3/2020; on 2/4/2020, FDA issued an EUA to enable emergency use of the test.
- Provided the Emergency Use Authorization template to (b)(5) developers of diagnostics for this outbreak as of 2/21/20

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/14/2020 8:14:53 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/14/20 6 PM update - 2019-nCoV

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/14/20 6 PM update on 2019-nCoV

**Status of activities on diagnostics:**

- Conference call this afternoon with CDC to discuss the community transmission surveillance plan and to identify regulatory strategy options to ensure that the surveillance will be conducted in compliance with FDA law and regulation.
  - CDC will give FDA a draft protocol of their community surveillance plan for review and comment next week.

(b) (5)

  - Definite regulatory decision was not given - pending recommendations from OCC

- CoV Diagnostic WG call (FDA, BARDA & NIH) this afternoon to discuss availability of 2019-nCoV genomic material:

(b) (5)

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- BARDA and NIH stated that they are reviewing grant proposals from various companies. DMD is reviewing pre-EUA applications received to date.
- The WG will compile a priority list of companies to UTMB that should receive 2019-nCoV genomic material for their studies.

- DMD received 7 pre-EUA applications in the last 4 days (see table below) with study proposals and in silico primer analysis. We are currently reviewing the submissions.

2019-nCoV pre-EUAs currently under review by DMD:

| CTS | FIRM | ASSAY | Received |
|---|---|---|---|
| PEU200001 | InBios | Smart Detect 2019-nCoV | 2/11/2020 |
| PEU200002 | Roche Molecular | cobas 2019-nCoV on cobas 6800/8800 Systems | 2/11/2020 |
| PEU200003 | BioFire Defense | BioFire 2019-nCoV Test | 2/11/2020 |
| PEU20000x | ScienCell Research Laboratories | SARS-Cov-2 RT-PCR Detection Kit | 2/13/2020 |
| (b) (4) | | | |
| PEU20000x | Cepheid | Xpert SARS-CoV-2 test | 2/13/2020 |
| PEU20000x | Vela Diagnostics | ViroKeyTM SA201 2019-nCoV RT-PCR Test | 2/11/2020 |

- A total of 60 IVD Developers have requested and received EUA review template.

- Tri-agency Taskforce for Emergency Diagnostics (FDA/CDC/CMS) held a teleconference today to share information on the activities concerning the issued EUA and Pre-EUA proposals.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/23/2020 12:39:58 PM
**To:** Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Thanks, Uwe

---

**From:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 12:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Okay, I will try to keep an eye on my e-mail. Feel free to call/text me, or e-mail at (b) (6) if you need me urgently and I haven't checked my FDA e-mail.

Brittany
(b) (6)

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 12:26 PM
**To:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Brittany,

Thanks, it is not confirmed that we will have a call today, but I wanted to give you heads us. As soon as I hear from CDC I will let you know. Uwe

---

**From:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 12:24 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Sure, 4pm this afternoon? I can do that.

I might step out from 2pm-3pm, but I should be back after that.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:53 AM
**To:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Brittany,

This went out to CDC just a moment ago. It contains your suggested edits for the benefit-risk analysis. In case we will have an telecom this after 4PM would you be avialalbe?

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:13 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

The following email just went out to CDC. Thank you all for the fast turnabout to get this done.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:09 AM
**To:** Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear Laura,

Attached please find the following documents you submitted on February 21, 2020 to support the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in surveillance activities. These documents have been reviewed and edited by FDA's OCET and OCC.

1. Draft COVID-19 sentinel surveillance
2. Draft SARS-CoV-2 surveillance risk benefit
3. Draft CDC Surveillance EUA Request Cover letter

Please do not hesitate to reach out to me with questions.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/18/2020 7:33:04 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/18/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/18/20 6 AM update:

**Status of activities on diagnostics:**

- Extensive work with CDC on 2 major requests:

1. Testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship

On February 15, 2020, CDC submitted to FDA a request for testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

FDA did not object to the use of the device for testing asymptomatic passengers from the ship, under several conditions including that testing being done only at CDC's headquarters in Atlanta.

2. CDC's request for a possible cut-off change to their issued EUA

(b) (5)

Uwe

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**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/13/2020 11:06:30 AM
**To:** Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]
**Subject:** RE: FDA Novel coronavirus (2019-nCoV) EUA Information

Thanks, Kris.

---

**From:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 10:56 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: FDA Novel coronavirus (2019-nCoV) EUA Information

Will do.
Thanks

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 10:42 AM
**To:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Subject:** FW: FDA Novel coronavirus (2019-nCoV) EUA Information

Kris,

Could you please respond and set something up for Th/Fr next week. Thanks, Uwe

---

**From:** Lama Ramzi Suleiman <lrsuleiman@unicef.org>
**Sent:** Thursday, February 13, 2020 9:41 AM
**To:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Abdallah Makhlof <amakhlof@unicef.org>; Wandani Sebonego <wsebonego@unicef.org>; Tatsiana Ptashnik <tptashnik@unicef.org>
**Subject:** FDA Novel coronavirus (2019-nCoV) EUA Information

Dear Roth and Uwe,

Greetings from UNICEF supply Division

Hope you are doing well

It has been a long time since we have discussed our global needs for Ebola and Zika Dx . However, I'm reaching out to you again to touch base with you regarding 2019 Novel Coronavius Diagnostics

We were glad to notice the launch of FDA Novel coronavirus (2019-nCoV) EUA and the related Information on your website that FDA has issued . would you or any of your team be available for a call sometime next week to get more updates on the EUA for 2019-nCov diagnostics and the scope of products in the pipeline

Looking forward to hearing from you

Regards
Lama

AMERICAN OVERSIGHT

Lama R. Suleiman
Contracts Manager – Malaria Prevention & Diagnostics Unit / Health Technology Centre
Tel: (b) (6) Email: lrsuleiman@unicef.org www.unicef.org/supply

United Nations Children's Fund
Supply Division, Oceanvej 10-12, 2150 Nordhavn, Copenhagen, Denmark
Follow us on Facebook, Twitter, YouTube and at www.unicef.org

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**From:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Sent:** Wednesday, 27 September 2017 8:53 PM
**To:** Lama Ramzi Suleiman <lrsuleiman@unicef.org>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Nagwa Hasanin <nhasanin@unicef.org>; Abdallah Makhlof <amakhlof@unicef.org>
**Subject:** RE: Request for a discussion related to global need for Ebola diagnostics

Dear Lama,
Thank you for your engagement. We are glad to discuss both infection agents and will have the appropriate individuals on the phone. I propose we schedule a call for either:

Thursday October 12 at 3 pm CEST (9 am Eastern time zone in the US)
Or
Friday October 13 at 3 pm CEST (9 am Eastern time zone in US)

Do these times work for you?

Kind regards,
Kris

**From:** Lama Ramzi Suleiman [mailto:lrsuleiman@unicef.org]
**Sent:** Tuesday, September 26, 2017 6:26 AM
**To:** Roth, Kristian
**Cc:** Scherf, Uwe; Nagwa Hasanin; Abdallah Makhlof
**Subject:** FW: Request for a discussion related to global need for Ebola diagnostics

Dear Kris,

It is great to hear from you again and thank you so much for reaching out to Unicef.

It is indeed important to discuss our shared interest in improving global health with respect to Ebola.

we would like to schedule call with you to discuss our plans and need for the the Ebola Diagnostics and update you ( if relevant) on our progress with Zika Dignostics as well

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How about the week of 9th October?

Looking forward to hearing from you

Regards
Lama

Lama R. Suleiman
Contracts Manager – Malaria Prevention & Diagnostics Unit / Health Technology Centre
Tel: (b) (6) Email: lrsuleiman@unicef.org www.unicef.org/supply

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**From:** Roth, Kristian [mailto:Kristian.Roth@fda.hhs.gov]
**Sent:** Friday, 8 September 2017 20:46
**To:** CPHHQ-SD-DAN Supply <supply@unicef.org>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Request for a discussion related to global need for Ebola diagnostics

Dear Shanelle Hall,

About 1.5 years ago I attended the Zika Vaccine and Diagnostics Industry Consultation which was a very well organized meeting. We at the US FDA are currently re-evaluating the need (both globally and within the US) for Ebola in vitro diagnostic tests. I was hoping that we could arrange a telephone call between UNICEF and FDA to discuss UNICEF's evaluation of the need for a rapid antigen test for Ebola.

As you may know the US has issued a number of Emergency Use Authorizations for Ebola diagnostics. These authorizations are not permanent and FDA is mandated to revisit the need for these devices as the epidemic changes. We have heard that UNICEF may be planning to acquire these types of products therefore we would like to understand your needs to ensure that any action FDA may take in this area does not negatively impact your mission.

If it is acceptable to you, I propose having an approximately one hour teleconference to discuss our shared interest in improving global health with respect to Ebola.

Kind regards,
Kris

Kristian Roth, Ph.D.

AMERICAN OVERSIGHT

*Branch Chief Bacterial Multiplex and Medical Counter Measures*
**Center for Devices and Radiological Health**
**Office of In Vitro Diagnostics and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 301-796-7024
kristian.roth@fda.hhs.gov




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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/22/2020 2:05:37 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Kim,

Thanks for keeping this moving. I could not contribute because I was taking care of the excluding the N3 component.

FYI, this is what I sent to Tim just a minute ago.

Can I give you a call?

Uwe

As discussed in our phone conversation, we received a dataset with the results of (b) (5) specimens tested at CDC, to evaluate the proposal of dropping the N3 component.

Here is a summary of our review of the data:

- Out of a total of (b) (5) specimens, (b) (5) were positive (i.e., N1, N2, N3 positive), (b) (5) were negative (i.e., N1, N2, N3 negative).
- Of the (b) (5) "Inconclusive" specimen (b) (5) were initially N3 positive only (i.e., N1 and N2 negative), (b) (5) were N1 positive only (i.e., N2 and N3 negative), 1 was N2 positive only (i.e., N1 and N3 negative), and 1 was N1 and N3 positive.
- Upon retesting, al (b) (5) specimens that were initially N3 positive only were negative for all three components; al (b) (5) specimens that were initially N1 positive only were negative for all three components upon retesting; (b) (5) that was initially N2 positive only was negative for all three components; and (b) (5) that was initially N1 and N3 positive was positive for all three components upon retesting.

In conclusion, specimens that were initially N3 positive only, upon retesting were negative for all three components [(b) (5) 100% (95% CI 67.6% - 100%)], suggesting that the initial results were likely false positives (b) (5) 0.4%). None of the (b) (5) specimens were presumptive positive (i.e., all three components positive) upon retesting, suggesting that all (b) (5) specimens were likely true negatives.

Based on this limited data, it appears that if the N3 were to excluded from the test panel, the risk of missing a presumptive positive specimen is low. It is the Division's opinion that with the issue of compromised N3 reagent, the benefit/risk profile is in favor of temporarily excluding the N3 component from the panel. The potential risk of this exclusion is the risk of missing true low positives during early phase of the infection. Based on this limited data set, the risk appears to be small.

CDC must provide a risk/benefit analyses or justification as why the N3 should be permanently, rather than temporarily, eliminated from the panel while they address the reagent contamination or probe/primer design issues.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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CDRH | Food and Drug Administration
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uwe.scherf@fda.hhs.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 12:35 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

Revised documents attached for your review. I have tried to play down surveillance without completely deleting it.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 10:57 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

AMERICAN OVERSIGHT

My comments are in the attached. (b) (5) [redacted]

Anyway let me know what you think
Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 9:19 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hi all,

Comments from me and Marcy on the protocol are attached (b) (5) [redacted] Please let us know if you have any questions – my calendar is up to date on when I am available this weekend.

Thanks!
Claire

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 5:22 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: DRAFT CDC EUA Request for Sentinel Surveillance Activities

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All,

Here the draft EUA request we just discussed. Thanks for getting this addressed so quickly.

Uwe

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Friday, February 21, 2020 10:40 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** DRAFT CDC EUA Request for Sentinel Surveillance Activities

Good morning Kim and Uwe,

Please find attached a draft EUA request submission for the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in sentinel surveillance activities. We would appreciate your review of this draft submission to ensure it contains the information and wording request necessary to support FDA's planned issuance of a second letter of authorization for the diagnostic panel to support this critical epidemiologic activity.

Please do not hesitate to reach out with questions, ideas, recommendations as you review the attached. I look forward to hearing from you.

Warm regards,
Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

OLSS Office of Laboratory Science and Safety

*Strengthening the culture of laboratory science and safety at CDC*

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/18/2020 10:31:54 PM
**To**: Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: Contract Manufacturer

Great, thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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---

**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 9:24 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Contract Manufacturer

Looks good to me – I included a few minor, additional revisions below in red.

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 6:40 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: Contract Manufacturer

Predecisional/Deliberative

See suggested edits below.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 6:07 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Contract Manufacturer

Ellen and Marcy,

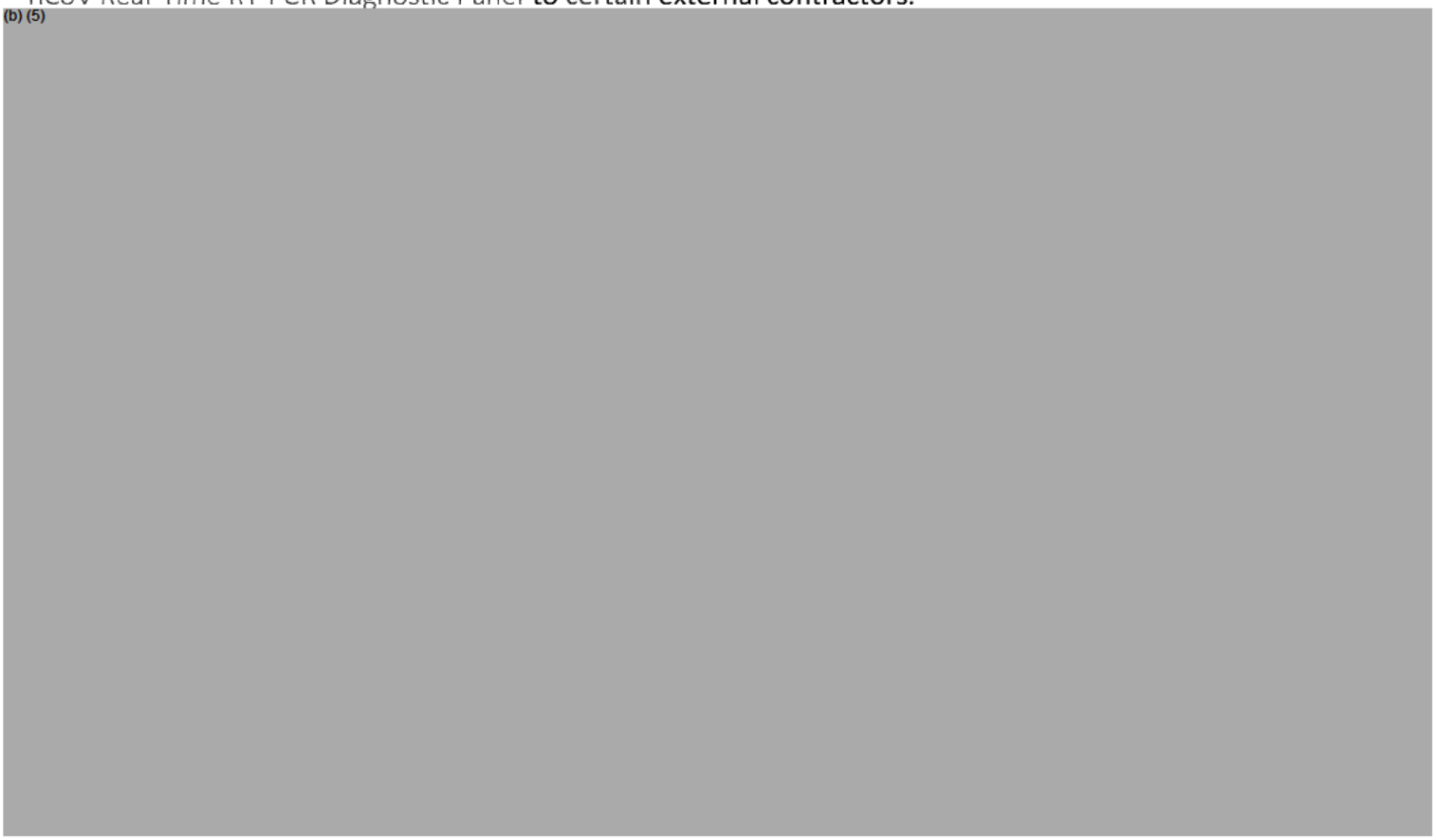
Here the draft for the response to CDC regarding their wish to contract out the manufacturing. I tried to capture as much from our conversation as I could. Please provide any edits you have. Uwe

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Predecisional/Deliberative:

CDC has communicated to FDA that you wish to contract out primer & probe manufacturing for the 2019-nCoV Real-Time RT-PCR Diagnostic Panel to certain external contractors.

(b) (5)



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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/19/2020 8:37:17 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]

**Subject:** Fwd: Update on EUA for CDC "surveillance"
**Attachments:** COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx
**Location:** webex

**Start:** 2/20/2020 8:30:00 AM
**End:** 2/20/2020 9:00:00 AM
**Show Time As:** Tentative

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Date:** February 19, 2020 at 8:25:54 PM EST
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Update on EUA for CDC "surveillance"

CDC says they will submit a new EUA referencing the data in their first EUA in a day or two.
Protocol attached.
It would be good to touch base to ensure we are all on the same page for next steps.

Maybe we would also be able to discuss a little about the draft letter of authorization:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the SARS-CoV-2 (formerly 2019-nCoV) in nasopharyngeal (NP) or oropharyngeal (OP) respiratory specimens collected from individuals consented or notified prior to sample collection that SARS-CoV-2 testing would be performed if specimens are negative for influenza and other respiratory pathogens in order to determine if unrecognized community transmission of SARS-CoV-2 is occurring, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing is limited to qualified laboratories designated by CDC to conduct testing according to protocol xxx and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.
-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

Meeting number (access code): (b) (6)
Meeting password: (b) (6)

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Join meeting

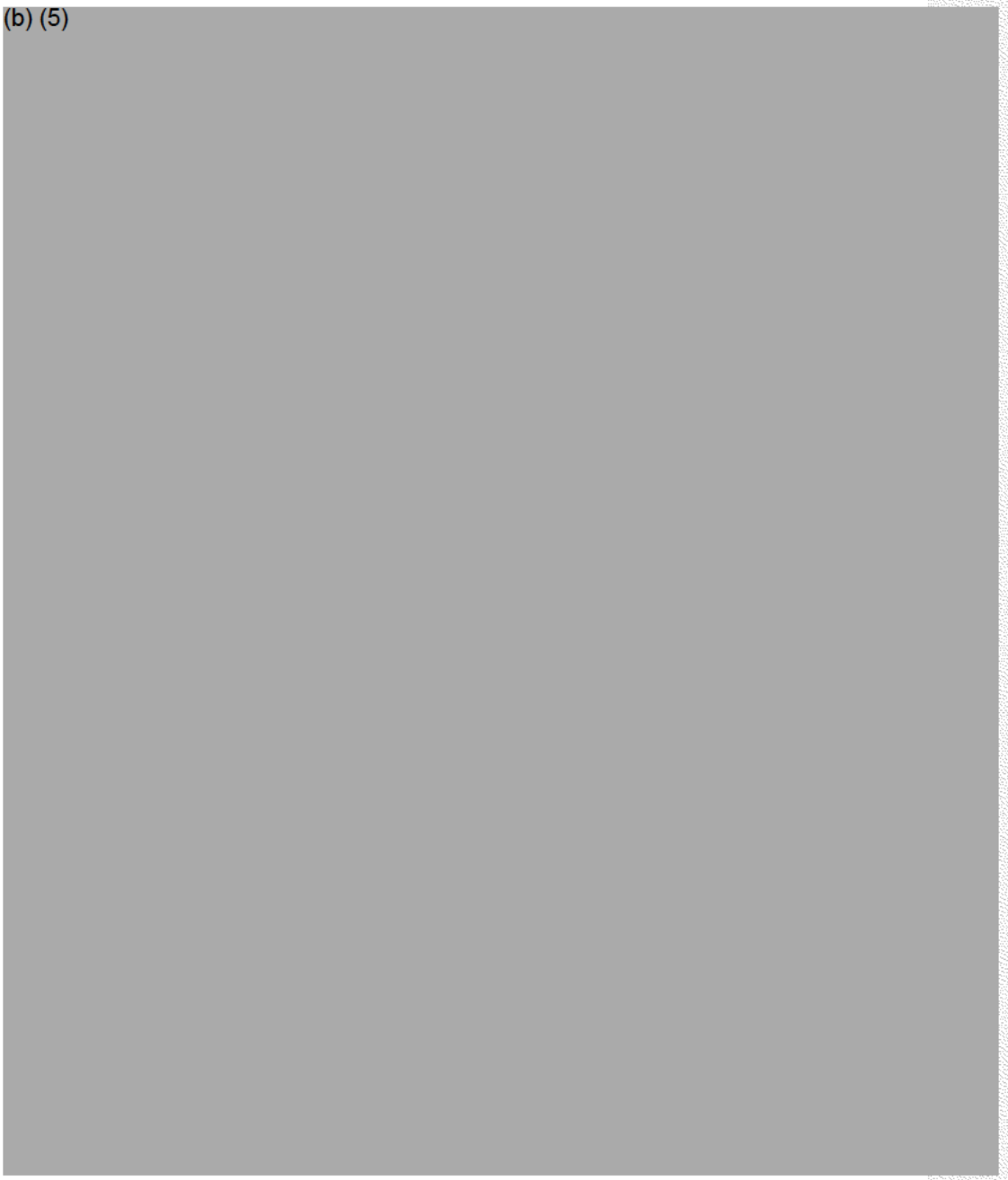
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AMERICAN OVERSIGHT

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

DRAFT



AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/23/2020 8:03:01 AM
**To**: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**CC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Attachments**: DRAFT CDC Surveillance EUA Request Cover letter 20FEB2020 6pm FDA 2.22.2020_US.docx; COVID_19 sentinel surveillance Feb 21 2020 FINAL CLEAN_FDA 2.22.2020us.docx

Hello,

I have two minor comments in the letter, highlighted in yellow and as a comment at the end of the letter and

One minor edits in one of the comments in the procedure (yellow) and a recommendation for clarification in the second to last sentence under the Consideration for Individuals Tested.

Thanks,
Uwe

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 7:27 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hello,

I had one minor comment on the letter, highlighted in yellow.

Thanks,
Jennifer

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 12:19 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe

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<Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

Please find attached the final documents with edits/comments back to CDC for your final review. I would like to send them back to CDC tomorrow morning. I will be unavailable 9-10:30am and 11:30 am – 1:00pm. If I could get any comments before 10:30 am hopefully I can send final docs back to CDC in the 10:30-11:30 window.

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 6:22 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Importance:** High

Hi Team,

I just heard from Jeff. We have to get these documents cleaned up and back to CDC ASAP, per direction of the FDA Commissioner and the CDC Director.

(b) (5)

(b) (5)

OVERSIGHT

Thanks,
Ellen

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 3:19 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Thanks Ellen,

Some comments/suggestions based on your feedback

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 2:08 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hi all,

I attached two of the documents with my comments and suggestions.

In the Risk/Benefit document: it says (b) (5)

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Thanks,
Ellen

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 12:35 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

Revised documents attached for your review. I have tried to play down surveillance without completely deleting it.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 10:57 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

My comments are in the attached. (b) (5)

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Anyway let me know what you think

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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---

**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 9:19 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hi all,

Comments from me and Marcy on the protocol are attached (b) (5) . Please let us know if you have any questions – my calendar is up to date on when I am available this weekend.

Thanks!
Claire

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 5:22 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: DRAFT CDC EUA Request for Sentinel Surveillance Activities

All,

Here the draft EUA request we just discussed. Thanks for getting this addressed so quickly.

Uwe

AMERICAN OVERSIGHT

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Friday, February 21, 2020 10:40 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** DRAFT CDC EUA Request for Sentinel Surveillance Activities

Good morning Kim and Uwe,

Please find attached a draft EUA request submission for the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in sentinel surveillance activities. We would appreciate your review of this draft submission to ensure it contains the information and wording request necessary to support FDA's planned issuance of a second letter of authorization for the diagnostic panel to support this critical epidemiologic activity.

Please do not hesitate to reach out with questions, ideas, recommendations as you review the attached. I look forward to hearing from you.

Warm regards,
Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

OLSS Office of Laboratory Science and Safety
*Strengthening the culture of laboratory science and safety at CDC*

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 8:53:58 PM
**To:** Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: CoV Dx FDA/developer needs discussion

---

**From:** Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>
**Sent:** Wednesday, February 12, 2020 11:20 AM
**To:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA <jason.a.opdyke.civ@mail.mil>; Lee, John S (OS) <John.Lee@hhs.gov>
**Cc:** Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Stemple, Jojo J (NIH) <(b) (6) @niaid.nih.gov>
**Subject:** RE: CoV Dx FDA/developer needs discussion

Dear Dx Team,
I have updated information from BEI regarding the possible availability of COVID-2019 genomic RNA and inactivated viruses. Keeping our fingers crossed - it looks as though these reagents may become available in the next 4-6 weeks.

| BEI catalog # | Reagent | Quantity | Estimated time |
|---|---|---|---|
| NR-52281 | Novel Coronavirus 2019-nCoV/USA-WA1/2020 (culture) | 150 | Available now, pending QC tests |
| NR-52285 | Genomic RNA, 2019-nCoV/USA-WA1/2020 | 200 | Available as BSL-2 product# on 21 Feb 2020 with pending QC testing; after full QC the product will be available mid-March* |
| NR-52286 | Heat inactivated, 2019-nCoV/USA-WA1/2020 | 100 | late March* |
| NR-52287 | Irradiated infected cell lysate, 2019-nCoV/USA-WA1/2020 | 400 | early April* |

* Includes safety testing of reagent (4 weeks duration, 2 passages each for 14 days).
#For native viral RNA product release as BSL-2 product after a 7-days of safety testing. The safety test will continue for the 4-week duration for release as BSL-1 product.

I'm still waiting for information from WRCEVA.
Thanks,
Maureen

-----Original Appointment-----
**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Sunday, February 9, 2020 12:49 PM
**To:** Humes, Rosemary (OS/ASPR/BARDA); Scherf, Uwe (FDA/CDRH); Sapsford, Kim E (FDA/CDRH); Feldblyum, Tamara (FDA/CDRH); Li, Li (CDRH) (FDA/CDRH); Kuhnert-Tallman, Wendi (CDC/DDID/OD); Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI); Opdyke, Jason A CIV USARMY (USA; Lee, John (OS/ASPR/BARDA)
**Cc:** Faison, Tremel (OS/ASPR/BARDA); Beanan, Maureen (NIH/NIAID) [E]
**Subject:** CoV Dx FDA/developer needs discussion
**When:** Monday, February 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** WebEx info added

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Agenda
(b) (5)

Next steps
***DO NOT DELETE OR CHANGE ANY OF THE TEXT BELOW THIS LINE***

Rosemary Humes has scheduled this WebEx meeting.

CoV Dx FDA/developer needs discussion
Host: Rosemary Humes

When it's time, start or join the WebEx meeting from here:
(b) (6)

Access Information

Meeting Number: (b) (6)
Meeting Password: (This meeting does not require a password.)

Audio Connection

(b) (6) (Meeting Server Main Number)

Access Code:
(b) (6)

Hosts, need your host access code or key? Go to the meeting information page:
(b) (6)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/19/2020 6:51:12 PM
**To**: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx
**Attachments**: Draft CDC 2nd 2019-nCoV Letter of Authorization 2-19-20.doc

Here some preliminary notes.

Mary is trying to set up a meeting tomorrow. We will make sure you will be invited to this call. Thanks, Uwe

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:19 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

Draft EUA letter of authorization. I could set up a meeting in the morning to touch base with you (b) (5) [redacted]

Thanks,

Jennifer

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 1:57 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/24/2020 8:53:24 PM
**To**: Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: Information request - WRCEVA SARS-CoV-2 genomic RNA product sheet
**Attachments**: WRCEVA Product Information Sheet - RNA - 2-21-2020.docx

---

**From:** Beanan, Maureen (NIH/NIAID) [E] <(b) (6) @mail.nih.gov>
**Sent:** Friday, February 21, 2020 2:15 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** RE: Information request - WRCEVA SARS-CoV-2 genomic RNA product sheet

Uwe,
Here's the WRCEVA product sheet for the SARS-CoV-2 genomic RNA.
Maureen

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# WRCEVA Product Information Sheet (SARS-CoV-2 RNA)

| | |
|---|---|
| **Sample Type** | RNA |
| **Virus** | SARS-CoV-2 (aka, 2019-nCoV) |
| **Strain** | USA_WA1/2020 |
| **Source** | Human |
| **Location** | Washington State, USA (traveler from Wuhan, China) |
| **Date** | January 20, 2020 |
| **Isolate Depositor** | Natalie Thornburg, Centers for Disease Control and Prevention, Atlanta, GA |
| **Lot** | TVP 23156 |
| **Passage History** | Vero 4 |
| **Most Recent Propagation Host** | Vero E6 (African green monkey) (*Chlorocebus aethiops*) |
| **QC** | Plaque Assay<br>Next Generation Sequencing |
| **Host Genomic Material Present?** | Yes |
| **RNA Purification Method** | TRIzol LS |
| **RNA Purity** | 25% viral RNA, 75% host RNA by NGS reads |
| **RNA Concentration** | 100ng/µl<br>(approximately $6x10^4$ pfu equivalents/µl)<br>Note that pfu equivalents are not the same as genome copies, which frequently exceed pfu counts in the range of 1,000:1. |
| **RNA Preparation Date** | February 21, 2020 |
| **Total Amount Per Tube** | 1µg RNA (10µl at 100ng/µl) |
| **Notes** | NGS yielded a 100% consensus-level match to the original patient specimen (GenBank accession MN985325.1). Raw files and a report on any minor variants (<5% of total reads) are available upon request. |

Material provided by the World Reference Center for Emerging Viruses and Arboviruses (Galveston, TX), NIH R24 AI120942.

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/19/2020 6:43:52 PM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Mielech, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]
**Subject**: RE: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel: addition of ZEN probes

This information is also relevant for the LabCorp pre-EUA. As I recall LabCorp is obtaining their primer/probes from IDT.

Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 5:32 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>
**Subject:** FW: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel: addition of ZEN probes
**Importance:** High

Hi all,

The proposal looks good to me. This is consistent with the approach we agreed when they changed the quencher from (b) (5) for the CDC influenza RT-PCR panel. They can use the verification material (IVT) for the LoD equivalency study.

Thanks,
Li

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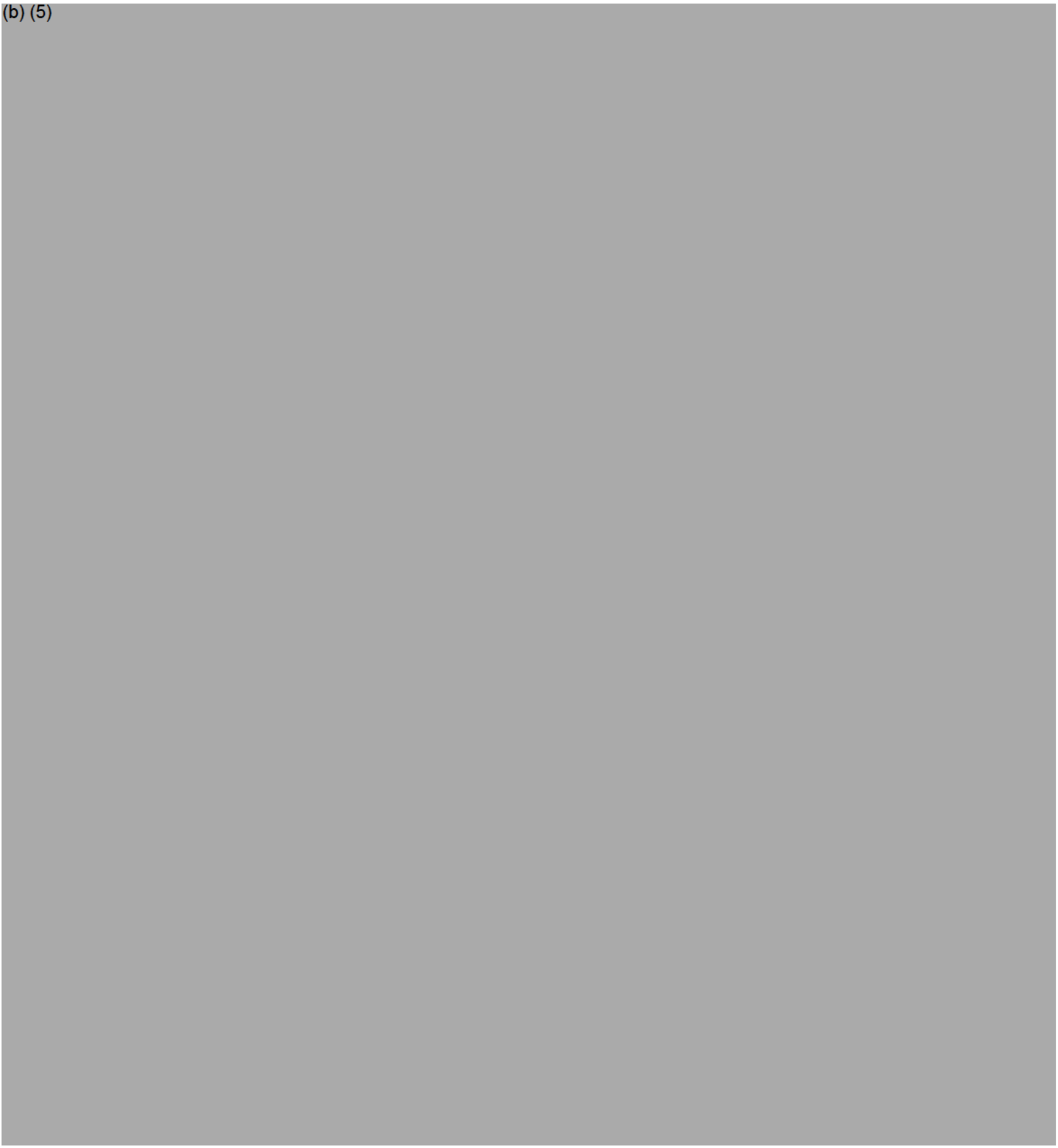
**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Wednesday, February 19, 2020 5:04 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>
**Subject:** CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel: addition of ZEN probes
**Importance:** High

Dear Uwe,

(b) (5)

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(b) (5)



Do you have time tomorrow to discuss this proposal? We are available from 9-10am, 11-11:30am, or after 3pm.

Thanks,

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/22/2020 9:03:19 AM
**To**: Garcia, Mayra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7db05677732d4023bcdf772ee0474055-GarciaM]
**Subject**: RE: Coronavirus and MERS culturing

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 9:01 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Coronavirus and MERS culturing

FYI

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**From:** Garcia, Mayra
**Sent:** Saturday, February 22, 2020 8:59 AM
**To:** Wang, Tony <Tony.Wang@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; McGivern, David <David.McGivern@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Dear Tim,

As I mentioned to Uwe yesterday, the idea was to handle the COVID-19 materials for the CDRH devices as we did for Zika. CBER has the laboratories and knowledge to propagate the virus. DMD will be able to design the panel that will best challenge the sensitivity and specificity of the devices we are getting in house. Therefore, after Tony grows and inactivates the BSL-3 stocks, I would be preparing the dilutions of the viral stocks with David's help to formulate the final panel. In addition, I was also the one receiving at CDRH the orders, distributing the panels when available to the companies, as well as receiving the results of the testing. This strategy allowed DMD to have knowledge of the progress companies where doing with the panel testing and compile all the results for the EUA devices.

The preparation of the panel will take some time as the virus strains need still to be grown (and as Tony said the BSL-3 just got validated to work with COVID-19), inactivated, titrated, and the panel will have to be prepared with different dilutions that could satisfy the sensitivity observed in our devices.

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I proposed a meeting with CBER for next week, now that that the BSL-3 and the funds are available since 2/21/2020, to set up a timeline for the next steps.

Regards,

Mayra

---

**From:** Wang, Tony <Tony.Wang@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 8:27 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; McGivern, David <David.McGivern@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Dear Tim,

I am adding Drs. Carolyn Wilson, Mayra Garcia from CDRH and David McGivern to this email chain for communication purpose. Dr. Wilson is the director of office of research at CBER who oversees all 2019-nCoV activities. Dr. McGivern at the Office of Blood Research and Review at CBER will work with Mayra at CDRH to generate reference standards for industry to use.

My group is to propagate virus and then work with David's group to establish conditions for heat-inactivation of the virus. We have just received the approval to conduct the work, but there are a few house-keeping items that we need to take care of before we can start the work.

I would leave to Dr. Wilson, Mayra and Dr. McGivern to speak on the part regarding dialogues with industries.

Best,

Tony

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 3:14 PM
**To:** Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>; Wang, Tony <Tony.Wang@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Coronavirus and MERS culturing

Hi Tony, Shufeng and Christopher,

We are getting inquiries from IVD test developers who are ready to finish the validation of their molecular Coronavirus assays so they can submit them to CDRH for EUA authorization. I have heard that you are developing a source of Coronavirus and mers and was wondering if you are in dialogue with companies already and if we can introduce them to you so they can get in line to receive samples when they are ready.

Thanks so much in advance!

Best,
*Tim*

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**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*

*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:42 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Hello Tim,
Likewise, I am delighted to meet you today. Please see attached for the IBC application we received from CBER for review and approval. We will have to contact the PI's at CBER to find out when they will have the materials ready. Based on the application, it seems like they are only preparing nConV19 (SARS CoV 2) and MERS CoV materials. (b) (5) [redacted] Hope this is helpful and let me know if I can be of further assistance. Take care.

Pillai

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:13 PM
**To:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Coronavirus and MERS culturing

Hi Pillai,

Great to meet you today! I wanted to reach out and have copied Jeff to find out more details about the coronavirus and mers cultures. We have a number of test developers who cannot complete validation of their EUA assays until they have at least mock samples made with virus to test.

How soon will virus be available?
Can we connect developers with someone here at the agency so they can coordinate access?

Thanks!

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Best,

*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/19/2020 4:00:32 PM
**To**: Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Tim,

Laura send me the summary of the conversation we had today. Please see added comments from the team. Anything else that you heard/want to add for clarification.

Thanks, Uwe

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Wednesday, February 19, 2020 2:32 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Good afternoon Uwe,

Thank you again for taking the time to meet with us today to discuss the regulatory considerations for community transmission surveillance. I wanted to share my understanding of the outcome of the meeting to ensure CDC and FDA are on the same page.

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(b) (5)

[redacted]

Please let me know if I have misunderstood our conversation or if I have missed a key point.

Many thanks,
Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 8:52:58 PM
**To:** Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: USG SSWG Updates - Current and scheduled availability of SARS-2 genomic RNA and scheduled availability of inactivated virus

---

**From:** Beanan, Maureen (NIH/NIAID) [E] <(b) (6) @mail.nih.gov>
**Sent:** Monday, February 24, 2020 11:30 AM
**To:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Chandrasekera, Ruvani (OS) <Ruvani.Chandrasekera@hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Woodson, Sara E (NIH) <(b) (6) @nih.gov>; Stemple, Jojo J (NIH) <(b) (6) @niaid.nih.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>
**Subject:** RE: USG SSWG Updates - Current and scheduled availability of SARS-2 genomic RNA and scheduled availability of inactivated virus

Dear All,
Here's a summary of the availability of the following reagents:

SARS-2 Viral Genomic RNA

- The World Reference Center for Emerging Viruses and Arboviruses (WRCEVA) prepared small quantities of SARS-2 viral genomic RNA. The material was prepared from cell culture of SARS-CoV-2 virus (USA_WA1/2020), it is being distributed as BSL-2. The following companies were prioritized by the Diagnostics WG of the MCM Task Force to receive this reagent and have received a communication informing them of the availability of limited amounts of RNA: Cepheid, BioFire Defense, Diasorin, Luminex Corp., Quidel, Qiagne, GenMark, Roche Diagnostics, Hologic, Altona, and MesBioTech.
- BEI Resources is in the process of generating a larger supply of SARS-2 viral genomic RNA. The initial lot is 200 aliquots, and as Rosemary mentioned 75 vials will be reserved for FDA use to facilitate studies associated with EUA submissions for diagnostics. This lot of SARS-2 genomic RNA is scheduled to be available either by the end of this week or early next week.

Inactivated SARS-2 virus

- Heat inactivated, 2019-nCoV/USA-WA1/2020 is scheduled to become available by the end of March
- Irradiated infected cell lysate, 2019-nCoV/USA-WA1/2020 is schedule to become available by early/mid-March

Thanks,
Maureen

Maureen J. Beanan, Ph.D.
Program Officer
Translational Centers of Excellence and Research Coordination Section
DMID/NIAID/NIH
5601 Fishers Lane, Rm, 8G24 MSC 9825
Rockville, MD 20852-9825
Phone: 240-292-0999

---

**From:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 11:00 AM
**To:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR)

AMERICAN OVERSIGHT

<Ruvani.Chandrasekera@hhs.gov>
**Cc:** Woodson, Sara (NIH/NIAID) [E] (b) (6) @nih.gov>; Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <kim.sapsford@fda.hhs.gov>
**Subject:** RE: USG SSWG Updates

Thanks Rosemary. We are trying to be up to date regarding availability of materials, that is why I was checking back with Ruvani. Any future updates will be also appreciated. Mayra

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 24, 2020 10:50 AM
**To:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>; Chandrasekera, Ruvani (OS) <Ruvani.Chandrasekera@hhs.gov>
**Cc:** Woodson, Sara E (NIH) (b) (6) @nih.gov>; Beanan, Maureen J (NIH) (b) (6) @mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: USG SSWG Updates

Hi Mayra,
Following up on your message to Ruvani. Sounds like Uwe has filled you in on the distribution of genomic RNA that was coordinated through the Diagnostics WG of the MCM Task Force. The RNA was prepared by WRCEVA under contract to NIAID as a way to expedite some material to the Dx developers moving forward with SARS-CoV-2 assays for existing FDA-cleared platforms. WRCEVA also has live virus, and is working on producing more RNA.
BEI is producing genomic RNA that may be available this week or next. They are also working on inactivated (irradiated) virus. Once sufficient quantity of virus is produced, it needs to be irradiated and then QC tested to ensure it's not viable – this requires 2 passages, each 14 days. Maureen Beanan at NIH reported to the Dx WG on 2/14 that BEI estimated material would be avaible late March. I've copied Maureen here to see if she has any updates. In an email with Uwe last week, Maureen agreed to have BEI reserve some RNA and irradiated virus for Dx developers. We can use the Dx WG to discuss prioritization.
Hope this helps.
Rosemary

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**From:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 7:53 PM
**To:** Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>
**Cc:** Woodson, Sara (NIH/NIAID) [F] (b) (6) @nih.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Subject:** RE: USG SSWG Updates

Thanks Ruvani, we are aware of the purified RNA. We have obtained the BEI strain and will be starting soon to work with it at CBER as you know. However, inactivated virus will be the ideal material ASAP. Please let us know when this becomes available. Mayra

---

**From:** Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>
**Sent:** Saturday, February 22, 2020 5:32 PM
**To:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Cc:** Woodson, Sara E (NIH) (b) (6) @nih.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Subject:** Re: USG SSWG Updates

Hi Mayra,

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It is my understanding that BARDA (Rosemary Humes) and NIH have been working together to get WRCEVA to produce purified RNA for diagnostic developers (which should be available sooner than inactivated virus). I also understand that

the Diagnostics subworking Group led by Rosemary under the MCM Task Force has prioritized recipients for the purified virus.

I'm not sure about the timeline for availability of inactivated stocks. Copying Rosemary and Sara to verify.

Best,
Ruvani

Sent from my iPhone

On Feb 22, 2020, at 4:44 PM, Garcia, Mayra <Mayra.Garcia@fda.hhs.gov> wrote:

Dear Ruvani,

We are in urgent need of BSL-2 level viral stocks to provide to developers. I have checked the WRCEVA web site and found they are distributing the USA_WA1/2020 strain. Have you received any updates about other viral stocks that may be available soon at UTMB/WRCEVA or BEI?

I believe UTMB/WRCEVA was also attempting to have an inactivated stock faster than what was promised by BEI or what we can get done at FDA. Is this still the case?

Let me know if you prefer I contact Sara Woodson directly.

Many thanks,

Mayra

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**From:** Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>
**Sent:** Friday, February 07, 2020 4:03 PM
**To:** Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Fernandez, Jose A (OS) <Jose.Fernandez@hhs.gov>; Weinberger, Collin (OS) <Collin.Weinberger@hhs.gov>; Moudy, Robin (OS) <Robin.Moudy@hhs.gov>; Donis, Ruben (OS) <Ruben.Donis@hhs.gov>; Erlandson, Karl (OS) <Karl.Erlandson@hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Raychaudhuri, Gopa <Gopa.Raychaudhuri@fda.hhs.gov>; Munster, Vincent J (NIH) (b) (6) @nih.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>; Graham, Barney S (NIH) (b) (6) @mail.nih.gov>; Embry, Alan C (NIH) (b) (6) @niaid.nih.gov>; 'Earnhart, Christopher G CIV USARMY DOD JPEO CBRND (US' (b) (6) @mail.mil>; 'Hepburn, Matthew J CIV USARMY (USA' (b) (6) @mail.mil>; 'Kurnat, Rebecca J CIV USARMY DOD JPEO CBRND (USA' (b) (6) @mail.mil>; 'Kilianski, Andrew CIV USARMY DOD JPEO CBRND (USA' (b) (6) @mail.mil>; 'Ivan.Zapata@(b) (6) 'julia.limage@(b) (6) 'kimberly.coleman@(b) (6) 'andrew.scott@(b) (6) 'Jodi.Kouts@bis.doc.gov'; 'Kimberly.Orr@bis.doc.gov'; 'Karin.Ferriter@USPTO.GOV'; 'Minna.Moezie@USPTO.GOV'; Stahlman, James (MIL) (b) (6) @mail.mil>; 'dan.e.harms.civ@(b) (6) Music, Francesca (MIL) (b) (6) @mail.mil>; 'brett.m.forshey.mil@(b) (6) 'jose.l.sanchez(b) (6) 'jonathan.r.kording(b) (6) ; 'nathan.j.pawlicki(b) (6) 'kathleen.a.hinds.civ@(b) (6) 'adam.w.armstrong(b) (6) ; 'cindy.k.fuchs.(b) (6) (b) (6) @fbi.gov'; (b) (6) @fbi.gov'; Lobel, Hannah (STATE.GOV) <lobelhj@state.gov>; 'Pandemic-Response-OES@state.gov'; 'SeedorffJE@state.gov'; Tobert, Gwen (STATE.GOV) <tobertgm@state.gov>; (b) (6) @omb.eop.gov'; (b) (6) @ustr.eop.gov'; (b) (6) @ustr.eop.gov'; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Humes, Rosemary (OS)

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**Subject:** USG SSWG Updates

Colleagues,

Since sending out the request for information, we have two good news developments:

1) BEI Resources is now accepting orders for 2019-nCoV virus under catalog number NR-52281. Please note that this material is a BSL-3 pathogen requiring BEI Level 3 registration and a CDC permit for domestic shipments. To request virus, please go to the BEI Resources website.

2) UTMB/WRCEVA should also be ready distribute on Wednesday. WRCEVA has not updated their website yet, so if you want to request virus, contact Sara Woodson (sara.woodson@nih.gov)

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A HUGE thanks to the teams at CDC, NIH, BEI, and WRCEVA who are making all of this happen!! The SSWG will continue monitoring the availability of viral isolates, but expect BEI and UTMB will be able to meet USG priority needs.

Other important updates (attached document has more detail) include:

One vial of PBMC was collected under the NIH IRB-protocol. Due to the urgent nature to prioritize a recipient, a small group consultation with representation from CDC, DoD, FDA and NIH, made a decision was made to share this with AbCellera.

We were made aware that WHO is providing problematic guidance to countries on negotiating material transfer agreements (MTA), which could result in protracted MTA negotiations. This issue has been raised with WHO at a high-
1) level and we hope to have a resolution soon. If you encounter this and any other types of challenges related to sample sharing, please let us know.

2)

Best,
Ruvani

**Ruvani Chandrasekera**
Executive Secretariat, USG Sample Sharing Working Group
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**Subject:** [URGENT REQUEST] USG SSWG Request and other Updates

Colleagues,

Please revisit your needs for live virus that was collated in the attached spreadsheet last month. If there is an urgent need for virus that cannot wait until BEI is up and running next week, please provide a strong justification and the contact information. CDC has a small number available for very high priority requests. Please coordinate this information through your agency POCs (unless told otherwise by someone in your agency) and provide a response to me by **3pm today**.

Below are some of the POCs I have:
DoD- COL Kishimori, Dan Harms, Christy Music
FDA- Michael Mair

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CDC- Wendi Kuhnert-Tallman
NIH- Hilary Marston
DHS- Ivan Zapata

Other News/Reminders:
1) *IMPORTANT* BEI can distribute virus to BSL-3 labs that are registered with them. If your BSL-3 lab is not already registered with BEI, you might want to do this so you can order virus.
2) Good news! Dr. Kadlec and Dr. Redfield have signed and transmitted letters to their counterparts in the interagency requesting use of the EUSLA. I will share the pdfs later today for your awareness.

Thanks,
Ruvani

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(CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; 'Reames, Marie-Christine (CDC/DDPHSS/OS/OTI)' <ppk0@cdc.gov>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Hobson, John (Peyton) (FDA/CBER) <JOHN.HOBSON@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] (b) (6) @OD.NIH.GOV>; Cassetti, Cristina (NIH/NIAID) [E] (b) (6) @niaid.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] (b) (6) @niaid.nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] (b) (6) @niaid.nih.gov>; Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; 'kchittenden@usaid.gov'; 'Beth.N.Harris@aphis.usda.gov'; 'Burke.L.Healey@aphis.usda.gov'; 'David.Stiefel@dm.usda.gov'; 'Kishimori, Jennifer M LTC USARMY MEDCOM USAMMDA (US' (b) (6) >; 'Smith, Michael Aaron CIV OSD OUSD A-S (USA)' (b) (6) .>; Galloway, Summer (CDC/DDID/NCIRD/ID) <nmd3@cdc.gov>; Thornton, Cody (mail.mil) (b) (6) ; 'Beth Lautner' <Elizabeth.a.lautner@usda.gov>; 'Randall Levings' <Randall.l.levings@usda.gov>; 'Stiefel, David - OHS, Washington, DC' <david.stiefel@usda.gov>; 'Costello, Kelly E' <CostelloKE@state.gov>; Williams, Seymour (CDC/DDPHSIS/CGH/DGHP) <sjw9@cdc.gov>; 'Letizia, Andrew G CDR USN NAVMEDRSCHCEN SVS MD (USA' (b) (6) >; 'Bumb, Ambika' <BumbA@state.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Donabedian, Armen (OS/ASPR/BARDA) <armen.donabedian@hhs.gov>; Vaught, Andrea (OS/ASPR/BARDA) (CTR) <Andrea.Vaught@hhs.gov>; Woodbury, Robyn (OS/ASPR/BARDA) (CTR) <Robyn.Woodbury@hhs.gov>; 'Viar, William T (Todd) COL USARMY OSD OUSD POLICY (USA' (b) (6) .>; 'Eddy, Vanessa M CIV OSD OUSD POLICY (USA' (b) (6) ; 'HARVEY, MELISSA' (b) (6) ; Marinissen, Maria (HHS/OS/OGA) <Maria.Marinissen@hhs.gov>; Huntley, Heather (CDC/OCOO/OGC) <hhh1@cdc.gov>; McClee, Von (CDC/DDPHSIS/CPR/DSAT) <clo2@cdc.gov>; Deming, Damon (FDA/CDER) <Damon.Deming@fda.hhs.gov>; 'Armstrong, Adam W CAPT USN NAVMEDRSCHCEN SVS MD (USA' (b) (6) >; Donaldson, Eric (FDA/CDER) <Eric.Donaldson@fda.hhs.gov>; 'Kording, Jonathan R CTR OSD HA (USA' (b) (6) >; 'Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (USA' <cindy.k.fuchs.civ@mail.mil>; 'Hinds, K Allison (Dr. ) CIV JS J3 (USA' <(b) (6) >; 'Zapata, Ivan' (b) (6) ; 'Jodi Kouts' <Jodi.Kouts@bis.doc.gov>; 'Taylor, Justin (CTR' (b) (6) ; 'Moe, Matthew' (b) (6) >; 'Seedorff, Jennifer E' <SeedorffJE@state.gov>; 'Watson, Ian D. EOP/OSTP' (b) (6) @ostp.eop.gov>; 'Ferro, Phil J. EOP/NSC' (b) (6) @nsc.eop.gov>; 'Harms, Dan E CIV DHA HSDS (USA' (b) (6) >; 'Wahl, Victoria M. (CTR' (b) (6) ; 'Schlater, Linda K - APHIS' <linda.k.schlater@usda.gov>; Tse, Brian (OS/ASPR/BARDA) <Brian.Tse@hhs.gov>; Stemple, Kimberly (NIH/NIAID) [E] (b) (6) @niaid.nih.gov>; Ledgerwood, Julie (NIH/NIAID) [E] (b) (6) @niaid.nih.gov>; 'Hoey, Lee D CTR (USA' (b) (6) ; (b) (6) @ostp.eop.gov' (b) (6) @ostp.eop.gov>; Degrace, Marciela (NIH/NIAID) [E] <(b) (6) @nih.gov>; Bozick, Brooke (NIH/OD) [E] (b) (6) @nih.gov>; 'Tomlinson.Christine@epa.gov' <Tomlinson.Christine@epa.gov>

**Cc:** Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>; Tewell, Adam (OS/ASPR/SPPR) <Adam.Tewell@hhs.gov>; Locus, Tiffany (OS/OGA) <Tiffany.Locus@hhs.gov>; Kibunja, Julia (OS/OGA) <Julia.Kibunja@hhs.gov>; Elvander, Erika (OS/OGA) <Erika.Elvander@hhs.gov>; 'Smith, Steven T (Geneva' <SmithST1@state.gov>; Tracy Carson <CarsonTL@state.gov>; Lawrence, Theresa (OS/ASPR/SPPR) <Theresa.Lawrence@HHS.GOV>; DeBord, Kristin (OS/ASPR/SPPR) <Kristin.DeBord@hhs.gov>; LaHood, Natalie (OS/OGA) <Natalie.Lahood@hhs.gov>; Aasen, Adam (HHS/OS/OGA) <Adam.Aasen@hhs.gov>

**Subject:** RE: USG SSWG Call to coordinate 2019-nCoV sharing

Colleagues,

Attached are the notes from our call yesterday with a few updates based on developments today (Feb 5). If you note any inaccuracies, please let me know. I've also attached the updated Permit/License requirements document.

<< File: PermitLicense requirements_20200205.docx >> << File: SSWG Notes_20200204.docx >>

To provide BEI with the priority USG recipients as we discussed on the call, I will work with our core SSWG members (reps from NIH, FDA, CDC, DoD, BARDA, DHS, etc) in the next two days to review the list of recipients that were submitted to the SSWG last month.

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Best,

Ruvani

***Ruvani Chandrasekera***
*HHS/ASPR/ International Policy*
Office (b) (6) | Cell: (b) (6)

-----Original Appointment-----
**From:** Chandrasekera, Ruvani (OS/ASPR/SPPR)
**Sent:** Wednesday, January 29, 2020 1:33 PM
**To:** Chandrasekera, Ruvani (OS/ASPR/SPPR); Kerr, Lawrence (HHS/OS/OGA; Disbrow, Gary (OS/ASPR/BARDA); Fernandez, Jose (OS/OGA); Weinberger, Collin (OS/OGA); Moudy, Robin (OS/ASPR/SPPR); Donis, Ruben (OS/ASPR/BARDA); Erlandson, Karl (OS/ASPR/BARDA); Abram, Anna (FDA/OC); Mair, Michael (FDA/OC); Farley, John (FDA/CDER); Marks, Peter (FDA/CBER); Birnkrant, Debra B (FDA/CDER); Styrt, Barbara (FDA/CDER); Scherf, Uwe (FDA/CDRH); Sapsford, Kim E (FDA/CDRH); Cho, David S (CBER) (FDA/CBER); Raychaudhuri, Gopa (FDA/CBER); Munster, Vincent (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; Graham, Barney (NIH/VRC) [E]; Embry, Alan (NIH/NIAID) [E]; 'Earnhart, Christopher G CIV USARMY DOD JPEO CBRND (US'; 'Hepburn, Matthew J CIV USARMY (USA'; 'Kurnat, Rebecca J CIV USARMY DOD JPEO CBRND (USA'; 'Kilianski, Andrew CIV USARMY DOD JPEO CBRND (USA'; 'Ivan.Zapata@(b) (6) '; 'julia.limage@(b) (6) '; 'kimberly.coleman@(b) (6) '; 'andrew.scott@(b) (6) '; 'Jodi.Kouts@bis.doc.gov'; 'Kimberly.Orr@bis.doc.gov'; 'Karin.Ferriter@USPTO.GOV'; 'Minna.Moezie@USPTO.GOV'; Stahlman, James (MIL); 'dan.e.harms.civ@mail.mil'; Music, Francesca (MIL); 'brett.m.forshey.(b) (6) '; 'franca.r.jones.(b) (6) '; 'jose.l.sanchez(b) (6) ; 'jonathan.r.kording.(b) (6) 'nathan.j.pawlicki(b) (6) '; 'kathleen.a.hinds.(b) (6) ; 'adam.w.armstrong1(b) (6) '; 'cindy.k.fuchs(b) (6) ; (b) (6) @fbi.gov'; (b) (6) @fbi.gov'; Lobel, Hannah (STATE.GOV); (b) (6) ; 'SeedorffJE@state.gov'; Tobert, Gwen (STATE.GOV); (b) (6) @omb.eop.gov'; (b) (6) @ostp.eop.gov'; (b) (6) @nsc.eop.gov'; (b) (6) @ustr.eop.gov'; (b) (6) @ustr.eop.gov'; 'Hafez.Ahmed@epa.gov'; Bright, Rick (OS/ASPR/BARDA); Humes, Rosemary (OS/ASPR/BARDA); Lueptow, Rebekka (OS/ASPR/BARDA); CGH/OD Policy Office Inbox (CDC.GOV); Kuhnert-Tallman, Wendi (CDC/DDID/OD); Montgomery, Joel M. (CDC/DDID/NCEZID/DHCPP); Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI); Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Brand, Kevin (CDC/DDPHSS/OS/OTI); Sanchez, Angela J. (CDC/DDPHSS/OS/OTI); Garcia, Mayra (FDA/CDRH); Hobson, John (Peyton) (FDA/CBER); Berkley, Dale (NIH/OD) [E]; Cassetti, Cristina (NIH/NIAID) [E]; Mowatt, Michael (NIH/NIAID) [E]; Ranjan, Mukul (NIH/NIAID) [E]; Ferrey, Seth (OS/OGA); Stewart, Jessica L. (HHS/OS/OGA); Foster, Joseph (CDC/OCOO/OGC); Sherman, Susan (HHS/OGC); 'kchittenden@usaid.gov'; 'Beth.N.Harris@aphis.usda.gov'; 'Burke.L.Healey@aphis.usda.gov'; 'David.Stiefel@dm.usda.gov'; Kishimori, Jennifer M LTC USARMY MEDCOM USAMMDA (US; 'Smith, Michael Aaron CIV OSD OUSD A-S (USA)'; Galloway, Summer (CDC/DDID/NCIRD/ID); 'Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA'; 'Smith, Steven T (Geneva'; Locus, Tiffany (OS/OGA); Kibunja, Julia (OS/OGA); Elvander, Erika (OS/OGA); Tracy Carson; Lawrence, Theresa (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Beth Lautner; Randall Levings; Stiefel, David - OHS, Washington, DC; Costello, Kelly E; Williams, Seymour (CDC/DDPHSIS/CGH/DGHP); Letizia, Andrew G CDR USN NAVMEDRSCHCEN SVS MD (USA; Bumb, Ambika; Armstrong, Kimberly (OS/ASPR/BARDA); Donabedian, Armen (OS/ASPR/BARDA); Vaught, Andrea (OS/ASPR/BARDA) (CTR); LaHood, Natalie (OS/OGA); Woodbury, Robyn (OS/ASPR/BARDA) (CTR); Viar, William T (Todd) COL USARMY OSD OUSD POLICY (USA; Eddy, Vanessa M CIV OSD OUSD POLICY (USA; HARVEY, MELISSA; Marinissen, Maria (HHS/OS/OGA); Huntley, Heather (CDC/OCOO/OGC); McClee, Von (CDC/DDPHSIS/CPR/DSAT); Ayala, Ana (OS/ASPR/SPPR); Tewell, Adam (HHS/ASPR/OPP)
**Cc:** Deming, Damon; Armstrong, Adam W CAPT USN NAVMEDRSCHCEN SVS MD (USA); Donaldson, Eric; Kording, Jonathan R CTR OSD HA (USA); Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (USA); Hinds, K Allison (Dr. ) CIV JS J3 (USA); Zapata, Ivan; Jodi Kouts; Taylor, Justin (CTR); Moe, Matthew; Seedorff, Jennifer E; Watson, Ian D. EOP/OSTP; Ferro, Phil J. EOP/NSC; Harms, Dan E CIV DHA HSDS (USA); Wahl, Victoria M. (CTR); Kimberly Orr; Schlater, Linda K - APHIS; Tse, Brian (OS/ASPR/BARDA); KELLY, SUZETTE P; Abu.Sayed@aphis.usda.gov; Deborah.L.Dufficy@aphis.usda.gov; Troy.T.Bigelow@aphis.usda.gov; Zhaowei.Liu@aphis.usda.gov; Wesley.Johnson@bis.doc.gov; Degruy, Glen A. (CDC/DDPHSIS/CPR/DSAT); Cremer, Thomas (CDC/DDPHSIS/CPR/DSAT); KStauffer@cdc.gov; Mullan, Robert (CDC/DDID/NCEZID/DGMQ); Malarkey, Mary (FDA/CBER); Dunn, Jessica

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(FDA/CBER); LAPITAN, ROMELITO; tamesha_woulard.fws.gov; Stemple, Kimberly (NIH/NIAID) [E]; Ledgerwood, Julie (NIH/NIAID) [E]; Valentin, Sarita; Aasen, Adam (HHS/OS/OGA); Hoey, Lee D CTR (USA); Stauffer, Kendra E. (CDC/DDID/NCEZID/DGMQ)
**Subject:** USG SSWG Call to coordinate 2019-nCoV sharing
**When:** Tuesday, February 4, 2020 1:30 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** Number: (b) (6)

**Updated with attachments:**
1) Agenda
2) EUSLA Template for nCoV
3) Permit/License requirements to import/export samples (draft)
<< File: EUSLATemplate_2019-nCoV_Final.docx >> << File: SSWG Agenda_20200201.docx >> << File: PermitLicense requirements_20200130_collated.docx >>

**Teleconference info:**
Number: (b) (6)

If you encounter issues with the line, please use the following number
Number: (b) (6)

**
USG Sample Sharing Working Group Colleagues,

We will hold a call on Tuesday, Feb 4 at 1.30pm for the group to share updates related to 2019-nCoV sample sharing.

If you have specific items you would like to discuss, please send them to me (Ruvani.chandrasekera@hhs.gov) for inclusion in the agenda (to be sent closer to the date of the call).

Thanks,
Ruvani

**Ruvani Chandrasekera**
Executive Secretariat, USG Sample Sharing Working Group
Office of the Assistant Secretary for Preparedness and Response
International Policy Branch

**HEALTH AND HUMAN SERVICES (DHHS)** | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515
o: (b) (6) m: (b) (6)
ruvani.chandrasekera@hhs.gov | (b) (6)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/22/2020 8:39:56 AM
**To**: Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Mielech, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Cut-off change - lot release testing criteria

**Importance**: High

Steve,

DMD reviewed your QC data summary for oligo sets N1, N2 and RP. The component testing of N1, N2 and RP each on (b) (5) well plates of NTC sample generating a total number of (b) (5) data points for each target component. No false positive results were observed. N1, N2, and RP passed your QC testing criteria.

The review team does not have any questions regarding this data set, so would not request a conference call today. Were there other items, you and your team are planning to address in a call?

When the N3 QC testing data is available and shows no false positive results for N3 on 288 data NTC samples, please combine the new QC testing data and submit the complete QC testing results of all components in one email for FDA concurrence.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
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**From:** Scherf, Uwe
**Sent:** Friday, February 21, 2020 5:50 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, we will review and will get back to you tomorrow.

Best, Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 3:37 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hello Uwe,
We would like to share with you our bulk QC data summary for oligo sets N1, N2 and RP for your review. We continue to manufacture N3 and will forward as soon as that data is reviewed.
Please be aware there are two tab in the excel file.
Please let us know if you have questions.
Do you and your colleagues have a time tomorrow that you would like to arrange a call to discuss?
Thank you very much.
Steve

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
For clarification the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel consists of two separate boxes. Box #1 contains the primers and probes as described below:

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**2019-nCoVEUA-01 Box #1: Primers and Probes**

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
|---|---|---|---|---|
| 2019-nCoV_N1 | RV202001 | 2019-nCoV_N1 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N2 | RV202002 | 2019-nCoV_N2 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N3 | RV202003 | 2019-nCoV_N3 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| RP | RV202004 | Human RNase P Forward Primer/Probe Mix | 22.5 nmol | 1000 |

Primer and probes from three individual boxes that were randomly selected after kit assembly were tested as presented in the powerpoint file provided earlier.

Also as requested, please find attached the QC testing process of primer/probe reagents at bulk and post-fill analysis.

We hope this helps to clarify the data presented and addresses your request.
Thank you very much.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 10:07 AM
**To:** 'Scherf, Uwe' <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
The samples tested represent 3 randomly selected kits at “final kit”. I hope this addresses your question.
We will send a meeting invitation shortly for 1pm if that time is still OK for your team.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum,

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Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing(b) (5)

Thanks,
Uwe

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| (b) (5) | | | | |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

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Dear Steve,

Thank you for the update, when will you send us the performance data for all assays to understand your rational to exclude N3?

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

Q1: Clarify how many total lots of EUA reagents are being distributed?
(b) (5)

Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5)

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (5)

Please let us know if you have any additional questions.
Thank you very much!
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5)

[redacted]

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara

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<Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5)

If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts (b) (5) [redacted]

Thanks,
Uwe

---

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

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Thanks,
Uwe

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) . We will need to work to find more detailed information for you.

Thanks,
Julie

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) , is that correct?

Thank you for your feedback.

Uwe

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/24/2020 8:50:11 PM
**To**: Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: Information request

---

**From:** Scherf, Uwe
**Sent:** Friday, February 21, 2020 12:54 PM
**To:** Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Subject:** RE: Information request

Yes, thanks. Uwe

---

**From:** Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>
**Sent:** Friday, February 21, 2020 12:53 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Subject:** RE: Information request

Thanks Uwe. At this time, BEI anticipates the inactivated virus will be available at the end of March – for planning purposes, would it be helpful to ask them to reserve 75 vials of this reagent as well?
Maureen

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 12:44 PM
**To:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>
**Cc:** Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>
**Subject:** RE: Information request

Maureen,

Yes, it will be very helpful to reserve a portion of this lot (b) (5) ) to be used for bridging studies with the CDC assay.

Thanks, Uwe

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Friday, February 21, 2020 12:17 PM
**To:** Beanan, Maureen J (NIH) (b) (6) @mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** RE: Information request

Hi Maureen,
Thanks for the follow up. I will defer to FDA on this, but seems to me the better material to reserve would be inactivated virus when it is available. The CDC is still working on replacement reagents for their assay, so it will be awhile before PHLs are equipped to do testing and have the capacity to do any bridging studies. Prioritizing inactivated

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viruses to companies that they can use to contrive clinical samples may be the best way to get some initial performance data for EUA, especially if surge capacity is needed quickly.
Thanks again,
Rosemary

**From:** Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>
**Sent:** Friday, February 21, 2020 12:02 PM
**To:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Cc:** Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>
**Subject:** RE: Information request

Hi Rosemary and Uwe,
We haven't yet heard back from UTMB, however (b) (5) viral genomic RNA is going to become available in the catalog either today or Monday. There are (b) (5) vials available from this first lot. Would it be helpful to reserve a portion of this lot (b) (5) vials?) to be used for bridging studies with the CDC assay?
Maureen

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Friday, February 21, 2020 10:44 AM
**To:** Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Cc:** Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>
**Subject:** Information request

Hi Maureen,
Uwe Scherf (copied here) contacted me this morning to ask if UTMB would provide more information on the RNA that is being sent to the companies so FDA can better evaluate any data that companies may produce with the RNA. If Dr. Plante has a product sheet that he can share with BARDA and FDA that would be extremely helpful. Thanks very much!!

Uwe:
The companies agreed to by the Diagnostics Interagency WG are: (b) (4) We also added (b) (4), so the total is 11 companies. All of these companies have or use FDA-cleared platforms that are currently placed in U.S. healthcare centers. All have confirmed they are working on an assay for SARS-CoV-2, and have contacted FDA for the EUA template. The (b) (4) assays have potential for POC use depending on FDA requirements.

Companies were notified by NIH with this message:
The World Reference Center for Emerging Viruses and Arboviruses (WRCEVA) supported by NIH/NIAID has prepared small quantities of genomic RNA. In collaboration with our interagency partners, (company name) has been prioritized for receipt since you are actively developing a SARS-CoV-2 assay for use on an FDA cleared platform. The material was prepared from cell culture of SARS-CoV-2 virus (USA_WA1/2020), it will be distributed as BSL-2 and shipped on dry ice. Permits may be required for international shipments. If you are interested in receiving the materials, or have additional questions, please contact (contact information provided) for more details and a copy of the Material Transfer Agreement.
Additional material including genomic RNA and Irradiated virus will be available from BEI Resources (b) (4) in the coming weeks. that the material is available, and if they are interested they should contact UTMB. Contact information was provided.

Please let me know if there is anything else I can do to help.
Rosemary

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Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
Cell: (b) (6)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 5:49:39 PM
**To**: Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) [sql5@cdc.gov]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Mielech, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]
**Subject**: RE: Cut-off change - lot release testing criteria

Steve,

Thanks, we will review and will get back to you tomorrow.

Best, Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 3:37 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hello Uwe,
We would like to share with you our bulk QC data summary for oligo sets N1, N2 and RP for your review. We continue to manufacture N3 and will forward as soon as that data is reviewed.
Please be aware there are two tab in the excel file.
Please let us know if you have questions.
Do you and your colleagues have a time tomorrow that you would like to arrange a call to discuss?
Thank you very much.
Steve

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht,

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Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
For clarification the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel consists of two separate boxes. Box #1 contains the primers and probes as described below:

**2019-nCoVEUA-01 Box #1: Primers and Probes**

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
|---|---|---|---|---|
| 2019-nCoV_N1 | RV202001 | 2019-nCoV_N1 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N2 | RV202002 | 2019-nCoV_N2 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N3 | RV202003 | 2019-nCoV_N3 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| RP | RV202004 | Human RNase P Forward Primer/Probe Mix | 22.5 nmol | 1000 |

Primer and probes from three individual boxes that were randomly selected after kit assembly were tested as presented in the powerpoint file provided earlier.

Also as requested, please find attached the QC testing process of primer/probe reagents at bulk and post-fill analysis.

We hope this helps to clarify the data presented and addresses your request.
Thank you very much.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 10:07 AM
**To:** 'Scherf, Uwe' <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
The samples tested represent 3 randomly selected kits at “final kit”. I hope this addresses your question.
We will send a meeting invitation shortly for 1pm if that time is still OK for your team.
Thank you very much.

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Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing (b) (5)

Thanks,
Uwe

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| (b) (5) | | | | |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM

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**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Steve,

Thank you for the update, when will you send us the performance data for all assays to understand your rational to exclude N3?

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

Q1: Clarify how many total lots of EUA reagents are being distributed?
(b) (5)

Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5)

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (5)

Please let us know if you have any additional questions.
Thank you very much!
Steve

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**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5)

[redacted]

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5)

If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

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**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts (b) (5) [redacted]

Thanks,
Uwe

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.

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4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) . We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) , is that correct?

Thank you for your feedback.

Uwe

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/27/2020 8:57:20 AM
**To:** Humes, Rosemary (OS/ASPR/BARDA) [Rosemary.Humes@hhs.gov]
**Subject:** RE: Qiagen

Rosemary,

Thanks, Qiagen has requested the EUA template but has not submitted it to us yet. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Thursday, February 27, 2020 8:06 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Qiagen

Hi Uwe,
FYSA- As discussed , we are being asked about U.S. status everytime a company makes a press announcement about the availability of their test outside the US. This one from Qiagen raised a bunch of questions last night.

FEB 26 2020

# QIAGEN announces worldwide shipments of QIAstat-Dx test kits for SARS-CoV-2

**• QIAstat-Dx Respiratory 2019-nCoV Panel rapidly differentiates novel coronavirus from 21 other pathogens implicated in serious respiratory syndromes**

**• Panel being tested at four hospitals in China after initial evaluation on clinical samples by a leading Paris hospital**

**• Adds to QIAGEN's portfolio of molecular testing solutions to aid in global public health emergency**

**Hilden, Germany, and Germantown, Maryland, February 26, 2020 –** QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced it has shipped its newly developed QIAstat-Dx Respiratory Panel 2019-nCoV test kit to four hospitals in China for evaluation. The

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new kit detects the novel coronavirus SARS-CoV-2 and adds rapid Sample to Insight syndromic testing to QIAGEN's portfolio of molecular testing solutions in the public health emergency. QIAGEN is also in the process of shipping QIAstat-Dx testing kits to public health institutions in other regions, including Europe, South-East Asia, and the Middle East.

Since January QIAGEN has been providing instruments and consumables to support detection of the virus in China and other markets. Official protocols for SARS-CoV-2 detection include QIAGEN extraction kits, reagents and instruments for real-time polymerase chain reaction (RT-PCR) workflows. Customers also are deploying QIAsymphony modular instruments and NeuMoDx integrated PCR systems to automate higher-throughput processing of their laboratory-developed tests for SARS-CoV-2.

"Our dedicated task force has moved very fast to develop and make available the QIAstat-Dx respiratory panel with SARS-CoV-2 detection. We are partnering closely with authorities and customers around the world to bring rapid, accurate diagnosis to the fight against this deadly infectious disease," said Thierry Bernard, Interim CEO of QIAGEN and Senior Vice President, Head of the Molecular Diagnostics Business Area. "As we have in past health crises such as SARS and the swine flu, QIAGEN is working hard to deliver better, faster testing solutions for hospitals and public health institutions to aid in the effort to monitor and bring the outbreak under control. Our employees' extraordinary response embodies QIAGEN's core mission to make improvements in life possible."

The QIAstat-Dx system was introduced in Europe in 2018 as a CE-product and cleared by the Food and Drug Administration (FDA) in the United States in mid-2019. It enables fast, cost-effective and easy-to-use syndromic testing with novel Sample to Insight workflows. The system streamlines molecular testing from end to end. A technician simply loads a clinical sample (such as a swab) into a single-use QIAstat-Dx cartridge and places it in the analyzer. QIAGEN chemistries for sample processing and analysis are built in, and the QIAstat-Dx instrument delivers results in about one hour.

**New QIAstat-Dx testing solution for SARS-CoV-2**

The QIAstat-Dx Respiratory 2019-nCoV Panel is a new version of the existing QIAstat-Dx Respiratory Panel for differential analysis of 21 viral and bacterial pathogens in respiratory syndromes. Once the SARS-CoV-2 genome was sequenced in January, QIAGEN developed two highly sensitive assays to detect SARS-CoV-2 targeting Orb1ab and the E gene. The addition of these targets provides parallel tools for combined detection of the novel coronavirus with increased sensitivity.

The expanded QIAstat-Dx panel is currently being evaluated at the Bichat-Claude Bernard Hospital in Paris. "After more than a year of experience using the existing QIAstat-Dx Respiratory Panel to evaluate patients coming into our Emergency Department with respiratory syndromes, we are evaluating the new panel with SARS-CoV-2 against RT-PCR testing using WHO recommended protocols. The QIAstat-Dx solution can provide results in about one hour, with high sensitivity and specificity and minimal hands-on time for hospital or laboratory personnel," said Dr. Benoit Visseaux, Associate Professor of Virology at Bichat-Claude Bernard Hospital in Paris.

Amid the rapidly evolving response to the coronavirus outbreak, the regulatory status of the QIAstat-Dx Respiratory Panel will vary by location. QIAGEN will apply for emergency authorization for marketing of the new panel from the U.S., the Korean KCDC/MFDS, and FDA and China's National Medical Products Administration (NMPA); the panel will be available with CE-IVD marking in Europe and other markets.

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**Multiple other QIAGEN testing solutions for SARS-CoV-2**

QIAGEN has moved quickly on several fronts to provide molecular testing solutions to researchers working to counter the international threat from the SARS-CoV-2 virus. Building on its strong position and experience in molecular testing for infectious diseases, QIAGEN is providing a variety of solutions:

- Enabling laboratory-developed tests (LDTs) – extraction kits, PCR enzymes and instruments, supporting in-house testing by laboratories and public health institutions. CDC guidelines for RT-PCR testing list QIAGEN's EZ1 DSP Virus kits, which run on EZ1 Advanced workstations, and QIAamp DSP Viral RNA Mini kits, which can be automated on QIAcube instruments. Chinese authorities and the Berlin Charitè protocol also include QIAGEN consumables.
- Mid- and high-throughput automation – QIAsymphony modular systems for sample preparation and PCR analysis, as well as NeuMoDx 96 and 288 systems for fully integrated PCR analysis, enabling customers to implement higher-throughput solutions for laboratory-developed RT-PCR tests. QIAGEN recently started placing NeuMoDx systems in China, for use in with LDTs in SARS-CoV-2 testing.
- Additional real-time PCR tests – two new RT-PCR tests for detection of SARS-CoV-2 have been developed at QIAGEN sites in China and the United States and will be available for Research Use Only. The company is investigating potential emergency use options for the automated PCR-based test solutions.

Further information can be also found here

**About QIAGEN**

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in Molecular Diagnostics (human healthcare) and Life Sciences (academia, pharma R&D and industrial applications, primarily forensics). As of December 31, 2019, QIAGEN employed approximately 5,100 people in over 35 locations worldwide. Further information can be found athttp://www.qiagen.com.

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/22/2020 6:27:28 AM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

(b) (6)

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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uwe.scherf@fda.hhs.gov

***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 6:26 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Uwe I just called and got your voice mail – is there another number?

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 6:20 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

AMERICAN OVERSIGHT

I see you are online, can you give me a call to strategize? 301-796-5456. Thanks, Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 10:57 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

My comments are in the attached. (b) (5) [redacted]

Anyway let me know what you think
Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 9:19 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hi all,

AMERICAN OVERSIGHT

Comments from me and Marcy on the protocol are attached (b) (5) . Please let us know if you have any questions – my calendar is up to date on when I am available this weekend.

Thanks!
Claire

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 5:22 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: DRAFT CDC EUA Request for Sentinel Surveillance Activities

All,

Here the draft EUA request we just discussed. Thanks for getting this addressed so quickly.

Uwe

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Friday, February 21, 2020 10:40 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** DRAFT CDC EUA Request for Sentinel Surveillance Activities

Good morning Kim and Uwe,

Please find attached a draft EUA request submission for the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in sentinel surveillance activities. We would appreciate your review of this draft submission to ensure it contains the information and wording request necessary to support FDA's planned issuance of a second letter of authorization for the diagnostic panel to support this critical epidemiologic activity.

Please do not hesitate to reach out with questions, ideas, recommendations as you review the attached. I look forward to hearing from you.

Warm regards,
Laura

==

Laura E. Rose, RAC
CREDENTIALED PROFESSIONAL RAC RAC US
*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**
P: 404-639-1084 | E: LERose@cdc.gov

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---

OLSS Office of Laboratory Science and Safety

*Strengthening the culture of laboratory science and safety at CDC*

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 8:47:57 PM
**To:** Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** FW: Information request

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Friday, February 21, 2020 10:44 AM
**To:** Beanan, Maureen J (NIH) (b) (6) @mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Information request

Hi Maureen,
Uwe Scherf (copied here) contacted me this morning to ask if UTMB would provide more information on the RNA that is being sent to the companies so FDA can better evaluate any data that companies may produce with the RNA. If Dr. Plante has a product sheet that he can share with BARDA and FDA that would be extremely helpful. Thanks very much!!

Uwe:
The companies agreed to by the Diagnostics Interagency WG are: (b) (4) We also added (b) (4) so the total is 11 companies. All of these companies have or use FDA-cleared platforms that are currently placed in U.S. healthcare centers. All have confirmed they are working on an assay for SARS-CoV-2, and have contacted FDA for the EUA template. The (b) (4) assays have potential for POC use depending on FDA requirements.

Companies were notified by NIH with this message:
The World Reference Center for Emerging Viruses and Arboviruses (WRCEVA) supported by NIH/NIAID has prepared small quantities of genomic RNA. In collaboration with our interagency partners, (company name) has been prioritized for receipt since you are actively developing a SARS-CoV-2 assay for use on an FDA cleared platform. The material was prepared from cell culture of SARS-CoV-2 virus (USA_WA1/2020), it will be distributed as BSL-2 and shipped on dry ice. Permits may be required for international shipments. If you are interested in receiving the materials, or have additional questions, please contact (contact information provided) for more details and a copy of the Material Transfer Agreement.
Additional material including genomic RNA and Irradiated virus will be available from BEI Resources (www.beiresources.org ) in the coming weeks. that the material is available, and if they are interested they should contact UTMB. Contact information was provided.

Please let me know if there is anything else I can do to help.
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
Cell: (b) (6)

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/20/2020 11:51:05 AM
**To**: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**Subject**: RE: Draft Letter - EUA for CDC "surveillance"
**Attachments**: Draft CDC Protocol EUA 2019-nCoV Letter of Authorization 2-20-20.doc

Jennifer,

Kim and I worked on updating the draft letter, attached our comments.

Uwe

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 9:41 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** Draft Letter - EUA for CDC "surveillance"

Kim and Uwe,

If you revise the draft letter, then it may be ready for OCC to make edits. (b) (5)

Thanks,

Jennifer

-----Original Appointment-----
**From:** Ross, Jennifer
**Sent:** Wednesday, February 19, 2020 8:26 PM
**To:** Ross, Jennifer; Busch, Marcy; Dennis, Claire; Sadove, Elizabeth; Scherf, Uwe; Sapsford, Kim E
**Cc:** Stenzel, Timothy; Flannery, Ellen
**Subject:** Update on EUA for CDC "surveillance"
**When:** Thursday, February 20, 2020 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
**Where:** webex

CDC says they will submit a new EUA referencing the data in their first EUA in a day or two.
Protocol attached.
It would be good to touch base to ensure we are all on the same page for next steps.

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Maybe we would also be able to discuss a little about the draft letter of authorization:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the SARS-CoV-2 (formerly 2019-nCoV) in nasopharyngeal (NP) or oropharyngeal (OP) respiratory specimens collected from individuals consented or notified prior to sample collection that SARS-CoV-2 testing would be performed if specimens are negative for influenza and other respiratory pathogens in order to determine if unrecognized community transmission of SARS-CoV-2 is occurring, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing is limited to qualified laboratories designated by CDC to conduct testing according to protocol xxx and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.
-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

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Meeting password: (b) (6)

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If you are a host, go here to view host information.

Need help? Go to http://help.webex.com

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/17/2020 10:22:05 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: BY noon tomorrow
**Attachments:** Diagnostics for Coronavirus Timeline Projection v3.docx

Tim,

Attached my edits for the talking points. (b) (5)

Best,
Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:50 PM
**To:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Re: BY noon tomorrow

Hi Rosemary, That is news about the CDC assay. Thanks! Best, Tim

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Date:** February 17, 2020 at 8:47:31 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Re: BY noon tomorrow

Hi Tim,
Thanks for the response. One key point, the CDC assay, as I understand it, (b) (5)
(b) (5)

Look forward to feedback from you and Uwe on talking points and landscapes.
Rosemary

---

On: 17 February 2020 17:57,
"Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov> wrote:

Hi Rosemary, Here it is.

---

AMERICAN OVERSIGHT

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 17, 2020 at 1:05:25 PM EST

**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Thank you.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 17, 2020 at 12:40:22 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Uwe, My POC thoughts below. Copying Jeff for his awareness.

REALLLY need help from FDA and CDC to find a coordinated approach to communicate around Dx capacity, Dx testing development and DX utilization.
Need today -

1. throw some thoughts for what we can put in the one-pager into an email – will get a joint draft ready ASAP.

a. Uwe, please address regulatory issues, including EUA and CLIA requirements .

2. provide some ideas on what we can do to reality set this expectation.

Dear Rosemary,

Here are my thoughts.

(b) (5)

Development of POC devices:

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 17, 2020 at 9:59:06 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: BY noon tomorrow

Tim,

I need your help on this request, since I will not find time to provide feedback to Rosemary.

I am working with CDC on their change in cut-off proposal.

Thanks,
Uwe

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 8:36 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** BY noon tomorrow

Uwe and Wendi,
We have been asked to put together a one-pager and landscape on POC diagnostics discussing time (development and manufacturing (b) (5) costs and issues with developing a hand held diagnostic/tests.
As discussed on Friday's WG call, everything we have done to try to explain risk-benefit, issues and challenges with POC for this virus hasn't succeeded. I'll pull together what we have into a starting document, but REALLLY need help from FDA and CDC to find a coordinated approach to communicate around Dx capacity, Dx testing development and DX utilization.
Need today -

1. throw some thoughts for what we can put in the one-pager into an email – will get a joint draft ready ASAP.

a. Uwe, please address regulatory issues, including EUA and CLIA requirements .

2. provide some ideas on what we can do to reality set this expectation.

Thanks very much,
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
Cell: (b) (6)

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 8:47:30 PM
**To:** Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** FW: "Final" Dx development POC talking points and landscapes
**Attachments:** 2019-nCoV Diagnostics Landscape-POC 2-18-20.pptx; Diagnostics for Coronavirus Timeline Projection v4 clean.docx

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Tuesday, February 18, 2020 5:35 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Beanan, Maureen J (NIH) (b) (6) @mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA (b) (6) Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>; Schoske, Richard CIV DTRA J9 (USA) (b) (6)
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Eder, Paul (OS) <Paul.Eder@hhs.gov>; Lee, John S (OS) <John.Lee@hhs.gov>; Huynh, Chuong Q (OS) <Chuong.Huynh@hhs.gov>
**Subject:** "Final" Dx development POC talking points and landscapes

Dear Dx WG members,

1. Thanks to all for the quick turn around on the landscape and talking points. Attached are the versions that went up to BARDA OD at noon. The Dx landscape is fluid, changes in status and new companies discovered every day. We (b) (5) We appreciate your efforts to keep your leadership apprised of the requests and the WG strategy, please feel free to use these in briefing your leadership as needed.
2. Based on feedback received so far, (b) (5)
3. There is an MCM TF leads call Wednesday at 9am. I will provide the following report on our Dx WG activities:

(b) (5)

Again, sincere appreciation for all your help. If there are topics that you feel the WG should address, please let me know.
Thanks,
Rosemary

---

**From:** Humes, Rosemary (OS/ASPR/BARDA)
**Sent:** Monday, February 17, 2020 7:29 PM

AMERICAN OVERSIGHT

**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Carroll, Darin (CDC/DDID/NCEZID/OD) <zuz4@cdc.gov>; Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; 'Opdyke, Jason A CIV USARMY (USA' (b) (6) ; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] (b) (6) @nih.gov>; 'Schoske, Richard CIV DTRA J9 (USA)' (b) (6)
**Cc:** 'Stenzel, Timothy' <Timothy.Stenzel@fda.hhs.gov>; Eder, Paul (HHS/ASPR) (CTR) (Paul.Eder@hhs.gov) <Paul.Eder@hhs.gov>; Lee, John (OS/ASPR/BARDA) <John.Lee@hhs.gov>; Huynh, Chuong (OS/ASPR/BARDA) <Chuong.Huynh@hhs.gov>
**Subject:** For review by 11am Tuesday: Dx development POC talking points and landscapes

Diagnostics WG members,
Following up from earlier email. Thanks to all who were avaible to discuss/provide feedback today.
1. Slide deck: Need to deliver "POC" slide deck by noon Tuesday, please send comments by 11am (b) (5)

(b) (5)

Again, many thanks for all the support.
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
Cell: (b) (6)

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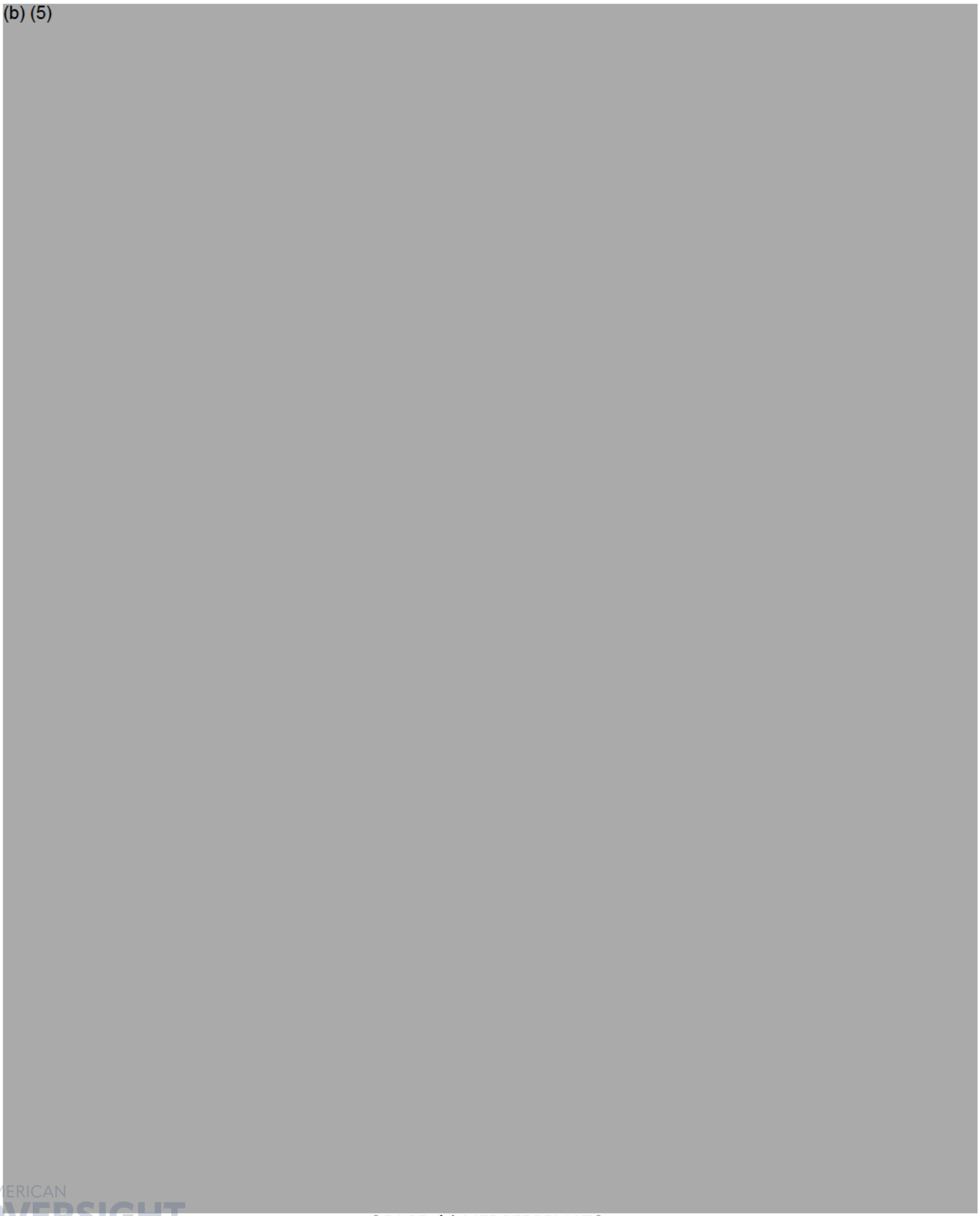



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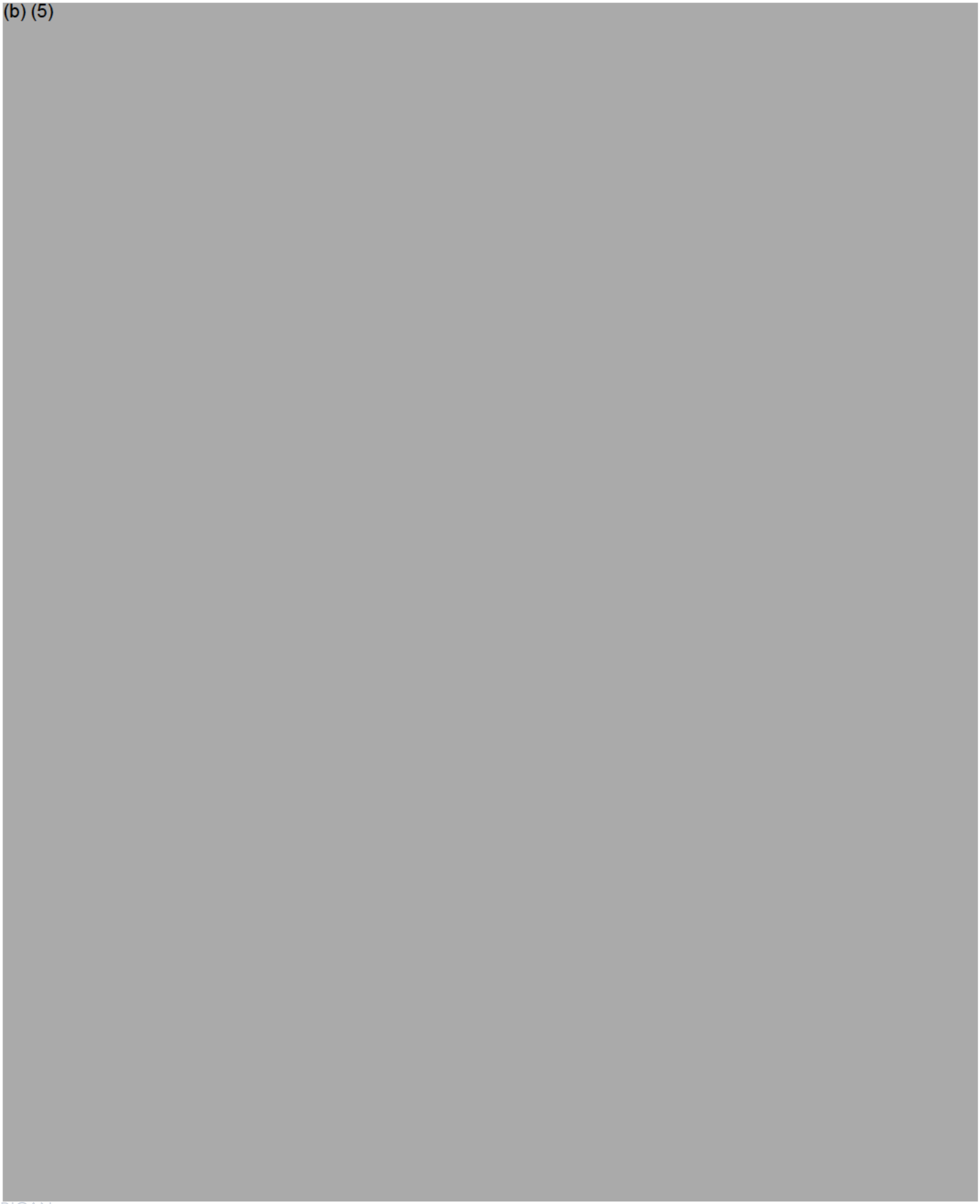

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(b) (5)



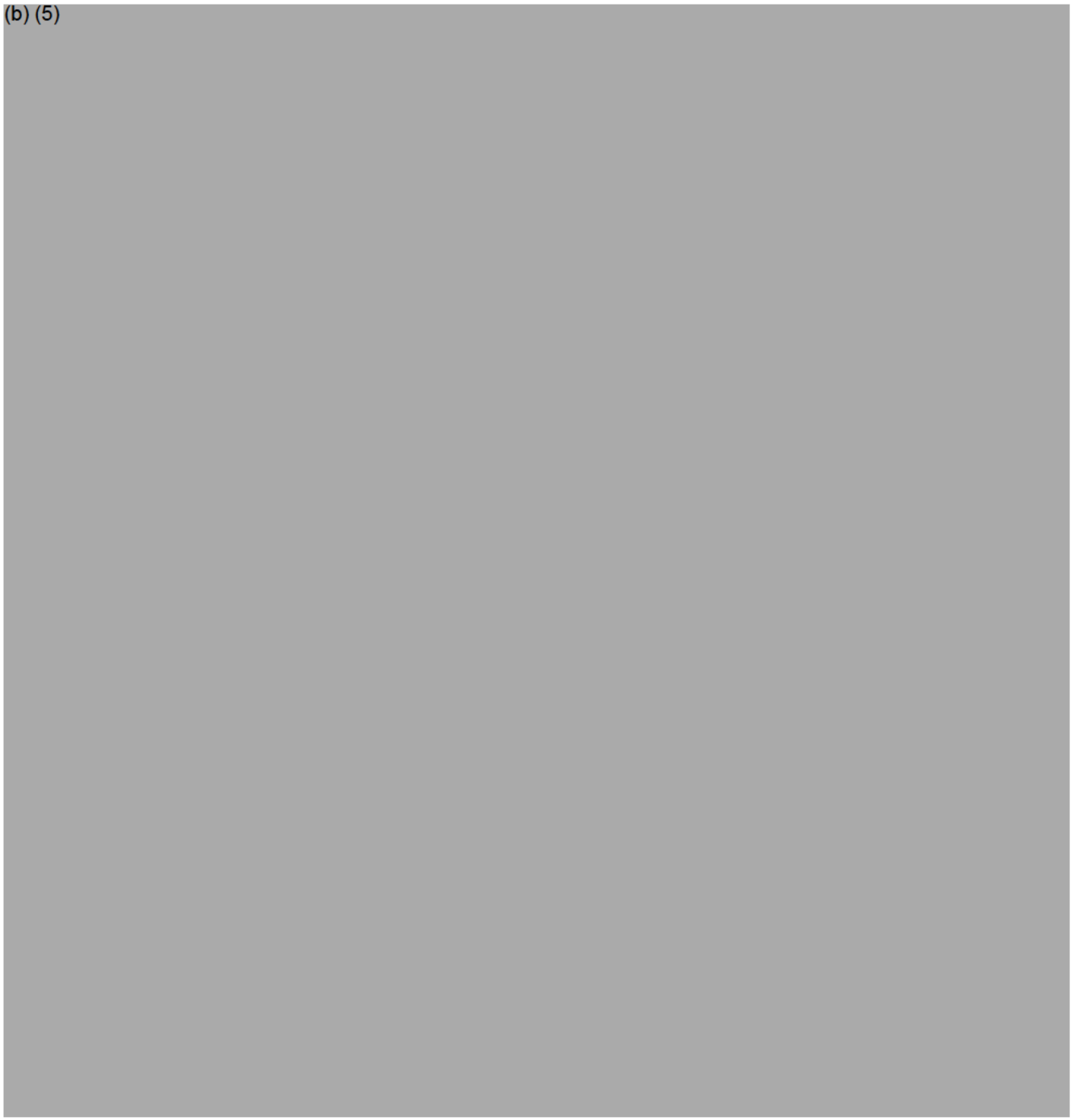
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(b) (5)



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(b) (5)



AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/19/2020 5:49:20 PM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Smith, Lia H (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cda5acfaea1403d98eeed026beb76bd-HHS-loh5-cd]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel: addition of ZEN probes

Julie,

Got it, will get back to you tomorrow. Might not need a phone call.

Best,
Uwe

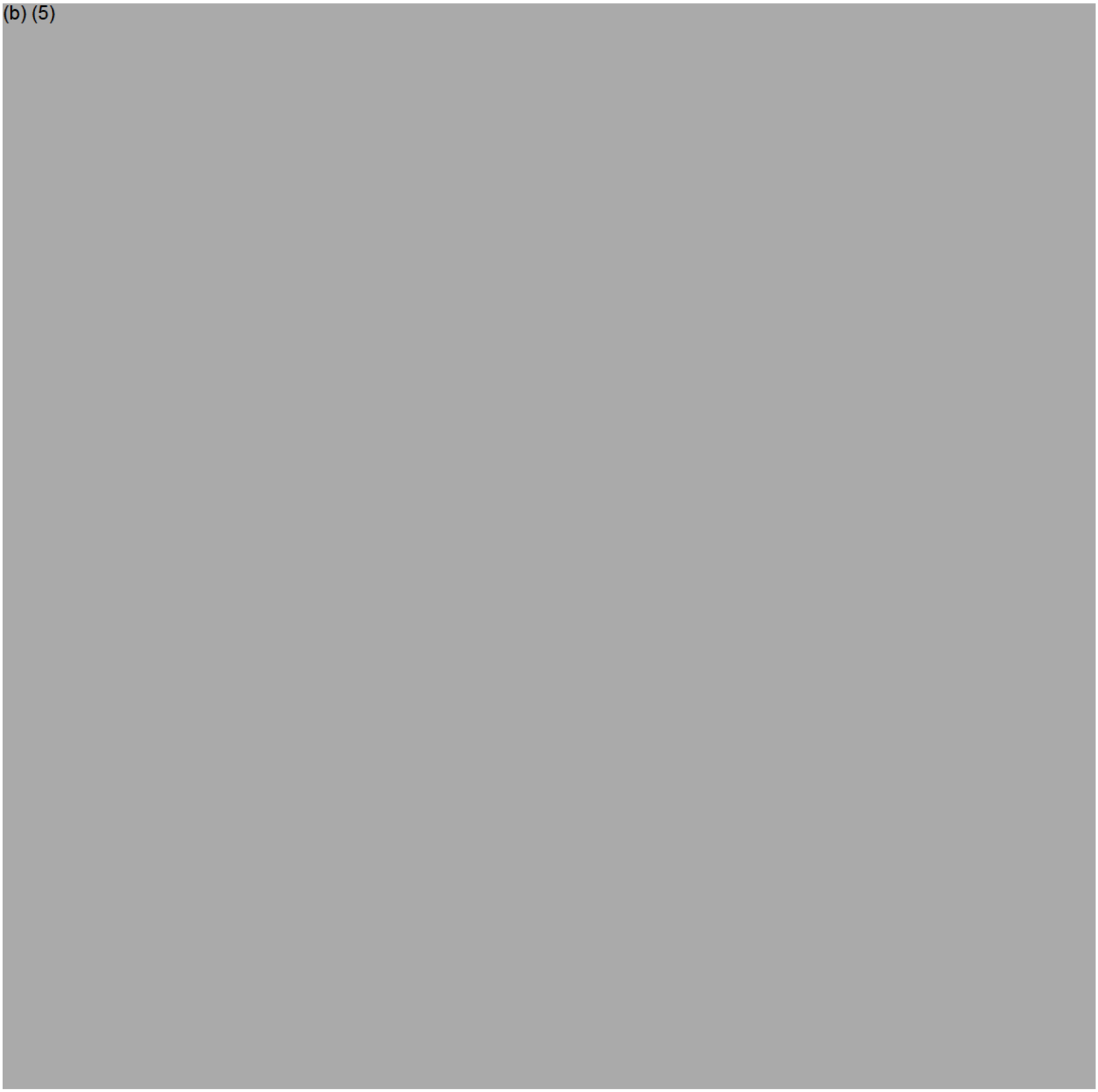
**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Wednesday, February 19, 2020 5:04 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>
**Subject:** CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel: addition of ZEN probes
**Importance:** High

Dear Uwe,

(b) (5)

AMERICAN OVERSIGHT

(b) (5)



Do you have time tomorrow to discuss this proposal? We are available from 9-10am, 11-11:30am, or after 3pm.

Thanks,

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/19/2020 5:43:22 PM
**To**: Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) [zey9@cdc.gov]
**CC**: Langley, Gayle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09640f099c74468d9480b73a6d194d5d-HHS-fez7-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Laura,

Here edits that clarify some of the points.

Thanks,
Uwe

(b) (5)

- Regulatory strategy

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

[redacted]

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Wednesday, February 19, 2020 2:32 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Good afternoon Uwe,

Thank you again for taking the time to meet with us today to discuss the regulatory considerations for community transmission surveillance. I wanted to share my understanding of the outcome of the meeting to ensure CDC and FDA are on the same page.

(b) (5)

[redacted]

AMERICAN OVERSIGHT

Please let me know if I have misunderstood our conversation or if I have missed a key point.

Many thanks,
Laura

==

Laura E. Rose, RAC




*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

**OLSS** Office of Laboratory Science and Safety

*Strengthening the culture of laboratory science and safety at CDC*

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/17/2020 12:27:56 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: Cut-off change - lot release testing criteria

Tim,

Here some information relevant for the discussion at 1 PM.

Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:58 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

(b) (5)

Thanks,
Li

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:41 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Cut-off change - lot release testing criteria

Good morning.

Based on the Ct range of the false positive N1 and N3 results, the proposed weak positive zone from (b) (5) Ct appears to be justified.

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

It will be very helpful if CDC can also share with us data from the public health laboratories in the field in the same format, especially the inconclusive specimens that were referred to the CDC for follow-up testing.

Thanks,
Li

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| (b) (5) | | | | |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Steve,

Thank you for the update, when will you send us the performance data for all assays to understand your rational to exclude N3?

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

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Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

Q1: Clarify how many total lots of EUA reagents are being distributed?
(b) (5)

Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5)

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (5)

Please let us know if you have any additional questions.
Thank you very much!
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>;

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Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5)

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

AMERICAN OVERSIGHT
(b) (5)

(b) (5)



If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

AMERICAN OVERSIGHT

Hi Julie & Steve,

As a part of your efforts in (b) (5) [redacted]

Thanks,
Uwe

---

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

AMERICAN OVERSIGHT

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/19/2020 1:12:25 PM
**To**: Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: Request for enforcement discretion

Information on testing of the passengers from the Diamond Princess cruise ship.

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Wednesday, February 19, 2020 12:14 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion

All, I wanted to follow up on this email thread related to the testing of the passengers from the Diamond Princess cruise ship. CDC does intend to test all passengers who have arrived in the US. Testing will occur this week and into the weekend from all 3 sites where these passengers are being housed (Travis, Lackland and Omaha). Once our testing is complete we will, as discussed here, provide information on the number of asymptomatic cases that are tested. Given that some of these passengers are now showing symptoms we plan to finalize that number upon completion of the testing to ensure accuracy.

Thanks,

**Wendi Kuhnert-Tallman**
**phone - 404-639-3103**

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:29 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion

Wendi,

We have worked through your request with the FDA attorneys. Given the limitations you describe and under the specific circumstances for which the testing will be performed, we will forgo requiring that CDC submit an application for a new EUA or a request to modify its existing EUA to include testing of asymptomatic individuals at CDC's headquarters in Atlanta, GA.

Kind regards,

Jeff

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Sunday, February 16, 2020 7:08 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC)

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<dbj0@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: Request for enforcement discretion

Jeff and others, we appreciate the response and will continue with our testing plan as discussed for this one set of samples.

Thanks, Wendi.

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 6:54:14 AM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Subject:** RE: Request for enforcement discretion

Wendi,

We are still working with the FDA attorneys to address your request. In the interim, CDC should proceed with its plans for testing the returning travelers from the Princess Diamond cruise ship. There should be no delay in the actions you need to take.

Kind regards,

Jeff

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Date:** February 15, 2020 at 7:12:25 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** RE: Request for enforcement discretion

Dear Uwe,

We wish to thank you and your colleagues at FDA for the rapid response to our urgent request for FDA enforcement discretion. We appreciate your willingness to allow our testing of returning US travelers from the Diamond Princess cruise ship, as required of CDC by HHS. CDC agrees to restrict testing to CDC's headquarters in Atlanta, GA and will agree to share data generated in this repatriation testing activity. However, CDC has concerns about the request that the intended use of the assay be modified to make testing of asymptomatic individuals a generally acceptable use of the authorized test.

AMERICAN OVERSIGHT
The testing CDC will be conducting on the returning passengers from the Diamond Princess is a unique activity. This population presents unique challenges that led to an HHS determination that testing of these individuals was necessary,

regardless of the presence of symptoms. CDC stands behind the PUI definition and testing guidance we have posted to CDC's website. This testing guidance provides guidelines appropriate to the current epidemiological situation within the United States. We are concerned that any change to the testing guidance/intended use to permit testing of asymptomatic individuals will unnecessarily increase testing demand and promote a use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel that CDC feels is inappropriate at the present stage of the response.

CDC would welcome the opportunity to discuss further.

We greatly appreciate FDA's partnership in this response.

Warm regards,
Wendi

**Wendi Kuhnert-Tallman**
**Office - 404-639-3103**
**Mobile – 678-576-2121**

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 5:29 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Cc:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion
**Importance:** High

Dear Dr. Kuhnert-Tallman,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

On February 15, 2020, CDC submitted to FDA a request for enforcement discretion from FDA for the testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Asymptomatic individuals do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC has stated that testing will be conducted at CDC's headquarters in Atlanta, GA. Specimens are expected to arrive at CDC for testing during this holiday weekend.

Our understanding of the facts and the public health concerns at issue here are that there is currently no other test available to respond to this emergency, significant public health concerns are presented by the infectious disease, and the proposed testing may help to prevent the spread of the infectious disease. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the following conditions: that the testing will be conducted only at CDC's headquarters in Atlanta, GA, that CDC will submit data to FDA on the number of asymptomatic cases identified as being positive during the testing, and that CDC will act promptly to submit an application for a new EUA or a request to modify its existing EUA to include testing of asymptomatic individuals at CDC's headquarters in Atlanta, GA.

AMERICAN OVERSIGHT

Regards,

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 15, 2020 12:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Request for enforcement discretion

Good afternoon Dr. Scherf,

CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC respectfully requests enforcement discretion from FDA for the testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Testing will be conducted at CDC's headquarters in Atlanta, GA. Specimens are expected to arrive at CDC for testing during this holiday weekend.

Laura Rose, Regulatory Affairs Activity Lead for OLSS, is the primary point of contact at CDC to facilitate communications about this request. She may be reached at 404-639-1084 or LERose@cdc.gov.

Warm regards,
Wendi

Wendi Kuhnert-Tallman
ADIM
Mobile – 678-576-2121
CDC IMS LAB TF
2019 nCoV Response
eocevent177@cdc.gov

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 11:33:05 AM
**To**: Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) [sql5@cdc.gov]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Cut-off change - Number of public health labs that verified CDC panel for use

Thanks for both updates.

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 11:22 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
Notifications that CDC received from public health laboratories regarding the reactivity of the N1 and N3 assay as well as those that notified CDC of successful verification are below:

(b) (5) notified CDC of issues with N3 assay
(b) (5) notified CDC of issues with N1 assay (these labs are included in those that also saw issues with N3)
(b) (5) reported that they successfully verified the test in their laboratories

We are reaching out to labs today to notify CDC if they have successfully verified the test and will update if this number changes.

Thank you very much.
Steve

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Friday, February 21, 2020 10:59 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,

AMERICAN OVERSIGHT

I just wanted to follow up with you to let you know that we are now working to compile the numbers we have and will get these to you shortly. Also, we will be sending a request to all labs that have received the reagents to please notify CDC if they successfully verified the test in their lab, so the number of verified labs may change from the numbers we initially report to you.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use
**Importance:** High

Julie & Steve,

As requested earlier, please clarify the number of labs that have successfully verified the CDC test panel for use asap. You communicated earlier that (b) (5) labs received your test and that (b) (5) PHL informed you that they could not verify the test.

The question is in the context of a statement by APHL today that only 3 out of 100 public health labs have verified the CDC test for use. Can you confirm that?
"Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.'

See article below:

The article also states, according to CDC, that CDC will distribute a second test and will need it approved by the FDA first.

- Please clarify what that means: Are we talking about the new lot that is being manufactured or the change in cut-off?

Thanks,
Uwe

**Problems with CDC coronavirus test delay expanded US screening**

By David Lim

02/20/2020 05:03 PM EST

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

AMERICAN OVERSIGHT

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to

use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

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**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

AMERICAN OVERSIGHT

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

AMERICAN OVERSIGHT

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/19/2020 3:21:53 PM
**To:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Thanks, Uwe

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 3:10 PM
**To:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

I have no additional comments,

Tamara

---

**From:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 2:52 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Minor comment from me in blue.

Thanks,
Brittany

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 2:44 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

See my edits below in red.
Li

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 2:37 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** FW: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

All,

I just got this. Can you plesae provide any feedback whether the information is capture correctly. I am going through this now as well.

AMERICAN OVERSIGHT

Thanks, Uwe

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Wednesday, February 19, 2020 2:32 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Good afternoon Uwe,

Thank you again for taking the time to meet with us today to discuss the regulatory considerations for community transmission surveillance. I wanted to share my understanding of the outcome of the meeting to ensure CDC and FDA are on the same page.

(b) (5)

Please let me know if I have misunderstood our conversation or if I have missed a key point.

Many thanks,
Laura

AMERICAN OVERSIGHT

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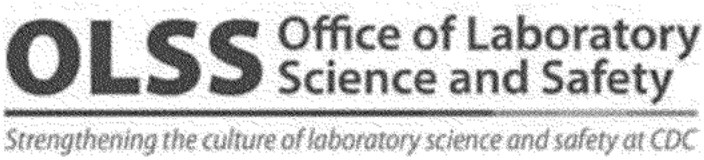
Laura E. Rose, RAC




*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---




AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/24/2020 8:33:07 PM
**To**: Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) [zey9@cdc.gov]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Intended Use

Confirm receipt. Uwe

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**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Monday, February 24, 2020 3:41 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** Intended Use

Good afternoon Uwe,

Thank you for taking the time to talk with us this afternoon. As requested, please find below a revised draft of the intended use statement demonstrating the proposed wording we discussed (highlighted text):

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

[redacted]

Warm regards,
Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

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OLSS Office of Laboratory Science and Safety

*Strengthening the culture of laboratory science and safety at CDC*

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 11:31:35 AM
**To**: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**CC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

We are trying to do that as fast as we can.

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 11:27 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Thanks! I should have OCET and OCC comments on the letter back to you today.

Are we trying to issue Monday?

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 21, 2020 at 11:08:29 AM EST
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: DRAFT CDC EUA Request for Sentinel Surveillance Activities

All,

This just came in. Uwe

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Friday, February 21, 2020 10:40 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** DRAFT CDC EUA Request for Sentinel Surveillance Activities

Good morning Kim and Uwe,

Please find attached a draft EUA request submission for the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in sentinel surveillance activities. We would appreciate your review of this draft submission to ensure it contains the information and wording request necessary to support FDA's planned issuance of a second letter of authorization for the diagnostic panel to support this critical epidemiologic activity.

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Please do not hesitate to reach out with questions, ideas, recommendations as you review the attached. I look forward to hearing from you.

Warm regards,
Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

OLSS Office of Laboratory Science and Safety

*Strengthening the culture of laboratory science and safety at CDC*

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 8:07:40 PM
**To**: Ross, Jennifer (Jennifer.Ross@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=RossJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Ellen Flannery (Ellen.Flannery@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Attachments**: DRAFT SARS-CoV-2 surveillance risk benefit 20Feb20_FDA_edits.docx

All,

Attached the updated benefit-risk document with comments from DMD.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Scherf, Uwe
**Sent:** Friday, February 21, 2020 5:22 PM
**To:** Ross, Jennifer (Jennifer.Ross@fda.hhs.gov) <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ellen Flannery (Ellen.Flannery@fda.hhs.gov) <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: DRAFT CDC EUA Request for Sentinel Surveillance Activities

All,

Here the draft EUA request we just discussed. Thanks for getting this addressed so quickly.

AMERICAN OVERSIGHT

Uwe

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Friday, February 21, 2020 10:40 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** DRAFT CDC EUA Request for Sentinel Surveillance Activities

Good morning Kim and Uwe,

Please find attached a draft EUA request submission for the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in sentinel surveillance activities. We would appreciate your review of this draft submission to ensure it contains the information and wording request necessary to support FDA's planned issuance of a second letter of authorization for the diagnostic panel to support this critical epidemiologic activity.

Please do not hesitate to reach out with questions, ideas, recommendations as you review the attached. I look forward to hearing from you.

Warm regards,
Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

OLSS Office of Laboratory Science and Safety
*Strengthening the culture of laboratory science and safety at CDC*

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/17/2020 11:39:24 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: Cut-off change - lot release testing criteria

2nd set of questions. Uwe

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5)

[redacted]

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5)

If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD

AMERICAN OVERSIGHT

Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts(b) (5) [redacted]

Thanks,
Uwe

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.

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- Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
- Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/24/2020 8:17:44 PM
**To**: Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Ross, Jennifer (Jennifer.Ross@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=RossJ]; Ellen Flannery (Ellen.Flannery@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: FW: Intended Use

All,

This is the proposed language from CDC that was communicated to FDA during a phone call this afternoon.

Uwe

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Monday, February 24, 2020 3:41 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** Intended Use

Good afternoon Uwe,

Thank you for taking the time to talk with us this afternoon. As requested, please find below a revised draft of the intended use statement demonstrating the proposed wording we discussed (highlighted text):

(b) (5)

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(b) (5)



Warm regards,
Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

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*Strengthening the culture of laboratory science and safety at CDC*

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/19/2020 1:00:09 PM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]
**Subject**: RE: Cut-off change - lot release testing criteria

Hi Julie,

Thanks a lot of the update. We understand this is very challenging.

Best, Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Wednesday, February 19, 2020 12:46 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,

For your awareness, CDC is just now initiating purchasing mechanisms for external manufacturing. I imagine that it will take at least a week or more to provide bulk material for CDC quality control testing. I will keep you informed of timelines when we know more. Thank you for your help.

Best regards,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 9:28 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie,

We look forward to obtaining this very important information for review and concurrence.

Thanks,
Uwe

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Wednesday, February 19, 2020 9:20 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Shuren, Jeff

AMERICAN OVERSIGHT

<Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,

Thank you for your email. We will share all quality control testing data for any potential manufacturers for FDA review before any actions are taken. As always, we greatly appreciate your collaboration as we move forward.

Best regards,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 6:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Julie,

CDC has communicated to FDA that you wish to contract out primer & probe manufacturing for the 2019-nCoV Real-Time RT-PCR Diagnostic Panel to certain external contractors.
CDC's EUA submission states under Section J. Product Manufacturing:

- "The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has been validated using only the components referenced in this submission and shall not be changed without prior concurrence from the FDA."
- "The product will be manufactured at the Centers for Disease Control and Prevention (FDA registration number 1050190) by personnel consistent with practices for the production of *in vitro* diagnostic devices based on the Quality System Regulation."

CDC may submit to FDA a written request to add contract manufacturers for the primers and probes. You have indicated that the two contract manufacturers might be Biosearch Technologies, Inc., at 2199 S. Mcdowell Blvd. Petaluma, CA, 94954 and Integrated DN Technologies, Inc., at 1710 Commercial Park, Coralville, IA, 52241. Prior to using or distributing any primers or probes that are contract manufactured, you must submit for review and concurrence by DMD/OHT7-OIR/OPEQ/CDRH the names and locations of the contract manufacturers and the quality control testing data following your extended quality control testing scheme for bulk testing and final lot release testing, which includes at least 3 randomly selected final devices and testing the N1, N2, N3 components each on 3 x 96 well plates of NTC sample generating a total number of 288 data points for each target component.
FDA will review the data and determine whether to provide concurrence or request additional information. Since the companies are contract manufacturers, CDC would be responsible for their activity and would be expected to report to FDA any performance issues, adverse events or other information required under the EUA.
This request should not delay any of your activities in preparing to move forward with the use of the contract manufacturers.

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Thanks,

Uwe

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 18, 2020 1:41 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

We are working to find answers to your questions below and will get back to you as soon as we have the information.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 3:53 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thank you for this information. A couple of additional questions regarding the manufacturing of the different lots at CDC:
Is there anything different in manufacturing of the lots being used at CDC headquarters and for the EUA:

1. Where they manufactured in the same room or at different locations at CDC?
2. Were there any differences in raw material?
3. Were there any changes made between the CDC headquarters lot and the EUA lot?
4. Were there an subsequent changes made for the current production of the new lot?

Also, did CDC (b) (5) ?

Thanks,

Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani

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<Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
For clarification the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel consists of two separate boxes. Box #1 contains the primers and probes as described below:

**2019-nCoVEUA-01 Box #1: Primers and Probes**

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
|---|---|---|---|---|
| 2019-nCoV_N1 | RV202001 | 2019-nCoV_N1 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N2 | RV202002 | 2019-nCoV_N2 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N3 | RV202003 | 2019-nCoV_N3 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| RP | RV202004 | Human RNase P Forward Primer/Probe Mix | 22.5 nmol | 1000 |

Primer and probes from three individual boxes that were randomly selected after kit assembly were tested as presented in the powerpoint file provided earlier.

Also as requested, please find attached the QC testing process of primer/probe reagents at bulk and post-fill analysis.

We hope this helps to clarify the data presented and addresses your request.
Thank you very much.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 10:07 AM
**To:** 'Scherf, Uwe' <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
The samples tested represent 3 randomly selected kits at "final kit". I hope this addresses your question.
We will send a meeting invitation shortly for 1pm if that time is still OK for your team.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing (b) (5)

Thanks,
Uwe

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| (b) (5) | | | | |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI)

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<jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Steve,

Thank you for the update, when will you send us the performance data for all assays to understand your rational to exclude N3?

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

Q1: Clarify how many total lots of EUA reagents are being distributed?
(b) (5)

Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5)

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (5)

Please let us know if you have any additional questions.
Thank you very much!
Steve

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**********
Stephen Lindstrom, Ph.D.

Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5)

[redacted]

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5)



If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

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**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch

Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts (b) (5) [redacted]

Thanks,
Uwe

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:

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- Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
- Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
- Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/21/2020 6:03:46 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: Cut-off change - lot release testing criteria
**Attachments:** QC Data Summary_2019-nCoVEUA-01 Replacement Lot.xlsx

Jeff,

We received the QC testing data for N1 & N2 following the heightened QC protocol. This data show that the new N1 and N2 lots are clean.
Data for N3 is outstanding.

Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 3:37 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hello Uwe,
We would like to share with you our bulk QC data summary for oligo sets N1, N2 and RP for your review. We continue to manufacture N3 and will forward as soon as that data is reviewed.
Please be aware there are two tab in the excel file.
Please let us know if you have questions.
Do you and your colleagues have a time tomorrow that you would like to arrange a call to discuss?
Thank you very much.
Steve

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
For clarification the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel consists of two separate boxes. Box #1 contains the primers and probes as described below:

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**2019-nCoVEUA-01 Box #1: Primers and Probes**

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
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| 2019-nCoV_N2 | RV202002 | 2019-nCoV_N2 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N3 | RV202003 | 2019-nCoV_N3 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| RP | RV202004 | Human RNase P Forward Primer/Probe Mix | 22.5 nmol | 1000 |

Primer and probes from three individual boxes that were randomly selected after kit assembly were tested as presented in the powerpoint file provided earlier.

Also as requested, please find attached the QC testing process of primer/probe reagents at bulk and post-fill analysis.

We hope this helps to clarify the data presented and addresses your request.
Thank you very much.
Steve

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Stephen Lindstrom, Ph.D.
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Respiratory Viruses Branch
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Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 10:07 AM
**To:** 'Scherf, Uwe' <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
The samples tested represent 3 randomly selected kits at “final kit”. I hope this addresses your question.
We will send a meeting invitation shortly for 1pm if that time is still OK for your team.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum,

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Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing the sampling scheme of your heightened NTC QC testing that was used for this evaluation.

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| (b) (5) | | | | |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

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Dear Steve,

Thank you for the update, when will you send us the performance data for all assays to understand your rational to exclude N3?

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

Q1: Clarify how many total lots of EUA reagents are being distributed?
(b) (5)

Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5)

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (5)

Please let us know if you have any additional questions.
Thank you very much!
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5)

[redacted]

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara

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<Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5)

If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts in investigating (b) (5) [redacted]

Thanks,
Uwe

---

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

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Thanks,
Uwe

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) , is that correct?

Thank you for your feedback.

Uwe

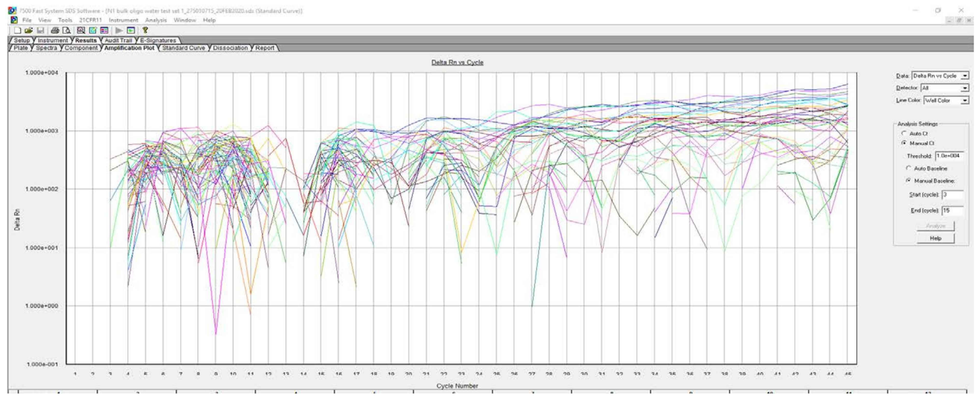
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**2019-nCoVEUA-01 Replacement Lot Heightened QC - Bulk (NTC Reactions)**

| Marker | Frequency |
|---|---|
| 2019-nCoV_N1 | 0/288 |
| 2019-nCoV_N2 | 0/288 |
| RP | 0/288 |

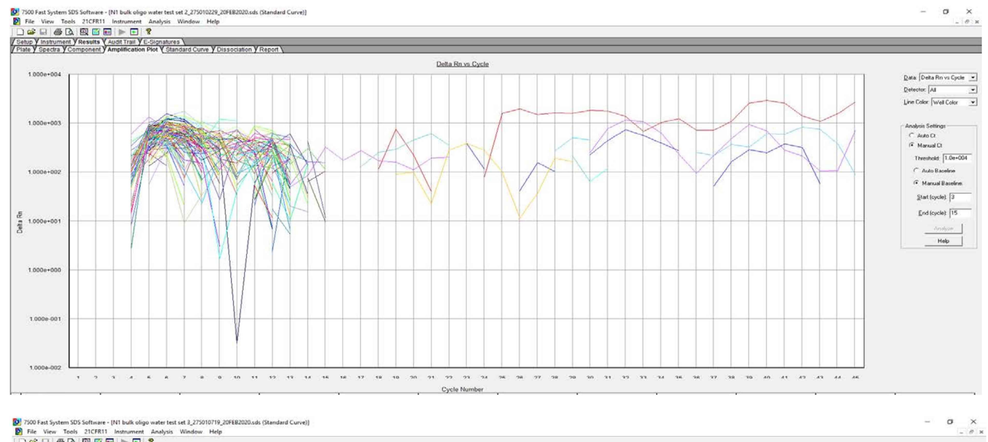
**N1 set 1 (0/96)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **B** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **C** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **D** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **E** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **F** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **G** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **H** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |



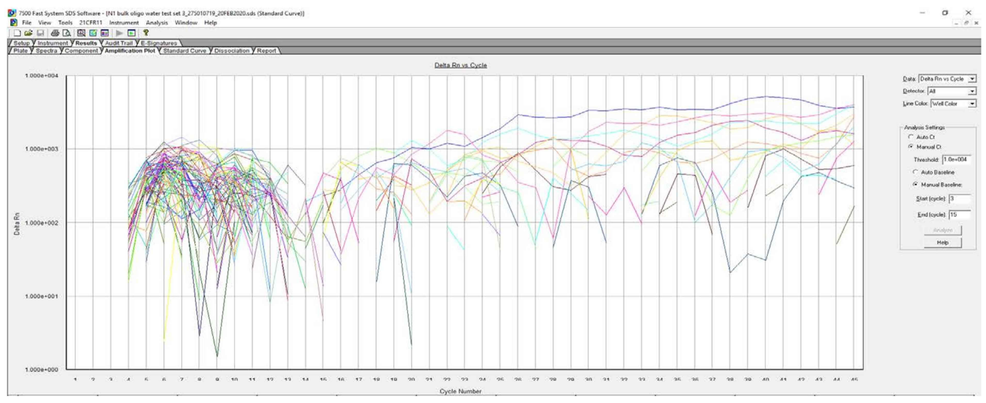

**N1 set 2 (0/96)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **B** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **C** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **D** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **E** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **F** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **G** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **H** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |



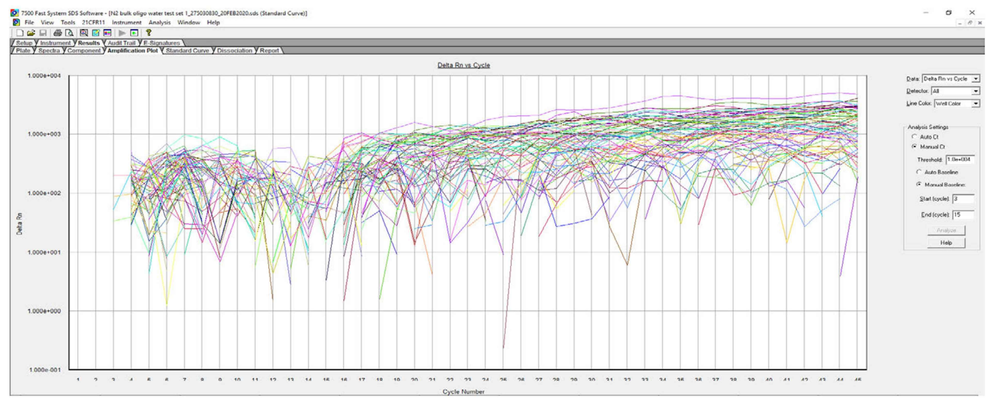

**N1 set 3 (0/96)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **B** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **C** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **D** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **E** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **F** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **G** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **H** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |



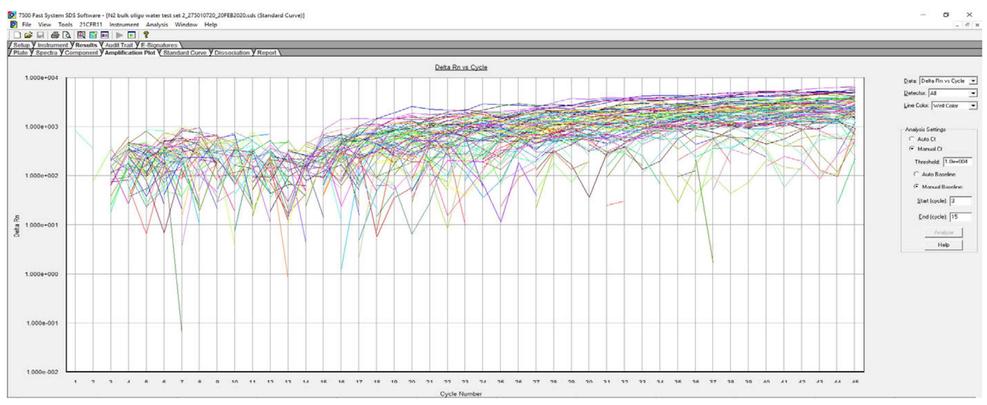

**N2 set 1 (0/96)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **B** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **C** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **D** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **E** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **F** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **G** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **H** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |



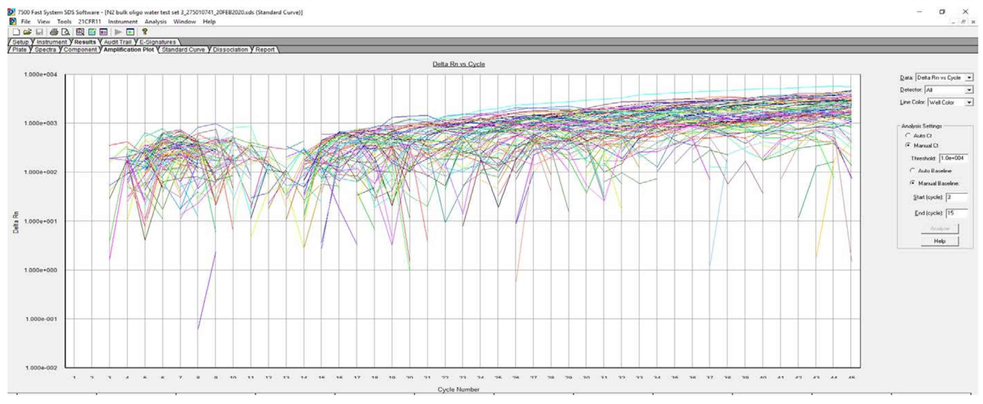

**N2 set 2 (0/96)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **B** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **C** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **D** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **E** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **F** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **G** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **H** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |



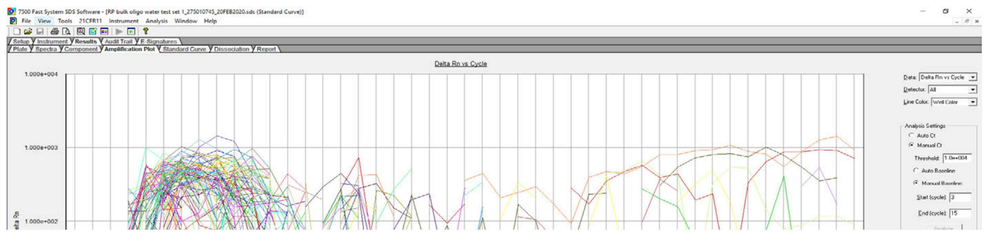

**N2 set 3 (0/96)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **B** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **C** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **D** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **E** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **F** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **G** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **H** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |

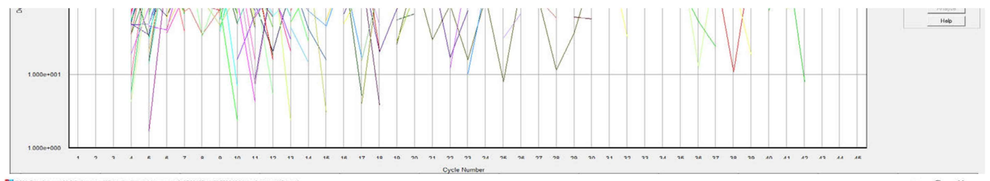



**RP set 1 (0/96)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **B** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **C** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **D** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **E** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **F** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **G** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **H** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |

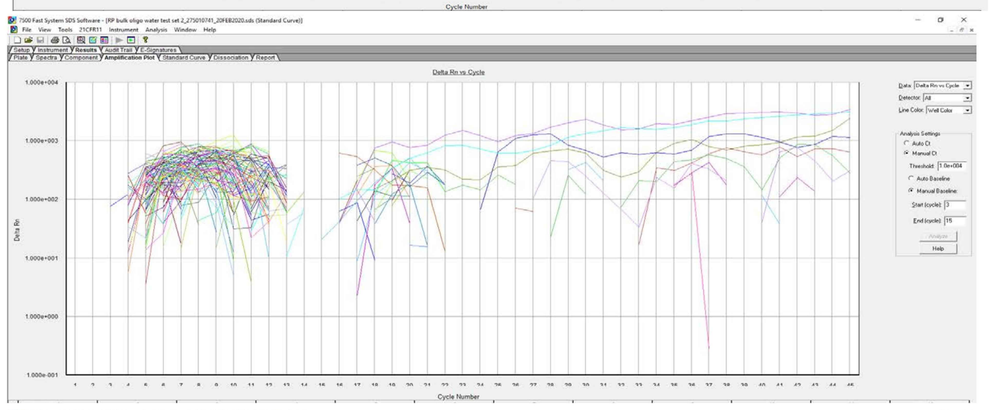



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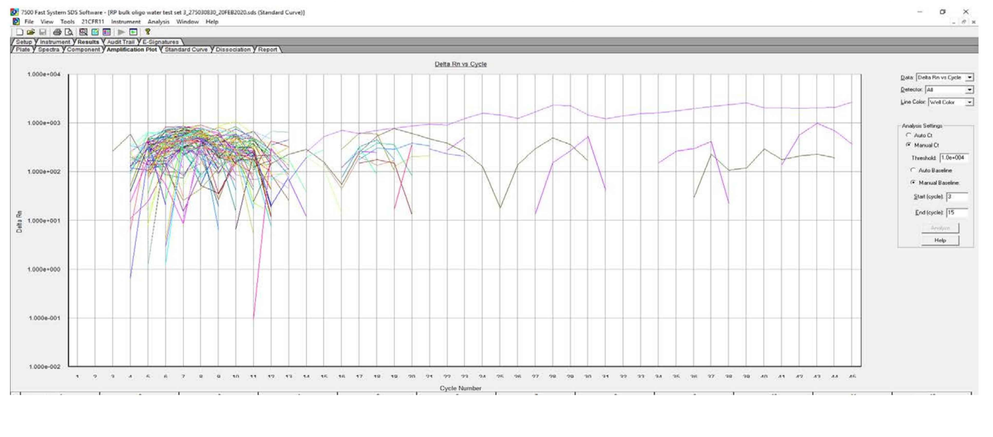

**RP set 2 (0/96)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **B** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **C** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **D** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **E** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **F** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **G** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **H** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |




**RP set 3 (0/96)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **B** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **C** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **D** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **E** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **F** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **G** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |
| **H** | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. | Undet. |




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## *2019-nCoV_EUA-01 Replacement Lot Bulk Oligo QC Data*

**Functional Performance Data**

| Marker | Dilution | Sample | Ct | Ct | Ct | Std. Dev | Average Ct | ΔCt | Average Ct | Std Dev Final | ΔCt Final |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2019-nCoV_N1 | 10^4 copies/µL | Reference | 22.20 | 22.17 | 22.06 | 0.07 | 22.14 | | | | |
| | | Set 1 | 22.08 | 22.09 | 22.01 | 0.04 | 22.06 | -0.08 | 22.24 | 0.15 | 0.10 |
| | | Set 2 | 22.34 | 22.38 | 22.41 | 0.04 | 22.38 | 0.24 | | | |
| | | Set 3 | 22.17 | 22.38 | 22.26 | 0.11 | 22.27 | 0.13 | | | |
| 2019-nCoV_N1 | 10^2 copies/µL | Reference | 29.01 | 29.00 | 29.09 | 0.05 | 29.03 | | | | |
| | | Set 1 | 29.03 | 28.78 | 28.87 | 0.13 | 28.89 | -0.14 | 28.83 | 0.18 | -0.20 |
| | | Set 2 | 28.53 | 28.91 | 28.96 | 0.24 | 28.80 | -0.23 | | | |
| | | Set 3 | 28.59 | 28.77 | 29.01 | 0.21 | 28.79 | -0.24 | | | |
| 2019-nCoV_N1 | PC | Reference | 21.58 | 21.63 | 21.76 | 0.09 | 21.66 | | | | |
| | | Set 1 | 21.64 | 21.60 | 21.60 | 0.02 | 21.61 | -0.05 | 21.87 | 0.20 | 0.21 |
| | | Set 2 | 22.05 | 22.00 | 22.09 | 0.05 | 22.05 | 0.39 | | | |
| | | Set 3 | 22.01 | 21.99 | 21.87 | 0.08 | 21.96 | 0.30 | | | |
| 2019-nCoV_N2 | 10^4 copies/µL | Reference | 23.20 | 23.24 | 23.13 | 0.06 | 23.19 | | | | |
| | | Set 1 | 23.11 | 23.07 | 23.11 | 0.02 | 23.10 | -0.09 | 22.97 | 0.14 | -0.22 |
| | | Set 2 | 22.74 | 22.85 | 22.85 | 0.06 | 22.81 | -0.38 | | | |
| | | Set 3 | 22.88 | 22.97 | 23.14 | 0.13 | 23.00 | -0.19 | | | |
| 2019-nCoV_N2 | 10^2 copies/µL | Reference | 30.04 | 30.28 | 30.01 | 0.15 | 30.11 | | | | |
| | | Set 1 | 30.06 | 30.18 | 29.65 | 0.28 | 29.96 | -0.15 | 29.98 | 0.21 | -0.13 |
| | | Set 2 | 30.21 | 30.02 | 30.04 | 0.10 | 30.09 | -0.02 | | | |
| | | Set 3 | 30.08 | 29.60 | 29.95 | 0.25 | 29.88 | -0.23 | | | |
| 2019-nCoV_N2 | PC | Reference | 23.05 | 22.98 | 22.75 | 0.16 | 22.93 | | | | |
| | | Set 1 | 22.76 | 23.01 | 22.74 | 0.15 | 22.84 | -0.09 | 22.44 | 0.56 | -0.49 |
| | | Set 2 | 21.60 | 21.79 | 21.72 | 0.10 | 21.70 | -1.23 | | | |
| | | Set 3 | 22.83 | 22.80 | 22.73 | 0.05 | 22.79 | -0.14 | | | |
| RP | 10^4 copies/µL | Reference | 23.65 | 23.87 | 24.05 | 0.20 | 23.86 | | | | |
| | | Set 1 | 22.97 | 22.95 | 23.06 | 0.06 | 22.99 | -0.87 | 22.97 | 0.23 | -0.89 |
| | | Set 2 | 23.15 | 23.22 | 23.06 | 0.08 | 23.14 | -0.72 | | | |
| | | Set 3 | 23.00 | 22.87 | 22.42 | 0.30 | 22.76 | -1.10 | | | |
| RP | 10^2 copies/µL | Reference | 29.53 | 29.98 | 30.16 | 0.32 | 29.89 | | | | |
| | | Set 1 | 29.17 | 29.34 | 29.43 | 0.13 | 29.31 | -0.58 | 29.74 | 0.54 | -0.15 |
| | | Set 2 | 29.06 | 29.84 | 29.73 | 0.42 | 29.54 | -0.35 | | | |
| | | Set 3 | 30.16 | 30.64 | 30.28 | 0.25 | 30.36 | 0.47 | | | |
| RP | PC | Reference | 22.85 | 23.01 | 22.75 | 0.13 | 22.87 | | | | |
| | | Set 1 | 22.11 | 22.04 | 22.03 | 0.04 | 22.06 | -0.81 | 21.91 | 0.29 | -0.96 |
| | | Set 2 | 22.25 | 22.18 | 21.92 | 0.17 | 22.12 | -0.75 | | | |
| | | Set 3 | 21.50 | 21.61 | 21.51 | 0.06 | 21.54 | -1.33 | | | |

| NTC Negative for All Replicates | |
|---|---|
| Reference Lot | Yes |
| Sample Set 1 | Yes |
| Sample Set 2 | Yes |
| Sample Set 3 | Yes |

Overall QC Result: Pass

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/23/2020 4:08:08 PM
**To**: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Authorization Letter

Jennifer, thank you very much.

Uwe

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 4:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Authorization Letter

Ok. I'll prepare an updated version tonight.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** February 23, 2020 at 2:56:01 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** RE: Authorization Letter

Sounds good

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 2:05 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** RE: Authorization Letter

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Let's assume that they accept our edits it would be good to be prepared. Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 1:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** Re: Authorization Letter

Uwe I think we were waiting for cdc to be okay with our suggested changes the finalize the letter from there

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 23, 2020 at 12:21:50 PM EST
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Authorization Letter

All,

Since the response it out, I was wondering where we are standing with the draft of the authorization letter.

Somehow I could not locate any email with an updated version.

Thanks,
Uwe

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:13 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

The following email just went out to CDC. Thank you all for the fast turnabout to get this done.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:09 AM
**To:** Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear Laura,

Attached please find the following documents you submitted on February 21, 2020 to support the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in surveillance activities. These documents have been reviewed and edited by FDA's OCET and OCC.

1. Draft COVID-19 sentinel surveillance
2. Draft SARS-CoV-2 surveillance risk benefit
3. Draft CDC Surveillance EUA Request Cover letter

Please do not hesitate to reach out to me with questions.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/26/2020 7:19:13 PM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Gitterman, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4747486679444f24aa8d1086cca27390-SRG]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: COVID-19 diagnostics

Elizabeth,
Can you help with this delicate request? Thanks, uwe

**From:** Fink, Doran <Doran.Fink@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 3:34 PM
**To:** Gitterman, Steven <Steven.Gitterman@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** COVID-19 diagnostics

Hi,

I am at the Advisory Committee for Immunization Practices (ACIP) meeting and getting lots of questions about use of investigational diagnostics at hospital labs. There is great interest in using laboratory developed tests to complement CDC and state health department efforts. However, people's understanding is that all tests for SARS-CoV-2, including laboratory developed tests (LDTs), must be reviewed and cleared or authorized by the FDA for emergency use, or they cannot be used for diagnostic testing, and therefore at this time only the CDC RT-PCR covered by the EUA can be used, and only in authorized labs. This is articulated on the CDC website:
https://www.cdc.gov/csels/dls/locs/2020/reminder_covid-19_diagnostic_testing.html

However, I am told that this directive conflicts with prior experience at CLIA-certified hospital labs where investigational diagnostics have frequently been used without FDA authorization. Can you provide any clarification that I can pass along regarding this directive and the intentions behind it?

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 4:04:03 PM
**To**: Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: Cut-off change - lot release testing criteria
**Attachments**: QC Data Summary_2019-nCoVEUA-01 Replacement Lot.xlsx

Tim, this just arrived. Data on reagent replacement. Let's discuss before you leave today. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 3:37 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hello Uwe,
We would like to share with you our bulk QC data summary for oligo sets N1, N2 and RP for your review. We continue to manufacture N3 and will forward as soon as that data is reviewed.
Please be aware there are two tab in the excel file.
Please let us know if you have questions.
Do you and your colleagues have a time tomorrow that you would like to arrange a call to discuss?
Thank you very much.
Steve

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

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Hi Uwe,

For clarification the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel consists of two separate boxes. Box #1 contains the primers and probes as described below:

**2019-nCoVEUA-01 Box #1: Primers and Probes**

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
|---|---|---|---|---|
| 2019-nCoV_N1 | RV202001 | 2019-nCoV_N1 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N2 | RV202002 | 2019-nCoV_N2 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N3 | RV202003 | 2019-nCoV_N3 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| RP | RV202004 | Human RNase P Forward Primer/Probe Mix | 22.5 nmol | 1000 |

Primer and probes from three individual boxes that were randomly selected after kit assembly were tested as presented in the powerpoint file provided earlier.

Also as requested, please find attached the QC testing process of primer/probe reagents at bulk and post-fill analysis.

We hope this helps to clarify the data presented and addresses your request.
Thank you very much.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 10:07 AM
**To:** 'Scherf, Uwe' <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
The samples tested represent 3 randomly selected kits at "final kit". I hope this addresses your question.
We will send a meeting invitation shortly for 1pm if that time is still OK for your team.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI)

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<jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing the sampling scheme of your heightened NTC QC testing that was used for this evaluation.

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| (b) (5) | | | | |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

AMERICAN OVERSIGHT

Dear Steve,

Thank you for the update, when will you send us the performance data for all assays to understand your rational to exclude N3?

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

Q1: Clarify how many total lots of EUA reagents are being distributed?
(b) (5)

Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5)

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (5)

Please let us know if you have any additional questions.
Thank you very much!
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5) [redacted]

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>

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**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5)



If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts in investigating (b) (5) [redacted]

Thanks,
Uwe

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

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Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/17/2020 11:12:38 AM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Mielech, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Cut-off change - lot release testing criteria

Li,

Thanks, so (b) (5) .

Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 11:11 AM
**To:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Sorry, wrong calculation.
(b) (5)

Li

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 10:53 AM
**To:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Some simple calculations based on the very limited CDC QC testing data for our consideration:

N1 assay: (b) (5)
N3 assay:

AMERICAN OVERSIGHT

So the worst case scenario based on this set of limited QC data using (b) (5) [redacted]

Thanks,
Li

**From:** Li, Li (CDRH)
**Sent:** Monday, February 17, 2020 10:18 AM
**To:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Thanks Himani. (b) (5) [redacted]

**From:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 10:12 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Agree with Li, based on the provided QC line data, the FP with N1 and N3 appears sporadic and the proposed weak positive range makes sense.

Not sure, how burdensome it is to (b) (5) [redacted]

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:58 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

(b) (5) [redacted]

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(b) (5)

Thanks,
Li

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:41 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Cut-off change - lot release testing criteria

Good morning.

Based on the Ct range of the false positive N1 and N3 results, the proposed weak positive zone from (b) (5) Ct appears to be justified.

(b) (5)

It will be very helpful if CDC can also share with us data from the public health laboratories in the field in the same format, especially the inconclusive specimens that were referred to the CDC for follow-up testing.

Thanks,
Li

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|

(b) (5)

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(b) (5)

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Steve,

Thank you for the update, when will you send us the performance data for all assays to understand your rational to exclude N3?

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

Q1: Clarify how many total lots of EUA reagents are being distributed?
(b) (5)

Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5)

AMERICAN OVERSIGHT

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (5) [redacted]

Please let us know if you have any additional questions.
Thank you very much!
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5) [redacted]

AMERICAN OVERSIGHT

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5)



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(b) (5) [redacted]

If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

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**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts (b) (5) [redacted]

Thanks,
Uwe

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**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

AMERICAN OVERSIGHT

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

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**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

AMERICAN OVERSIGHT

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 2:48:38 PM
**To**: Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Thanks, yes if you have any comments on the protocol, that would be good.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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---

**From:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:44 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

I had a number of edits and questions regarding the BR assessment provided by CDC, but I think they can be easily and quickly resolved. I wrote some proposed language as answers to many of my questions to try and speed this along.

I quickly read the other documents, but did not comment. Would you like me to comment on those as well? I didn't see anything egregious, but my read-through was admittedly very quick.

Brittany

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 1:58 PM
**To:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Importance:** High

Brittany,

Can you please do a benefit risk assessment for the surveillance study attached. The benefit risk sheet is a separate document.

Thanks Uwe

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**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Friday, February 21, 2020 10:40 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** DRAFT CDC EUA Request for Sentinel Surveillance Activities

Good morning Kim and Uwe,

Please find attached a draft EUA request submission for the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in sentinel surveillance activities. We would appreciate your review of this draft submission to ensure it contains the information and wording request necessary to support FDA's planned issuance of a second letter of authorization for the diagnostic panel to support this critical epidemiologic activity.

Please do not hesitate to reach out with questions, ideas, recommendations as you review the attached. I look forward to hearing from you.

Warm regards,
Laura

==
Laura E. Rose, RAC
*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

OLSS Office of Laboratory Science and Safety
*Strengthening the culture of laboratory science and safety at CDC*

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/18/2020 7:58:54 AM
**To:** Hwang, Leroy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5da97657ec944cebf943616bd848105-Leroy.Hwang]
**Subject:** FW: Cut-off change - lot release testing criteria
**Attachments:** 2019-nCoVEUA-01 Lot 20-0121 Heightened Water QC data for FDA_17Feb2020.pptx

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| (b) (5) | | | | |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Steve,

Thank you for the update, when will you send us the performance data for all assays to understand your rational to exclude N3?

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

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Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
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(b) (5)

Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5)

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (5)

Please let us know if you have any additional questions.
Thank you very much!
Steve

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Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5)

[redacted]

Thank you,
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*Director, Division of Microbiology Devices*

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**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

AMERICAN OVERSIGHT

(b) (5)



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Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts in (b) (5) [redacted]

Thanks,
Uwe

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**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

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4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
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   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

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Uwe

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**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>

AMERICAN OVERSIGHT

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**Subject:** RE: Cut-off change

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(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

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(b) (5)



AMERICAN OVERSIGHT

(b) (5)



AMERICAN OVERSIGHT

(b) (5)



AMERICAN OVERSIGHT

(b) (5)



AMERICAN OVERSIGHT

(b) (5)



AMERICAN OVERSIGHT

(b) (5)



AMERICAN OVERSIGHT

(b) (5)



AMERICAN OVERSIGHT

(b) (5)



AMERICAN OVERSIGHT

(b) (5)



AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 2:32:49 PM
**To**: Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) [sql5@cdc.gov]
**Subject**: RE: Cut-off change - Number of public health labs that verified CDC panel for use

Thanks, Uwe

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 11:22 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
Notifications that CDC received from public health laboratories regarding the reactivity of the N1 and N3 assay as well as those that notified CDC of successful verification are below:

(b) (5) notified CDC of issues with N3 assay
(b) (5) notified CDC of issues with N1 assay (these labs are included in those that also saw issues with N3)
(b) (5) reported that they successfully verified the test in their laboratories

We are reaching out to labs today to notify CDC if they have successfully verified the test and will update if this number changes.

Thank you very much.
Steve

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Friday, February 21, 2020 10:59 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
I just wanted to follow up with you to let you know that we are now working to compile the numbers we have and will get these to you shortly. Also, we will be sending a request to all labs that have received the reagents to please notify CDC if they successfully verified the test in their lab, so the number of verified labs may change from the numbers we initially report to you.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)

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<sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use
**Importance:** High

Julie & Steve,

As requested earlier, please clarify the number of labs that have successfully verified the CDC test panel for use asap. You communicated earlier that (b) (5) labs received your test and that (b) (5) PHL informed you that they could not verify the test.

The question is in the context of a statement by APHL today that only 3 out of 100 public health labs have verified the CDC test for use. Can you confirm that?
"Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.'

See article below:

The article also states, according to CDC, that CDC will distribute a second test and will need it approved by the FDA first.

- Please clarify what that means: Are we talking about the new lot that is being manufactured or the change in cut-off?

Thanks,
Uwe

**Problems with CDC coronavirus test delay expanded US screening**

By David Lim

02/20/2020 05:03 PM EST

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

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More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

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**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.

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- The number of labs that observed N-1 false positive results in the negative control material.

3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:

- Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
- Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
- Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

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Uwe

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/19/2020 6:54:45 AM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Mielech, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject**: RE: Cut-off change - lot release testing criteria

Dear Julie,

CDC has communicated to FDA that you wish to contract out primer & probe manufacturing for the 2019-nCoV Real-Time RT-PCR Diagnostic Panel to certain external contractors.
CDC's EUA submission states under Section J. Product Manufacturing:

- "The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has been validated using only the components referenced in this submission and shall not be changed without prior concurrence from the FDA."
- "The product will be manufactured at the Centers for Disease Control and Prevention (FDA registration number 1050190) by personnel consistent with practices for the production of *in vitro* diagnostic devices based on the Quality System Regulation."

CDC may submit to FDA a written request to add contract manufacturers for the primers and probes. You have indicated that the two contract manufacturers might be Biosearch Technologies, Inc., at 2199 S. Mcdowell Blvd. Petaluma, CA, 94954 and Integrated DN Technologies, Inc., at 1710 Commercial Park, Coralville, IA, 52241. Prior to using or distributing any primers or probes that are contract manufactured, you must submit for review and concurrence by DMD/OHT7-OIR/OPEQ/CDRH the names and locations of the contract manufacturers and the quality control testing data following your extended quality control testing scheme for bulk testing and final lot release testing, which includes at least 3 randomly selected final devices and testing the N1, N2, N3 components each on 3 x 96 well plates of NTC sample generating a total number of 288 data points for each target component.
FDA will review the data and determine whether to provide concurrence or request additional information. Since the companies are contract manufacturers, CDC would be responsible for their activity and would be expected to report to FDA any performance issues, adverse events or other information required under the EUA.

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This request should not delay any of your activities in preparing to move forward with the use of the contract manufacturers.

Thanks,
Uwe

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 18, 2020 1:41 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

We are working to find answers to your questions below and will get back to you as soon as we have the information.

Thanks,
Julie

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 3:53 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thank you for this information. A couple of additional questions regarding the manufacturing of the different lots at CDC:
Is there anything different in manufacturing of the lots being used at CDC headquarters and for the EUA:

1. Where they manufactured in the same room or at different locations at CDC?
2. Were there any differences in raw material?
3. Were there any changes made between the CDC headquarters lot and the EUA lot?
4. Were there an subsequent changes made for the current production of the new lot?

Also, (b) (5) [redacted]

Thanks,
Uwe

AMERICAN OVERSIGHT

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
For clarification the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel consists of two separate boxes. Box #1 contains the primers and probes as described below:

**2019-nCoVEUA-01 Box #1: Primers and Probes**

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
|---|---|---|---|---|
| 2019-nCoV_N1 | RV202001 | 2019-nCoV_N1 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N2 | RV202002 | 2019-nCoV_N2 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N3 | RV202003 | 2019-nCoV_N3 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| RP | RV202004 | Human RNase P Forward Primer/Probe Mix | 22.5 nmol | 1000 |

Primer and probes from three individual boxes that were randomly selected after kit assembly were tested as presented in the powerpoint file provided earlier.

Also as requested, please find attached the QC testing process of primer/probe reagents at bulk and post-fill analysis.

We hope this helps to clarify the data presented and addresses your request.
Thank you very much.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 10:07 AM
**To:** 'Scherf, Uwe' <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

AMERICAN OVERSIGHT

Hi Uwe,

The samples tested represent 3 randomly selected kits at "final kit". I hope this addresses your question.
We will send a meeting invitation shortly for 1pm if that time is still OK for your team.
Thank you very much.
Steve

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing the sampling scheme of your heightened NTC QC testing that was used for this evaluation.

Thanks,
Uwe

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| (b) (5) | | | | |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Steve,

Thank you for the update, when will you send us the performance data for all assays to understand your rational to exclude N3?

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe

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**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
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Q1: Clarify how many total lots of EUA reagents are being distributed?
(b) (5)

Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5)

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (5)

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Please let us know if you have any additional questions.
Thank you very much!

Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
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**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5)

[redacted]

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5)



If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

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Stephen Lindstrom, Ph.D.
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Phone: 404-639-1587
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**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts in (b) (5) [redacted]

Thanks,
Uwe

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.

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4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/18/2020 7:58:11 AM
**To**: Hwang, Leroy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5da97657ec944cebf943616bd848105-Leroy.Hwang]
**Subject**: FW: Cut-off change - lot release testing criteria
**Attachments**: 2019-nCoV Oligo QC Process.docx

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
For clarification the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel consists of two separate boxes. Box #1 contains the primers and probes as described below:

**2019-nCoVEUA-01 Box #1: Primers and Probes**

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
|---|---|---|---|---|
| 2019-nCoV_N1 | RV202001 | 2019-nCoV_N1 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N2 | RV202002 | 2019-nCoV_N2 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N3 | RV202003 | 2019-nCoV_N3 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| RP | RV202004 | Human RNase P Forward Primer/Probe Mix | 22.5 nmol | 1000 |

Primer and probes from three individual boxes that were randomly selected after kit assembly were tested as presented in the powerpoint file provided earlier.

Also as requested, please find attached the QC testing process of primer/probe reagents at bulk and post-fill analysis.

We hope this helps to clarify the data presented and addresses your request.
Thank you very much.
Steve

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Stephen Lindstrom, Ph.D.
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Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
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---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 10:07 AM

**To:** 'Scherf, Uwe' <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
The samples tested represent 3 randomly selected kits at "final kit". I hope this addresses your question.
We will send a meeting invitation shortly for 1pm if that time is still OK for your team.
Thank you very much.
Steve

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
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**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing the sampling scheme of your heightened NTC QC testing that was used for this evaluation.

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
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Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|

(b) (5)

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The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
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Steve

---

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Please let us know if you have any additional questions.
Thank you very much!
Steve

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I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5)

Thank you,
Uwe

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**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5)

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If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

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Steve

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Stephen Lindstrom, Ph.D.
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Phone: 404-639-1587
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**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts in (b) (5) [redacted]

Thanks,
Uwe

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**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:

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- The number of labs that have successfully verified the CDC test panel.
- The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
- The number of labs that observed N-1 false positive results in the negative control material.

3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) , is that correct?

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Thank you for your feedback.

Uwe

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| CDC Centers for Disease Control and Prevention | Respiratory Viruses Branch | | Page [ PAGE ] of [ NUMPAGES ] |
|---|---|---|---|
| | **2019-nCoV Oligo QC Process** | | |

**Purpose:** To perform bulk and post-fill functional performance analysis for the 2019-nCoV oligonucleotides.

**Sample Type:** Oligonucleotides

**Number of Samples:** Three vials per oligo

**Materials Needed:**

- Reference Materials:
  - Enzyme
    - Taq-Path™ 1-Step RT-qPCR Master Mix, CG; Cat# A15299, A15300
  - Oligonucleotides
    - 2019-nCoV_N1 Reference Oligos (Forward, Reverse, Probe)
    - 2019-nCoV_N2 Reference Oligos (Forward, Reverse, Probe)
    - 2019-nCoV_N3 Reference Oligos (Forward, Reverse, Probe)
    - RP Reference Oligos (Forward, Reverse, Probe)
  - RNA Transcript Material
    - 2019-nCoV transcript ($10^5$ copies/µL)
  - Assay Positive Control (APC)
    - 2019-nCoV Real-time RT-PCR Control
- Investigational Oligonucleotides
  - Bulk
    - 2019-nCoV_N1: Forward, Reverse, Probe (3 vials per oligo, 9 vials total)
    - 2019-nCoV_N2: Forward, Reverse, Probe (3 vials per oligo, 9 vials total)
    - 2019-nCoV_N3: Forward, Reverse, Probe (3 vials per oligo, 9 vials total)
    - RP: Forward, Reverse, Probe (3 vials per oligo, 9 vials total)
  - Post-Fill
    - 2019-nCoV_N1 combined oligos: 3 vials total
    - 2019-nCoV_N2 combined oligos: 3 vials total
    - 2019-nCoV_N3 combined oligs: 3 vials total
    - RP combined oligos: 3 vials total

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## Plate Layouts – Bulk and Post-fill QC

**Plate 1:**

| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2019-nCoV_N1 Reference→ | A | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| 2019-nCoV_N1 Set 1→ | B | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| 2019-nCoV_N1 Set 2→ | C | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| 2019-nCoV_N1 Set 3→ | D | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| 2019-nCoV_N2 Reference→ | E | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| 2019-nCoV_N2 Set 1→ | F | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| 2019-nCoV_N2 Set 2→ | G | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| 2019-nCoV_N2 Set 3→ | H | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |

Note: NTC = No Template Control

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**Plate 2:**

| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2019-nCoV_N3 Reference→ | A | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| 2019-nCoV_N3 Set 1→ | B | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| 2019-nCoV_N3 Set 2→ | C | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| 2019-nCoV_N3 Set 3→ | D | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| RP Reference→ | E | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| RP Set 1→ | F | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| RP Set 2→ | G | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |
| RP Set 3→ | H | NTC | NTC | NTC | $10^2$ copies/µL | $10^2$ copies/µL | $10^2$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | $10^4$ copies/µL | APC | APC | APC |

Note: NTC = No Template Control

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/18/2020 9:59:38 AM
**To:** Humes, Rosemary (OS/ASPR/BARDA) [Rosemary.Humes@hhs.gov]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Timothy Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: For review by 11am Tuesday: Dx development POC talking points and landscapes
**Attachments:** 2019-nCoV Diagnostics Landscape 2-17-20 v2_DMD.pptx; Diagnostics for Coronavirus Timeline Projection v3_DMD.docx

Rosemary,

Attached our feedback in the slide and in the talking points. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 7:29 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Beanan, Maureen J (NIH) (b) (6) @mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA (b) (6) >; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>; Schoske, Richard CIV DTRA J9 (USA) (b) (6) >
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Eder, Paul (OS) <Paul.Eder@hhs.gov>; Lee, John S (OS) <John.Lee@hhs.gov>; Huynh, Chuong Q (OS) <Chuong.Huynh@hhs.gov>
**Subject:** For review by 11am Tuesday: Dx development POC talking points and landscapes

Diagnostics WG members,
Following up from earlier email. Thanks to all who were avaible to discuss/provide feedback today.
1. Slide deck: Need to deliver "POC" slide deck by noon Tuesday, please send comments by 11am. (b) (5)
(b) (5)

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(b) (5)

Again, many thanks for all the support.
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
Cell: (b) (6)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/22/2020 8:13:44 PM
**To**: Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) [sql5@cdc.gov]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Cut-off change - Number of public health labs that verified CDC panel for use

Thanks Steve for the update. Very much appreciated. Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Saturday, February 22, 2020 8:01 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
Our request for response from labs that were able to successfully verify the test went out yesterday afternoon. As of now, a total of twelve labs have responded that they were successful with verification. This includes the seven labs previously identified. We will keep you updated on the status of responses.
I hope this is useful.
Thank you
Steve

Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30329
Phone: 404-639-1587

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 5:17:02 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>

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**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Steve and Julie,

Do you have any updates on the labs that successfully validated your assay and are ready to run clinical samples? Did any lab respond?

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 11:22 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
Notifications that CDC received from public health laboratories regarding the reactivity of the N1 and N3 assay as well as those that notified CDC of successful verification are below:

(b) (5) notified CDC of issues with N3 assay
(b) (5) notified CDC of issues with N1 assay (these labs are included in those that also saw issues with N3)
(b) (5) reported that they successfully verified the test in their laboratories

We are reaching out to labs today to notify CDC if they have successfully verified the test and will update if this number changes.

Thank you very much.
Steve

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Friday, February 21, 2020 10:59 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
I just wanted to follow up with you to let you know that we are now working to compile the numbers we have and will get these to you shortly. Also, we will be sending a request to all labs that have received the reagents to please notify CDC if they successfully verified the test in their lab, so the number of verified labs may change from the numbers we initially report to you.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use
**Importance:** High

Julie & Steve,

As requested earlier, please clarify the number of labs that have successfully verified the CDC test panel for use asap. You communicated earlier that (b) (5)labs received your test and that(b) (5) PHL informed you that they could not verify the test.

The question is in the context of a statement by APHL today that only 3 out of 100 public health labs have verified the CDC test for use. Can you confirm that?
"Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.'

See article below:

The article also states, according to CDC, that CDC will distribute a second test and will need it approved by the FDA first.

- Please clarify what that means: Are we talking about the new lot that is being manufactured or the change in cut-off?

Thanks,
Uwe

**Problems with CDC coronavirus test delay expanded US screening**

By David Lim

02/20/2020 05:03 PM EST

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

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The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

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**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

AMERICAN OVERSIGHT

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

AMERICAN OVERSIGHT

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/18/2020 7:57:50 AM
**To**: Hwang, Leroy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5da97657ec944cebf943616bd848105-Leroy.Hwang]
**Subject**: FW: Cut-off change - lot release testing criteria

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 10:07 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
The samples tested represent 3 randomly selected kits at "final kit". I hope this addresses your question.
We will send a meeting invitation shortly for 1pm if that time is still OK for your team.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing the sampling scheme of your heightened NTC QC testing that was used for this evaluation.

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

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Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| (b) (5) | | | | |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Steve,

Thank you for the update, when will you send us the performance data for all assays to understand your rational to exclude N3?

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

AMERICAN OVERSIGHT

Q1: Clarify how many total lots of EUA reagents are being distributed?

(b) (5)

Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5)

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (5)

Please let us know if you have any additional questions.
Thank you very much!
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5)

AMERICAN OVERSIGHT

(b) (5)

[redacted]

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5)

[redacted]

AMERICAN OVERSIGHT

(b) (5)

As you requested, we can provide information regarding the reagent lot release testing criteria and results at the CDC of the current EUA kits in distribution and address your other questions that were received earlier today. Also, we can share the sporadic aberrant reactivity that we have observed in our hands specifically with the N1 and N3 EUA assays to demonstrate the frequency and Ct range of false positive results.

If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts (b) (5)

Thanks,
Uwe

---

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara

AMERICAN OVERSIGHT

<Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

AMERICAN OVERSIGHT

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 2:28:44 PM
**To**: Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov]
**Subject**: RE: Information request - WRCEVA SARS-CoV-2 genomic RNA product sheet

Thanks, Uwe

---

**From:** Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>
**Sent:** Friday, February 21, 2020 2:15 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** RE: Information request - WRCEVA SARS-CoV-2 genomic RNA product sheet

Uwe,
Here's the WRCEVA product sheet for the SARS-CoV-2 genomic RNA.
Maureen

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Friday, February 21, 2020 10:44 AM
**To:** Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Cc:** Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>
**Subject:** Information request

Hi Maureen,
Uwe Scherf (copied here) contacted me this morning to ask if UTMB would provide more information on the RNA that is being sent to the companies so FDA can better evaluate any data that companies may produce with the RNA. If Dr. Plante has a product sheet that he can share with BARDA and FDA that would be extremely helpful. Thanks very much!!

Uwe:
The companies agreed to by the Diagnostics Interagency WG are: (b) (4) We also added (b) (4), so the total is 11 companies. All of these companies have or use FDA-cleared platforms that are currently placed in U.S. healthcare centers. All have confirmed they are working on an assay for SARS-CoV-2, and have contacted FDA for the EUA template. The (b) (4) assays have potential for POC use depending on FDA requirements.

Companies were notified by NIH with this message:
The World Reference Center for Emerging Viruses and Arboviruses (WRCEVA) supported by NIH/NIAID has prepared small quantities of genomic RNA. In collaboration with our interagency partners, (company name) has been prioritized for receipt since you are actively developing a SARS-CoV-2 assay for use on an FDA cleared platform. The material was prepared from cell culture of SARS-CoV-2 virus (USA_WA1/2020), it will be distributed as BSL-2 and shipped on dry ice. Permits may be required for international shipments. If you are interested in receiving the materials, or have additional questions, please contact (contact information provided) for more details and a copy of the Material Transfer Agreement.
Additional material including genomic RNA and Irradiated virus will be available from BEI Resources (www.beiresources.org ) in the coming weeks. that the material is available, and if they are interested they should contact UTMB. Contact information was provided.

AMERICAN OVERSIGHT

Please let me know if there is anything else I can do to help.
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
Cell: (b) (6)

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/19/2020 2:45:58 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Thanks, Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 2:44 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

See my edits below in red.
Li

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 2:37 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** FW: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

All,

I just got this. Can you plesae provide any feedback whether the information is capture correctly. I am going through this now as well.

Thanks, Uwe

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Wednesday, February 19, 2020 2:32 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission

Good afternoon Uwe,

Thank you again for taking the time to meet with us today to discuss the regulatory considerations for community transmission surveillance. I wanted to share my understanding of the outcome of the meeting to ensure CDC and FDA are on the same page.

(b) (5)



AMERICAN OVERSIGHT

(b) (5)



Please let me know if I have misunderstood our conversation or if I have missed a key point.

Many thanks,
Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

OLSS Office of Laboratory Science and Safety

*Strengthening the culture of laboratory science and safety at CDC*

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/22/2020 5:17:02 PM
**To**: Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) [sql5@cdc.gov]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Cut-off change - Number of public health labs that verified CDC panel for use

Steve and Julie,

Do you have any updates on the labs that successfully validated your assay and are ready to run clinical samples? Did any lab respond?

Thanks,
Uwe

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Friday, February 21, 2020 11:22 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
Notifications that CDC received from public health laboratories regarding the reactivity of the N1 and N3 assay as well as those that notified CDC of successful verification are below:

(b) (5) notified CDC of issues with N3 assay
(b) (5) notified CDC of issues with N1 assay (these labs are included in those that also saw issues with N3)
(b) (5) reported that they successfully verified the test in their laboratories

We are reaching out to labs today to notify CDC if they have successfully verified the test and will update if this number changes.

Thank you very much.
Steve

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Friday, February 21, 2020 10:59 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>

AMERICAN OVERSIGHT

**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use

Hi Uwe,
I just wanted to follow up with you to let you know that we are now working to compile the numbers we have and will get these to you shortly. Also, we will be sending a request to all labs that have received the reagents to please notify CDC if they successfully verified the test in their lab, so the number of verified labs may change from the numbers we initially report to you.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Cut-off change - Number of public health labs that verified CDC panel for use
**Importance:** High

Julie & Steve,

As requested earlier, please clarify the number of labs that have successfully verified the CDC test panel for use asap. You communicated earlier that (b) (5)labs received your test and that(b) (5) PHL informed you that they could not verify the test.

The question is in the context of a statement by APHL today that only 3 out of 100 public health labs have verified the CDC test for use. Can you confirm that?
"Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.'

See article below:

The article also states, according to CDC, that CDC will distribute a second test and will need it approved by the FDA first.

- Please clarify what that means: Are we talking about the new lot that is being manufactured or the change in cut-off?

Thanks,
Uwe

**Problems with CDC coronavirus test delay expanded US screening**

By David Lim
02/20/2020 05:03 PM EST

AMERICAN OVERSIGHT

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

AMERICAN OVERSIGHT

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

(b) (5) . We will need to work to find more detailed information for you.

Thanks,
Julie

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding (b) (5) is that correct?

Thank you for your feedback.

Uwe

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/15/2020 3:31:44 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Request for enforcement discretion

Jeff & Ellen,

Here suggested language for the asymptomatic individual testing for consideration:

(b) (5)

Regarding the request for a change in cut-off, I am still waiting for CDC's email describing their proposal in more detail.

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 3:25 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Subject:** RE: Request for enforcement discretion

Uwe,

Ellen is working with OCC on the "no objection" language, and to include that we don't object if this use on asymptomatic individuals if it is subsequently included under the EUA.

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Please let me know when the team has made a decision on the cut off request. Assuming we come accord with CDC on a new cut off, we would need to develop "no objection" language for that request, as well. If there's any information Ellen can use to start on that language now so we can wrap this up today, please let us know.

Jeff

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 2:18 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Subject:** FW: Request for enforcement discretion
**Importance:** High

Jeff and Ellen,

See below the official request from CDC.

As stated in my previous email, based on our knowledge of the device, DMD would not have objections allowing CDC to test asymptomatic individuals using the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship. Provided that testing be conducted at CDC's headquarters in Atlanta, GA.

Ellen, per my phone conversation with Jeff, he agrees but would like your input on FDA's intend to not object to the use of the 2019-Novel Coronavirus (2019-nCoV). Please let me know if your thoughts on CDC's request.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 15, 2020 12:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Request for enforcement discretion

Good afternoon Dr. Scherf,

CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC respectfully requests enforcement discretion from FDA for the

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testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Testing will be conducted at CDC's headquarters in Atlanta, GA. Specimens are expected to arrive at CDC for testing during this holiday weekend.

Laura Rose, Regulatory Affairs Activity Lead for OLSS, is the primary point of contact at CDC to facilitate communications about this request. She may be reached at 404-639-1084 or LERose@cdc.gov.

Warm regards,
Wendi

Wendi Kuhnert-Tallman
ADIM
Mobile – 678-576-2121
CDC IMS LAB TF
2019 nCoV Response
eocevent177@cdc.gov

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/17/2020 5:21:56 PM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: BY noon tomorrow

Tim,

Here the points we just talked about:

EUA requirements:

- Limited analytical validity studies (LoD, inclusivity, cross-reactivity)
- Limited clinical validity study (e.g., evaluation of contrived clinical samples)
- Possible bridging study to device previously issued under an Emergency Use Authorization

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 12:40 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: BY noon tomorrow

Uwe, My POC thoughts below. Copying Jeff for his awareness.

REALLLY need help from FDA and CDC to find a coordinated approach to communicate around Dx capacity, Dx testing development and DX utilization.
Need today -

1. throw some thoughts for what we can put in the one-pager into an email – will get a joint draft ready ASAP.

a. Uwe, please address regulatory issues, including EUA and CLIA requirements .

2. provide some ideas on what we can do to reality set this expectation.

Dear Rosemary,

Here are my thoughts.

(b) (5)

Development of POC devices:

There are two main types of tests, non-molecular such as rapid flu tests and molecular.

AMERICAN OVERSIGHT

(b) (5)

(b) (5)

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 17, 2020 at 9:59:06 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: BY noon tomorrow

Tim,

I need your help on this request, since I will not find time to provide feedback to Rosemary.

I am working with CDC on their change in cut-off proposal.

Thanks,
Uwe

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Monday, February 17, 2020 8:36 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** BY noon tomorrow

Uwe and Wendi,
We have been asked to put together a one-pager and landscape on POC diagnostics discussing time (development and manufacturing (b) (5) ), costs and issues with developing a hand held diagnostic/tests.
(b) (5)
I'll pull together what we have into a starting document, but REALLLY need help from FDA and CDC to find a coordinated approach to communicate around Dx capacity, Dx testing development and DX utilization.
Need today -

1. throw some thoughts for what we can put in the one-pager into an email – will get a joint draft ready ASAP.
   a. Uwe, please address regulatory issues, including EUA and CLIA requirements .
2. provide some ideas on what we can do to reality set this expectation.

Thanks very much,

AMERICAN OVERSIGHT

Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
Cell: (b) (6)

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 8:26:22 AM
**To:** Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: For Data Population and Review by 1pm Monday

Heather,

The number of EUA authorized and the templates send are current. I added this additional data point:

- **13** developers have submitted pre-EUA documents for FDA feedback as of 2/21/20

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 7:22 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: For Data Population and Review by 1pm Monday

Hi Kim and Uwe,

I just wanted to reach out to make sure you saw the ask below that is due at 1 pm today. If you need anything, let us know. I know the Commissioner really wants to have solid numbers and specifics.

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: 240-507-3139
Email: Heather.Agler@fda.hhs.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff
**Sent:** Monday, February 24, 2020 7:16 AM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Cc:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Subject:** FW: For Data Population and Review by 1pm Monday

Flagging as an FYI — I know you are working on it and need to include our IVD efforts, as well.

Jeff

---

**From:** Gross, Karas <Karas.Gross@fda.hhs.gov>
**Date:** February 24, 2020 at 7:02:19 AM EST
**To:** Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Solomon, Steven M <Steven.Solomon@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
**Subject:** FW: For Data Population and Review by 1pm Monday

Good morning-

Making sure the below effort to obtain more granular information for the Commissioner (as requested by the Secretary) is on your radar screens as well—particularly number of manufacturers contacted and what information we're learning. I know this request has come through different channels, but making you know that the Commissioner is briefing senators tomorrow at 8am where we've been told he'll get these types of questions.

We're working directly with your teams, but I have Keagan cc'd here, so let us know if you have questions or concerns. We've also made clear in the request to let us know if certain information can't be shared for a particular reason (legal, cci, etc).

Thanks to you and your teams for all of the support.

Karas

**From:** Gross, Karas
**Sent:** Sunday, February 23, 2020 8:33 PM
**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
**Subject:** RE: For Data Population and Review by 1pm Monday

Reminder that the deadline for this is tomorrow at 1pm. And highlighting the information that Michael flagged below should, indeed, be the immediate priority. If you are providing that information to the commissioner through other requests or channels, please cc OL or add it hear as well. Thank you!

AMERICAN OVERSIGHT

Karas

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 10:28 AM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
**Subject:** For Data Population and Review by 1pm Monday

Thanks Michael! And I'm sorry to do this, but since the Commissioner needs this for an 8am Tuesday morning, the paper will have to be populated by **1pm Monday** so that we can run it through OCC with enough time for him to offer feedback.

+OCC so they can see what is coming.

Thank you again.

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 8:46 AM
**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
**Subject:** RE: For Data Population and Review by COB Monday

Adding Brooke. While it will be really useful to compile an maintain quantifiable info that speaks to our response efforts across the full range of our activities for many uses – what the Secretary is specifically requesting is more specific/granular information regarding supply chain efforts (b) (5)

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 10:03 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
**Subject:** RE: For Data Population and Review by COB Monday

AMERICAN OVERSIGHT

Should also note that if there are other, more preferable ways to quantify or give specifics please feel free to suggest them in the document. That said, we expect the Commissioner may be asked questions along these lines as early as Tuesday, so the information or the rationale he can convey as to why he cannot disclose it will be very helpful.

Thank you all!

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 9:59 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
**Subject:** For Data Population and Review by COB Monday

IMG, CDER, CBER, CDRH, and ORA:

OL has developed a document to respond to the following directive from Leadership:

*Sec. Azar wants more specific and precise answers around our response efforts. Dr. Hahn wants to be as specific as we possibly can with regard to our response efforts, and if there is a legal reason we can't, he wants to know why. By COB Monday 2/24, JIC needs to provide these type of specifics throughout the remarks/materials prepared for Tuesday briefings, + in any press materials. The specifics don't have to be product-specific, but they want numbers, e.g., we have contacted ## manufacturing facilities in China as of DATE, and ## are still shipping product without delay.*

The document is linked below for your respective Centers/Office to populate data and review by **COB Monday, Feb. 24.** We anticipate that some of this information is not able to be shared publicly. If you believe that to be the case please so indicate in a comment bubble.

Also please note that the document may contain nonpublic and/or confidential commercial information. Please do not distribute it beyond FDA and limit its internal distribution as much as is possible.

Thank you for your efforts on this project. Please let us know if you have any questions or need additional information.

http://sharepoint.fda.gov/orgs/OC-OL/corona/For%20Clearance/Response%20By%20the%20Numbers901.docx

**Andrew Tantillo**
*Deputy Director*

**Office of Legislation**
**U.S. Food and Drug Administration**
O: 301-796-8919 M: 202-809-2989
andrew.tantillo@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/20/2020 9:42:36 AM
**To**: Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]
**CC**: Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Smith, Lia H (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cda5acfaea1403d98eeed026beb76bd-HHS-loh5-cd]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel: addition of ZEN probes

Dear Julie,

The listed proposal is appropriate to evaluate whether both probe chemistries will perform equivalent. We look forward to receiving the data for review and concurrence.

From FDA's site there is not need for further discussion of the protocol.

Best regards,

Uwe

---

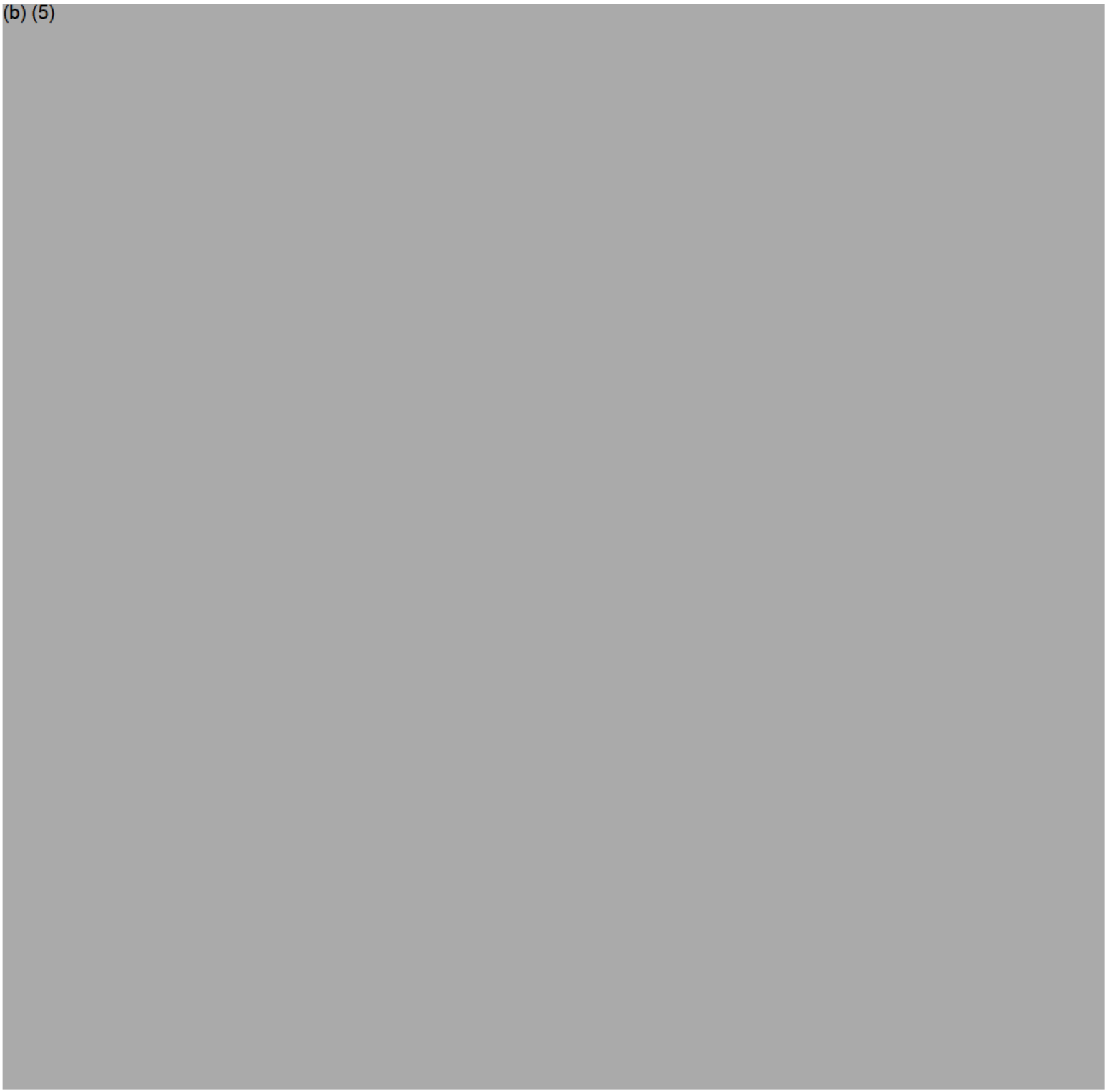
**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Wednesday, February 19, 2020 5:04 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>
**Subject:** CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel: addition of ZEN probes
**Importance:** High

Dear Uwe,

(b) (5)

AMERICAN OVERSIGHT

(b) (5)



Do you have time tomorrow to discuss this proposal? We are available from 9-10am, 11-11:30am, or after 3pm.

Thanks,

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/22/2020 4:10:13 PM
**To:** Garcia, Mayra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7db05677732d4023bcdf772ee0474055-GarciaM]
**Subject:** RE: Coronavirus and MERS culturing

Mayra,

Can you please give me a call at (b) (6) . Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 9:01 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Coronavirus and MERS culturing

FYI

---

**From:** Garcia, Mayra
**Sent:** Saturday, February 22, 2020 8:59 AM
**To:** Wang, Tony <Tony.Wang@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; McGivern, David <David.McGivern@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Dear Tim,

As I mentioned to Uwe yesterday, the idea was to handle the COVID-19 materials for the CDRH devices as we did for Zika. CBER has the laboratories and knowledge to propagate the virus. DMD will be able to design the panel that will best challenge the sensitivity and specificity of the devices we are getting in house. Therefore, after Tony grows and inactivates the BSL-3 stocks, I would be preparing the dilutions of the viral stocks with David's help to formulate the final panel. In addition, I was also the one receiving at CDRH the orders, distributing the panels when available to the companies, as well as receiving the results of the testing. This strategy allowed DMD to have knowledge of the progress companies where doing with the panel testing and compile all the results for the EUA devices.

The preparation of the panel will take some time as the virus strains need still to be grown (and as Tony said the BSL-3 just got validated to work with COVID-19), inactivated, titrated, and the panel will have to be prepared with different dilutions that could satisfy the sensitivity observed in our devices.

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I proposed a meeting with CBER for next week, now that that the BSL-3 and the funds are available since 2/21/2020, to set up a timeline for the next steps.

Regards,

Mayra

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**From:** Wang, Tony <Tony.Wang@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 8:27 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; McGivern, David <David.McGivern@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Dear Tim,

I am adding Drs. Carolyn Wilson, Mayra Garcia from CDRH and David McGivern to this email chain for communication purpose. Dr. Wilson is the director of office of research at CBER who oversees all 2019-nCoV activities. Dr. McGivern at the Office of Blood Research and Review at CBER will work with Mayra at CDRH to generate reference standards for industry to use.

My group is to propagate virus and then work with David's group to establish conditions for heat-inactivation of the virus. We have just received the approval to conduct the work, but there are a few house-keeping items that we need to take care of before we can start the work.

I would leave to Dr. Wilson, Mayra and Dr. McGivern to speak on the part regarding dialogues with industries.

Best,

Tony

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 3:14 PM
**To:** Lien, Christopher <Christopher.Lien@fda.hhs.gov>; Liu, Shufeng <Shufeng.Liu@fda.hhs.gov>; Wang, Tony <Tony.Wang@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Coronavirus and MERS culturing

Hi Tony, Shufeng and Christopher,

We are getting inquiries from IVD test developers who are ready to finish the validation of their molecular Coronavirus assays so they can submit them to CDRH for EUA authorization. I have heard that you are developing a source of Coronavirus and mers and was wondering if you are in dialogue with companies already and if we can introduce them to you so they can get in line to receive samples when they are ready.

Thanks so much in advance!

Best,
*Tim*

AMERICAN OVERSIGHT

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*

*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:42 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Coronavirus and MERS culturing

Hello Tim,
Likewise, I am delighted to meet you today. Please see attached for the IBC application we received from CBER for review and approval. We will have to contact the PI's at CBER to find out when they will have the materials ready. Based on the application, it seems like they are only preparing nConV19 (SARS CoV 2) and MERS CoV materials. (b) (5) [redacted] Take care.

Pillai

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:13 PM
**To:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Coronavirus and MERS culturing

Hi Pillai,

Great to meet you today! I wanted to reach out and have copied Jeff to find out more details about the coronavirus and mers cultures. We have a number of test developers who cannot complete validation of their EUA assays until they have at least mock samples made with virus to test.

How soon will virus be available?
Can we connect developers with someone here at the agency so they can coordinate access?

Thanks!

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Best,

*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/15/2020 2:36:30 PM
**To**: Kuhnert-Tallman, Wendi (CDC/DDID/OD) [wdk1@cdc.gov]
**CC**: Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Request for enforcement discretion

Dear Wendi,

I have received your email and I am conferring with CDRH leadership and counsel. Will get back to you as soon as possible.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 15, 2020 12:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Request for enforcement discretion

Good afternoon Dr. Scherf,

CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC respectfully requests enforcement discretion from FDA for the testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Testing will be conducted at CDC's headquarters in Atlanta, GA. Specimens are expected to arrive at CDC for testing during this holiday weekend.

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Laura Rose, Regulatory Affairs Activity Lead for OLSS, is the primary point of contact at CDC to facilitate communications about this request. She may be reached at 404-639-1084 or LERose@cdc.gov.

Warm regards,
Wendi

Wendi Kuhnert-Tallman
ADIM
Mobile – 678-576-2121
CDC IMS LAB TF
2019 nCoV Response
eocevent177@cdc.gov

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/22/2020 2:58:37 PM
**To**: Kuhnert-Tallman, Wendi (CDC/DDID/OD) [wdk1@cdc.gov]
**Subject**: RE: Quick question

Wendi,

Tim is the OIR's Office Director supporting the efforts around COVID-19. The discussion today will be around the N3 component.

Uwe

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Saturday, February 22, 2020 2:54 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Quick question

Uwe, we received a note from Tim and understand that he has landed in Atlanta. I am less familiar with FDAs structure and given that we have worked primarily with you and your office we were hoping to get some insight into how Tim relates to your office and this process as we navigate our EUA discussions.

I also understand that you are going to reach out for a call with us today. Can you please advise on this so we have some awareness?

Thanks.

Get Outlook for iOS

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/10/2020 7:44:22 PM
**To:** Annabel Tsai (b)(6) [redacted]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Estela Raychaudhuri (b)(6) [redacted] Allison Bardagjy (b)(6) [redacted] Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Coronovirus Diagnostic Assay pre-EUA

Dear Ms. Tsai and Estela,

I confirm the receipt of the electronic Pre-Emergency Use Authorization (Pre-EUA) request for the Smart *Detect*™ 2019-nCOV rRT-PCR kit.

DMD is looking forward to working with you and your team on this submission.

Kind regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Annabel Tsai (b)(6) [redacted]
**Sent:** Monday, February 10, 2020 5:52 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Estela Raychaudhuri (b)(6) [redacted] Allison Bardagjy (b)(6) [redacted]
**Subject:** Coronovirus Diagnostic Assay pre-EUA

Dear Dr. Sapsford-Medintz,

InBios International Inc. is submitting a Pre-Emergency Use (Pre-EUA) for the Smart *Detect*™ 2019-nCOV rRT-PCR kit in order to obtain feedback from FDA concerning the studies and/or testing outline in our Pre-EUA submission package.

As requested, one hard copy of the signed EUA Cover Letter and one electronic copy of our Pre-EUA submission package have been submitted to the Document Control Center. In addition, electronic copies of those documents are attached to this email. We have also attached to this email a document "Attachment 3 2019-02-03_nCoV_aligned – Copy" in FASTA file format and TXT file format. Please note, only the FASTA file format of this attachment was submitted through the Document Control Center.

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In case you should have any questions regarding the information provided and/or need additional information/data, please contact Estela Raychaudhuri either via email (b)(6) [redacted] or phone (b)(6) [redacted] We look forward to working with you on the Pre-EUA submission.

Sincerely,
Annabel Tsai

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/16/2020 10:09:48 PM
**To:** Hoady, Rita [rita.hoady@roche.com]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Angela Tucker (b)(6) @roche.com]; Heinz Steneberg [heinz.steneberg@roche.com]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: pre-EUA 2019-nCoV - Roche Molecular Systems

Rita,

Our plan is to get it to you either tomorrow or latest Tuesday. The review team has been working on it over the last several days.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Hoady, Rita <rita.hoady@roche.com>
**Sent:** Sunday, February 16, 2020 8:02 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Angela Tucker <(b)(6) @roche.com>; Heinz Steneberg <heinz.steneberg@roche.com>
**Subject:** Re: pre-EUA 2019-nCoV - Roche Molecular Systems

Hello Uwe and Kim,

I hope you're having a nice weekend. Is there any information that you can share with us on when we can expect the FDA responses to the study designs and questions in the pre-EUA for the RMS assay for SARS-CoV-2? Thank you.

Kind regards,

Rita Hoady, MS RAC CCRA
Senior Manager, Regulatory Affairs
Roche Molecular Solutions
Office: 925 730 8397
Mobile: 925 487 1055

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*Doing now what patients need next*

On Mon, Feb 10, 2020 at 6:42 PM <rita.hoady@roche.com> wrote:

Dear Uwe,

Thank you for confirming receipt of my email. We look forward to working with the DMD team as well.

Kind regards,
Rita Hoady
(925) 487-1055

On Feb 10, 2020, at 6:34 PM, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov> wrote:

Dear Rita,

I confirm the receipt of the electronic Pre-Emergency Use Authorization (Pre-EUA) request for the cobas 2019-nCoV test for use on the cobas 6800/8800 Systems and the request for FDA feedback on the planned studies.

DMD is looking forward to working with you and your team on this submission.

Kind regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456

uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Hoady, Rita <rita.hoady@roche.com>
**Sent:** Monday, February 10, 2020 8:11 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Angela Tucker

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<(b)(6) @roche.com>; Heinz Steneberg <heinz.steneberg@roche.com>
**Subject:** pre-EUA 2019-nCoV - Roche Molecular Systems

Dear Kim,

I hope you're doing well. Roche Molecular Systems has completed the pre-EUA template for the 2019 novel coronavirus (2019-nCoV) for the **cobas**® 2019-nCoV test for use on the **cobas**® 6800/8800 Systems and would like to request FDA feedback on the planned studies. The pre-EUA submission was sent to the DCC today (FedEx tracking number; (b) (4) , to the attention of Dr. Uwe Scherf and is attached for your reference. Please feel free to contact me at anytime to discuss the details of the submission. Thank you.

Kind regards,

Rita Hoady, M.Sc. RAC CCRA
Senior Manager, Regulatory Affairs
Roche Molecular Solutions
Office: (b) (6)
Mobile

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*Doing now what patients need next*

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/6/2020 9:43:24 AM
**To**: Lovell, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a4cfa4fc4094bbf8fac0e16bf710049-SXL]
**Subject**: EUA info

- **nCoV Diagnostic EUA Activity**
- CDRH approved the Emergency Use Authorization (EUA) for CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel on 2/4/2020. https://www.fda.gov/news-events/press-announcements/fda-takes-significant-step-coronavirus-response-efforts-issues-emergency-use-authorization-first
- Additional IVD developers have requested and received the EUA review template. To date CDRH has received a total of 35, additional requests are pending clarification about the device technology.
- Provided feedback on diagnostic 1 pager briefing document for the White House Task Force – currently scheduled to meet at 4pm on Thursday
- DMD participated in a call with the Tri-Agency Task Force for Emergency Diagnostics (TTFED) to talk about distribution of the CDC test.

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/12/2020 11:05:40 AM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject**: RE: nCoV EUA template request

Looks good, no additional comments. Thanks, Uwe

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 10:47 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** RE: nCoV EUA template request

Kim,

You responses look good. I made a couple of trivial edits in the attached file.

Thanks,

Tamara

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 9:33 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** FW: nCoV EUA template request

Dear Uwe, Tamara and Li,

When you get a chance - please find attached for your review my proposed draft email response to (b)(4) (just the parts in green need review) - I would like to respond tomorrow at the latest.

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311

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Kim.Sapsford@fda.hhs.gov






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**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Saturday, February 08, 2020 2:34 PM
**To:** (b) (4); CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** (b)(4), (b)(6) (b)(4), (b)(6) Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: nCoV EUA template request

Dear (b) (4),

Thank you – we are discussing the information and will respond early next week.

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov



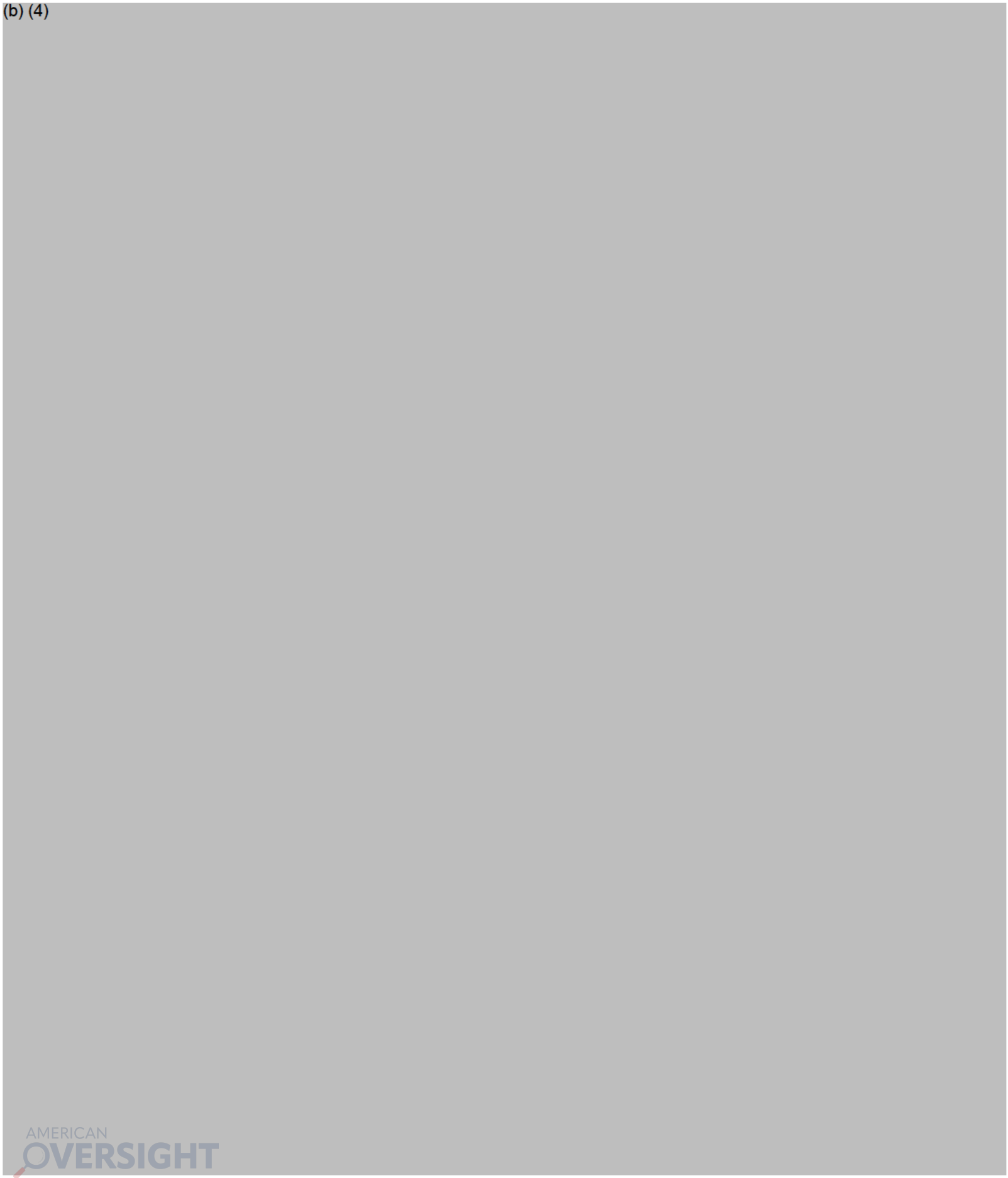



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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** (b) (4)
**Sent:** Friday, February 07, 2020 8:58 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** (b)(4), (b)(6) (b)(4), (b)(6)
**Subject:** RE: nCoV EUA template request

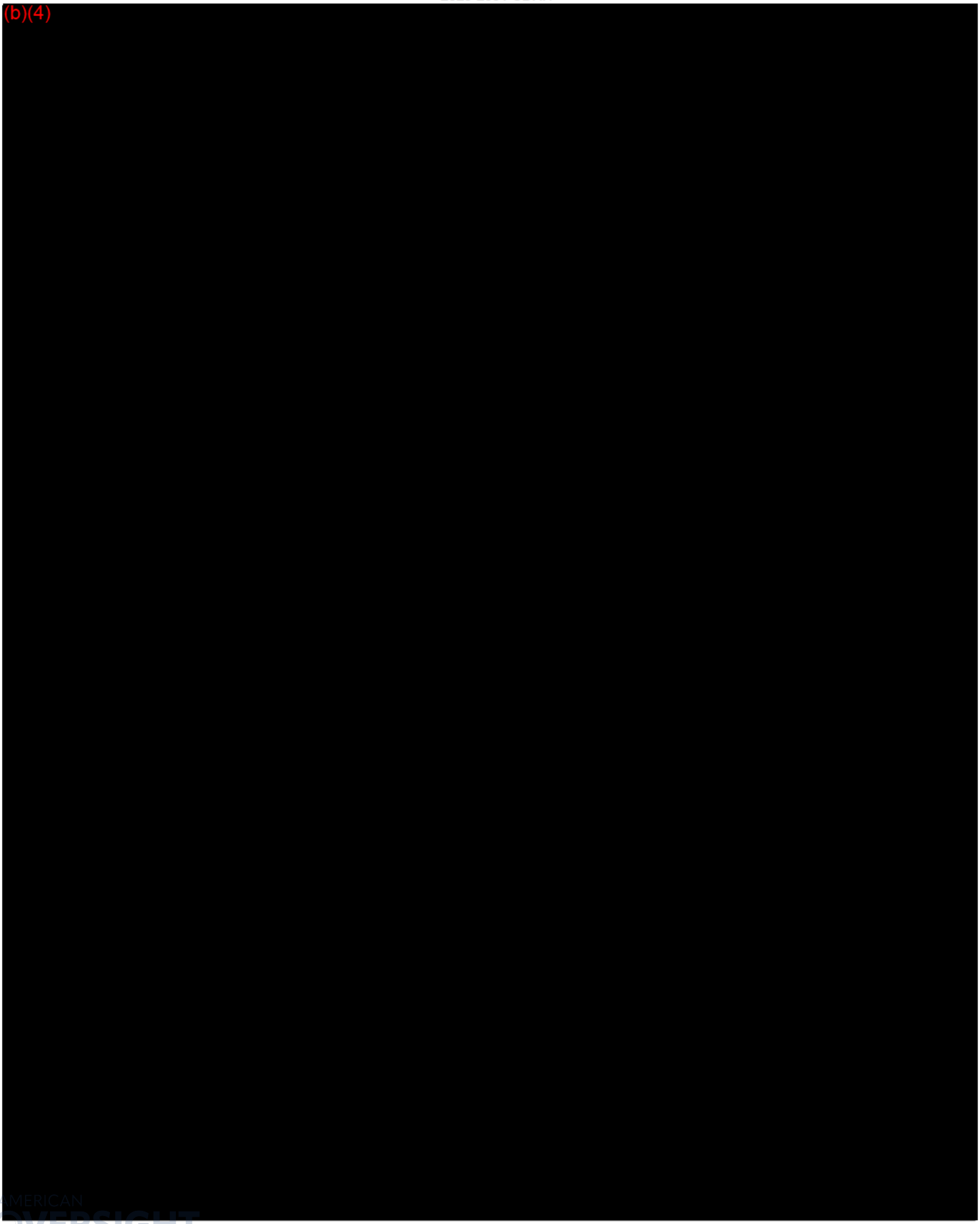
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(b) (4)



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(b)(4)



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**De:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Enviado el:** lunes, 3 de febrero de 2020 18:51
**Para:** (b) (4) ; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**CC:** (b)(4), (b)(6)
(b)(4), (b)(6) Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Asunto:** RE: nCoV EUA template request

Dear (b) (4)

Just checking you got my questions below (in red – sent friday) it will help us with our response:

We have been reviewing the template you sent us and these are our first doubts (for now):

(b) (4)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 6:36 AM
**To:** (b) (4) CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** (b)(4), (b)(6)
(b)(4), (b)(6) Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: nCoV EUA template request

Dear (b) (4)

Counter questions – so I can better answer, see red below:

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov






Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** (b) (4)
**Sent:** Friday, January 31, 2020 5:44 AM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** (b)(4), (b)(6)

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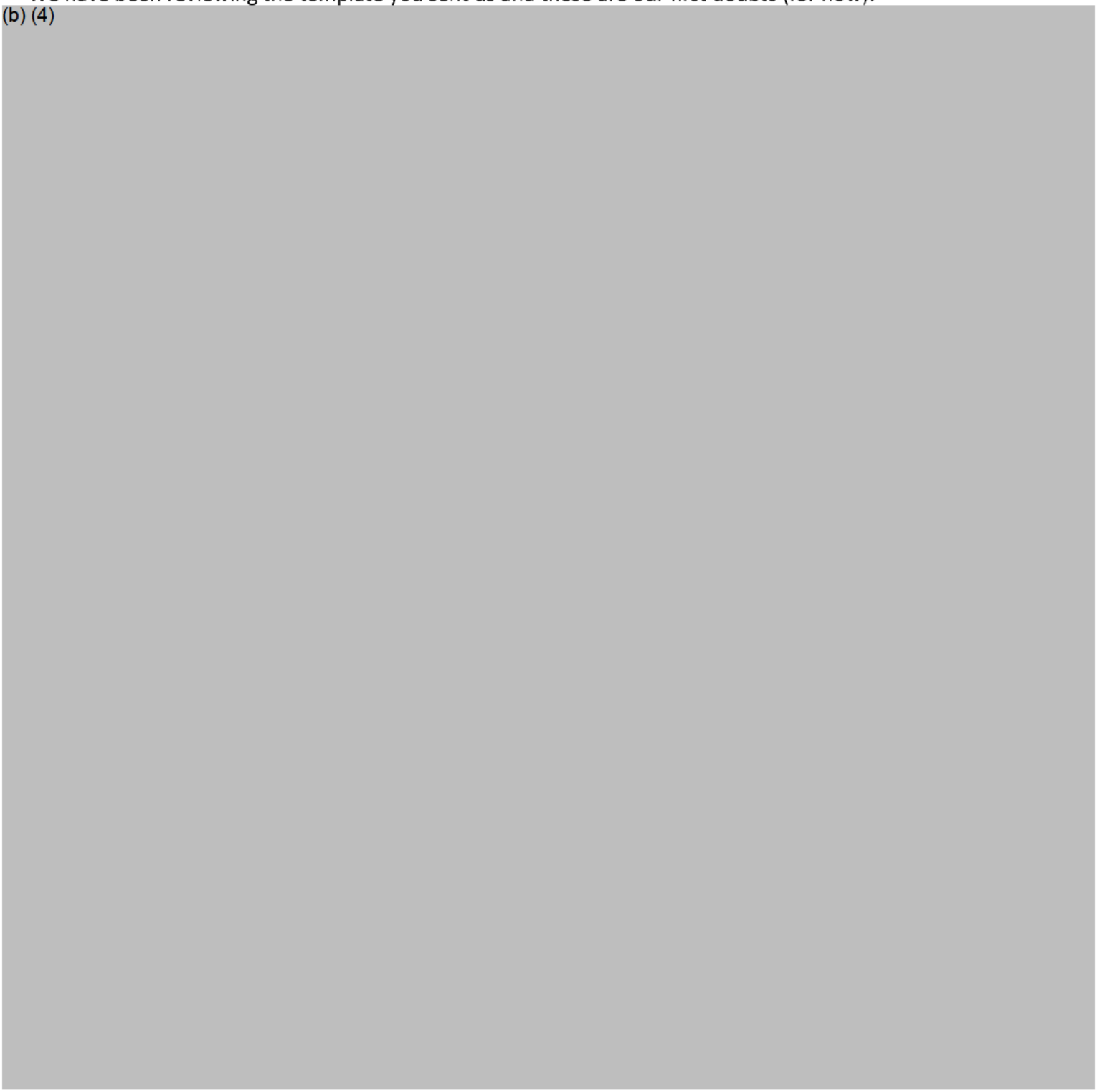
Llobet (b)(4), (b)(6)

**Subject:** RE: nCoV EUA template request

Dear Kim,

We have been reviewing the template you sent us and these are our first doubts (for now):

(b) (4)



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(b)(4)

[redacted]

**De:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Enviado el:** jueves, 30 de enero de 2020 12:48
**Para:** (b) (4) [redacted] CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**CC:** (b)(4), (b)(6) [redacted]
**Asunto:** RE: nCoV EUA template request

Dear (b) (4) [redacted]

Thank you for your email, we are accepting Pre-EUA submissions at this time. Please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of 2019-novel coronavirus (2019-nCoV). I suggest when you are ready, the first step is to populate this draft template with the information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center). The Pre-EUA review is an interactive process, so we will provide feedback after receiving and reviewing the information provided. The draft review template is a shared "work-in-progress" document which you will populate with information and data as obtained and which we will review and provide feedback to you.

I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of 2019-nCoV to FDA (it includes the address for the Document Control Center). Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under type of submission please check "other" and specify Pre-EUA.

One hard copy of the signed EUA Cover Letter and one electronic copy of you Pre-EUA submission package (including the EUA Review Template - MS word document) should be enclosed in your Pre-EUA submission to FDA, and we also

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request that you submit the information requested via electronic mail to myself Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;
- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please be reminded that ***in the U.S. a test*** for the detection of 2019-nCoV or to diagnoses 2019-nCoV infection must not be distributed and/or used for clinical diagnosis without premarket clearance, approval, or EUA by the FDA.
NOTE: The EUA Interactive Review Template from the FDA is considered an internal working document and must not be distributed outside of your organization.

Please let me know if you have any questions, we look forward to working with you,
Best regards,
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov






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**From:** (b) (4)
**Sent:** Thursday, January 30, 2020 6:19 AM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** (b)(4), (b)(6)
**Subject:** nCoV EUA template request

Dear all,

(b)(4)

(b)(4)

(b)(4)

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(b)(4)



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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/15/2020 1:17:51 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: Urgent - Action needed

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 1:12 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Urgent - Action needed

Jeff's cell if you need it: (b)(6) [redacted]

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 1:07 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Urgent - Action needed

Jeff,

Could you please call me at (b)(6) [redacted] Something else just came up when I got another call from CDC. This is related to (b) (5) [redacted].

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 12:53 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Urgent - Action needed

(b)(5) [redacted]

(b)(5) [redacted]

Jeff

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 15, 2020 at 12:36:47 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Urgent - Action needed

(b)(5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 12:35 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Urgent - Action needed

Thank you for the heads up. (b)(5) [redacted]

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 15, 2020 at 12:15:36 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Urgent - Action needed
**Importance:** High

Jeff and Ellen,

I want you to give you a heads up on this. I received a call from CDC (b)(5) [redacted]
(b)(5) [redacted]

(b)(5) [redacted]
(b)(5) [redacted]

I will let you know as soon as I receive CDC's formal request. I can be reached at (b)(6) [redacted]

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

Febuary 4, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Dear Dr. Redfield:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.[1]

On Feburary 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the 2019-nCoV. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) subject to the terms of any authorization issued under Section 564(a) of the Act.[2]

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (as described in the scope Section of this letter (Section II)) in individuals who

[1] For ease of reference, this letter will refer to "qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests" as "authorized laboratories."

[2] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. Feburary 4, 2020.

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meet CDC criteria for 2019-nCoV testing for the presumptive detection of 2019-nCoV by authorized laboratories, subject to the terms of this authorization.

## I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in individuals who meet CDC criteria for 2019-nCoV testing meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The 2019-nCoV can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel may be effective in diagnosing 2019-nCoV infection, and that the known and potential benefits of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, when used for diagnosing 2019-nCoV infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel for diagnosing 2019-nCoV infection.[3]

## II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel by authorized laboratories for the presumptive detection of 2019-nCoV in individuals who meet CDC criteria for 2019-nCoV testing.

### The Authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is for the presumptive detection of 2019-nCoV RNA in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate), and other authorized specimens collected from individuals who meet CDC criteria for 2019-nCoV testing. The testing procedure consists of nucleic acid extraction and purification from the human specimen using authorized extraction methods/instruments followed by real time RT-PCR, where the RNA is reverse transcribed into cDNA and then amplified using the primer sets and detected using specific probes. The real time reverse transcriptase (RT)-PCR is performed on the FDA cleared Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS 1.4 software, or other authorized instruments or software.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel includes the following materials or other authorized materials:

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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- 2019-nCoV_N1, 2019-nCoV_N2 and 2019-nCoV_N3 vials containing primers and probes that target the nucleocapsid (N) gene and are designed for both universal detection of SARS-like coronavirus as well as specific detection of the 2019-nCoV
- RP vial containing the internal control primers and probes that target the Human RNase P gene
- nCoVPC vial containing the 2019-nCoV positive control used in the assay

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel also requires the use of additional authorized materials and authorized ancillary reagents that are not included with the test but are commonly used in clinical laboratories and are described in the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel requires the following control materials, or other authorized control materials; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use:

- Human Specimen Control (HSC): A human cell culture preparation used as an extraction control and positive control for the RNase P primer and probe set that is extracted and tested concurrently with each specimen extraction run.
- Positive Control for 2019-nCoV (nCoVPC): Run with each batch of specimens. Monitors for failures of rRT-PCR reagents and reaction conditions.
- No Template Control (NTC): Nuclease-free water included in each run. Monitors for reagent and system contamination.
- RNase P (RP) control in clinical samples: The RP primer and probe set is included in each run to test for human RNase P, which controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

The above described CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, when labeled consistently with the labeling authorized by FDA, entitled "CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), which may be revised by CDC in consultation with, and with concurrence of, the Division of Microbiology Devices (DMD)/Office of Health Technology 7 Office of In Vitro Diagnostics and Radiological Health (OHT7-OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The above-described CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized to be accompanied by the following information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

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- Fact Sheet for Patients: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel when used for the presumptive detection of 2019-nCoV and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel may be effective in the presumptive detection of 2019-nCoV, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, when used for detection of the 2019-nCoV in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel described above is authorized to detect 2019-nCoV in individuals who meet CDC criteria for 2019-nCoV testing.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

**III. Waiver of Certain Requirements**

I am waiving the following requirements for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the

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intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12)

**IV. Conditions of Authorization**

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

**Centers for Disease Control and Prevention (CDC)**

A. CDC will notify DMD/OHT7-OIR/OPEQ/CDRH in advance of any changes to the CDC criteria for 2019-nCoV testing.

B. CDC will make available the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with the authorized labeling only to authorized laboratories. CDC may request changes to the authorized labeling. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

C. CDC will provide to authorized laboratories the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers and the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Patients. CDC may request changes to the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers and the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Patients. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

D. CDC will make available on its website the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers and the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Patients.

E. CDC will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, authorized labeling and authorized Fact Sheets.

F. CDC will ensure that the authorized laboratories using the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

G. Through a process of inventory control, CDC will maintain records of test usage.

H. CDC will collect information on the performance of the test. CDC will report to FDA any suspected occurrence of false positive and false negative results and significant

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deviations from the established performance characteristics of the test of which CDC becomes aware.

I. CDC is authorized to make available additional information relating to the emergency use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel that is consistent with, and does not exceed, the terms of this letter of authorization.

J. CDC may request new Fact Sheets to accompany the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, if appropriate, and may request changes to such Fact Sheets. Such requests will be made by CDC in consultation with, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

K. CDC may request the addition of other instruments and associated software for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

L. CDC may request the addition of other extraction methods for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. CDC may request the addition of other specimen types for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. CDC may request the addition and/or substitution of other control materials for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. CDC may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. CDC will evaluate the analytical limit of detection and assess traceability[4] of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, CDC will update its labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. CDC will track adverse events and report to FDA under 21 CFR Part 803.

[4] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

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**Authorized Laboratories**

R. Authorized laboratories will include with reports of the results of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

S. Authorized laboratories will perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel as outlined in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use. Deviations from the authorized procedures, including the authorized RT-PCR instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel are not permitted.

T. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

U. Authorized laboratories will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and CDC (respvirus@cdc.gov) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

V. All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

**CDC and Authorized Laboratories**

W. CDC and authorized laboratories will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

**Conditions Related to Advertising and Promotion**

X. All advertising and promotional descriptive printed matter relating to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

Y. All advertising and promotional descriptive printed matter relating to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;

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- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from 2019-nCoV, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of 2019-nCoV under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel may represent or suggest that this test is safe or effective for the detection of 2019-nCoV.

The emergency use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection and/or diagnosis of 2019-nCoV is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Denise M. Hinton

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/9/2020 7:14:20 AM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject**: RE: 2019 nCoV DMD EUA MCM Hours_01-22-2020.xlsx

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Saturday, February 8, 2020 3:28 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2019 nCoV DMD EUA MCM Hours_01-22-2020.xlsx

Tamara:

| |
|---|
| 1/1/20 - 2/1/20 = 19.5 |
| 2/2/20 - 2/8/20 = 16.5 |

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, February 07, 2020 5:41 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: 2019 nCoV DMD EUA MCM Hours_01-22-2020.xlsx

Li:

| |
|---|
| 1/1/20 - 2/1/20 = 46 |
| 2/2/20 - 2/8/20 = 23 |

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 07, 2020 5:02 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: 2019 nCoV DMD EUA MCM Hours_01-22-2020.xlsx

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Kim, LI, and Tamara,

Could you please fill in the number of our you worked on nCoV for the following time periods:

| |
|---|
| 1/1/20 - 2/1/20 = 110 |
| 2/2/20 - 2/8/20 = 43.25 |

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/6/2020 9:36:39 AM
**To:** Lovell, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a4cfa4fc4094bbf8fac0e16bf710049-SXL]
**Subject:** text

(b)(5)
[redacted]

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/13/2020 10:41:31 AM
**To**: Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]
**Subject**: FW: FDA Novel coronavirus (2019-nCoV) EUA Information

Kris,

Could you please respond and set something up for Th/Fr next week. Thanks, Uwe

---

**From:** Lama Ramzi Suleiman <lrsuleiman@unicef.org>
**Sent:** Thursday, February 13, 2020 9:41 AM
**To:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Abdallah Makhlof <amakhlof@unicef.org>; Wandani Sebonego <wsebonego@unicef.org>; Tatsiana Ptashnik <tptashnik@unicef.org>
**Subject:** FDA Novel coronavirus (2019-nCoV) EUA Information

Dear Roth and Uwe,

Greetings from UNICEF supply Division

Hope you are doing well

It has been a long time since we have discussed our global needs for Ebola and Zika Dx . However, I'm reaching out to you again to touch base with you regarding 2019 Novel Coronavius Diagnostics

We were glad to notice the launch of FDA Novel coronavirus (2019-nCoV) EUA and the related Information on your website that FDA has issued . would you or any of your team be available for a call sometime next week to get more updates on the EUA for 2019-nCov diagnostics and the scope of products in the pipeline

Looking forward to hearing from you

Regards
Lama

Lama R. Suleiman
Contracts Manager – Malaria Prevention & Diagnostics Unit / Health Technology Centre
Tel: +45 4533 5859 Email: lrsuleiman@unicef.org www.unicef.org/supply

United Nations Children's Fund
Supply Division, Oceanvej 10-12, 2150 Nordhavn, Copenhagen, Denmark
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unicef 70 YEARS FOR EVERY CHILD

---

**From:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Sent:** Wednesday, 27 September 2017 8:53 PM

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**To:** Lama Ramzi Suleiman <lrsuleiman@unicef.org>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Nagwa Hasanin <nhasanin@unicef.org>; Abdallah Makhlof <amakhlof@unicef.org>
**Subject:** RE: Request for a discussion related to global need for Ebola diagnostics

Dear Lama,

Thank you for your engagement. We are glad to discuss both infection agents and will have the appropriate individuals on the phone. I propose we schedule a call for either:

Thursday October 12 at 3 pm CEST (9 am Eastern time zone in the US)
Or
Friday October 13 at 3 pm CEST (9 am Eastern time zone in US)

Do these times work for you?

Kind regards,
Kris

---

**From:** Lama Ramzi Suleiman [mailto:lrsuleiman@unicef.org]
**Sent:** Tuesday, September 26, 2017 6:26 AM
**To:** Roth, Kristian
**Cc:** Scherf, Uwe; Nagwa Hasanin; Abdallah Makhlof
**Subject:** FW: Request for a discussion related to global need for Ebola diagnostics

Dear Kris,

It is great to hear from you again and thank you so much for reaching out to Unicef.

It is indeed important to discuss our shared interest in improving global health with respect to Ebola.

we would like to schedule call with you to discuss our plans and need for the the Ebola Diagnostics and update you ( if relevant) on our progress with Zika Dignostics as well

How about the week of 9th October?

Looking forward to hearing from you

Regards
Lama

Lama R. Suleiman
Contracts Manager – Malaria Prevention & Diagnostics Unit / Health Technology Centre
Tel: +45 4533 5859 Email: lrsuleiman@unicef.org www.unicef.org/supply

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**From:** Roth, Kristian [mailto:Kristian.Roth@fda.hhs.gov]
**Sent:** Friday, 8 September 2017 20:46
**To:** CPHHQ-SD-DAN Supply <supply@unicef.org>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Request for a discussion related to global need for Ebola diagnostics

Dear Shanelle Hall,

About 1.5 years ago I attended the Zika Vaccine and Diagnostics Industry Consultation which was a very well organized meeting. We at the US FDA are currently re-evaluating the need (both globally and within the US) for Ebola in vitro diagnostic tests. I was hoping that we could arrange a telephone call between UNICEF and FDA to discuss UNICEF's evaluation of the need for a rapid antigen test for Ebola.

As you may know the US has issued a number of Emergency Use Authorizations for Ebola diagnostics. These authorizations are not permanent and FDA is mandated to revisit the need for these devices as the epidemic changes. We have heard that UNICEF may be planning to acquire these types of products therefore we would like to understand your needs to ensure that any action FDA may take in this area does not negatively impact your mission.

If it is acceptable to you, I propose having an approximately one hour teleconference to discuss our shared interest in improving global health with respect to Ebola.

Kind regards,
Kris

**Kristian Roth, Ph.D.**
*Branch Chief Bacterial Multiplex and Medical Counter Measures*
**Center for Devices and Radiological Health**
**Office of In Vitro Diagnostics and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 301-796-7024
kristian.roth@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/5/2020 8:59:17 AM
**To**: STRÖHER, Ute [stroheru@who.int]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Vielen Dank fuer Deinen Besuch
**Attachments**: EUA Review Template_NAT_Novel Coronavirus 1.19.2020.doc; Draft cover letter for Sponsor 01212020.docx

**Importance**: High

Dear Ute,

This is what we normally send out to sponsors who request the EUA-template. This one is for the NAAT test, we are working on developing an antigen based test template now.

Thanks a gain for the great meeting yesterday and the presentation to my staff. Call/email me any time if you have any questions.

Herzlichst,
Uwe

Dear Jeff,

Thank you for your email. Please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of 2019-novel coronavirus (2019-nCoV). I suggest when you are ready, the first step is to populate this draft template with the information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center). The Pre-EUA review is an interactive process, so we will provide feedback after receiving and reviewing the information provided. The draft review template is a shared "work-in-progress" document which you will populate with information and data as obtained and which we will review and provide feedback to you.

I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of 2019-nCoV to FDA (it includes the address for the Document Control Center). Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under type of submission please check "other" and specify Pre-EUA.

One hard copy of the signed EUA Cover Letter and one electronic copy of you Pre-EUA submission package (including the EUA Review Template - MS word document) should be enclosed in your Pre-EUA submission to FDA, and we also request that you submit the information requested via electronic mail to myself Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;
- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please be reminded that in the U.S. a test for the detection of 2019-nCoV or to diagnoses 2019-nCoV infection must not be distributed and/or used for clinical diagnosis without premarket clearance, approval, or EUA by the FDA.
NOTE: The EUA Interactive Review Template from the FDA is considered an internal working document and must not be distributed outside of your organization.

Please let me know if you have any questions, we look forward to working with you, Best regards,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

-----Original Message-----
From: STRÖHER, Ute <stroheru@who.int>
Sent: Wednesday, February 5, 2020 8:28 AM
To: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: RE: Vielen Dank fuer Deinen Besuch

Dear Uwe,

Thanks so much for taking the time yesterday to meet.
Greatly appreciated, especially considering how busy the day was for you and your team.
It's great to see that the first assay was authorized!

I also received news today from my team that Korea has authorized the PowerChek 2019-nCoV Real-time PCR kit from Kogen Biotech.

If you have the chance to send me your nCoV template, it would help to align our requirements for manufacturers.

Thanks again.

Liebe Grüsse,
Ute

-----Original Message-----
From: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Sent: 05 February 2020 04:20
To: STRÖHER, Ute <stroheru@who.int>
Cc: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: Vielen Dank fuer Deinen Besuch

Dear Ute,

Thank you so much for your visit today.  We had a great conversation.

Sorry for being available only for such a short period of time.

Attached the reason.  Please let stay in touch.

Herzlichst, Uwe

https://www.fda.gov/news-events/press-announcements/fda-takes-significant-step-coronavirus-response-efforts-issues-emergency-use-authorization-first

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# EMERGENCY USE AUTHORIZATION (EUA)

## EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (2019-nCoV)

## GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow ***[Text]*** should be completed by the IVD developer (sponsor) as applicable to their specific test. Text in **bold** outlines the Food and Drug Administration (FDA) suggestions and clarifications for the sponsors' consideration when completing the required information in a specific section.

- This is a EUA interactive review template for Pre-EUA/EUA submissions concerning molecular-based single target tests for detection of 2019 Novel Coronavirus (2019-nCoV), Wuhan, China. If you are developing a multiplex molecular-based assay for the detection and differentiation of nucleic acids from a panel of microorganisms, please review Appendix A for FDA recommendations.

- This is a EUA interactive review template for Pre-EUA/EUA submissions and not a guidance document. The template is subject to change as we learn more about the 2019-nCoV disease and its risk-benefit profile. Recipients will receive notice and updated templates as they become available.

- This EUA interactive review template is an FDA internal document and any proprietary information provided within the template and during the interactive review process will remain confidential as it does in a regular FDA premarket submission.

- Feedback provided by FDA during the interactive review of your pre-EUA/EUA is subject to change as we learn more about the 2019-nCoV disease and the risk-benefit profile evolves to address unmet public health needs.

- Prior to a potential authorization FDA will require developers of molecular-based tests to assess traceability of their test to an FDA-recommended reference material panel if available at the time. Specific details about the traceability study and the FDA-recommended reference material panel will be provided by the Lead Reviewer assigned to the Pre-EUA submission once the analytical and clinical evaluation data has been reviewed and found to be acceptable.

- Please be reminded that tests for the detection of 2019-nCoV or 2019-nCoV infection must not be distributed and/or used for clinical diagnoses without premarket clearance, approval, or EUA by the FDA. Clinical samples for 2019-nCoV testing should be sent to the appropriate public health laboratories until the IVD device subject of this Pre-EUA submission has received authorization from the FDA.

- Clinical specimens may be required to support the EUA request. Furthermore, please note that applicable regulations for human subject protection do apply under the

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EUA. Please refer to the Clinical Evaluation section of this document for more details.

- If authorized, the EUA means that this 2019-nCoV IVD is temporarily authorized for use until the public health emergency is terminated or the EUA is revoked by the FDA.

    - FDA recommends that you consider registration and listing your EUA product once you have been issued an EUA. If this is problematic, please notify the Agency during your Pre-EUA.
    - The EUA is not a pathway to permanent marketing of your device. Therefore, we strongly recommend that you consider, in addition to an EUA, a traditional premarket submission for your IVD so that your device can still be legally marketed after termination of the emergency declaration. We recommend that you identify as soon as possible in the Pre-EUA review process any consideration of moving your product forward towards De Novo/510(k) clearance. If so some of our feedback to you may take such a long-term goal into consideration in order to prevent additional testing where it may not be needed. Therefore, please consider submitting a Pre-Submission to inquire what studies would be required for a premarket approval/ clearance of your 2019-nCoV IVD. Details on how to submit a Pre-Submission to the Agency are outlined in the FDA guidance document: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.* [ HYPERLINK "https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program" ]

## A. EXECUTIVE SUMMARY (as of X/XX/20XX)

## B. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the ***[test name]*** to ***[indicate labs, if applicable]*** for the *in vitro* qualitative detection of RNA from the 2019-nCoV in ***[add all claimed specimen types, e.g., nasopharyngeal/oropharyngeal swabs, sputa, BAL, stool, and serum, etc.]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated with 2019-nCoV infection) and CDC novel coronavirus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated) to aid in the diagnosis of 2019-nCoV infection.

## C. MEASURAND

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Specific nucleic acid sequences from the genome of the 2019-nCoV **[*please specify the targeted gene(s) of the pathogen*]**.

## D. APPLICANT

***[Official name, address and contact information of applicant]***

## E. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name - ***[test name]***
Established Name - ***[test name]***

## F. REGULATORY INFORMATION

***Approval/Clearance Status:***
The ***[test name]*** test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

***Product Code:***
[XXX – FDA will complete]

## G. PROPOSED INTENDED USE

***1) Intended Use:***
**The proposed IU will be finalized based on the data and recommendations from Public Health authorities at the time of authorization – example text is provided below for a qualitative molecular test that detects organism RNA but may be adapted according to the specific emergency situation addressed by the device.**

[***Test name***] is a [***specify test technology such as, real-time RT-PCR test***] intended for the qualitative detection of nucleic acid from the 2019-nCoV in [***describe all the specimen types***] from individuals meeting CDC 2019-nCoV clinical criteria (e.g., clinical signs and symptoms associated with 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated). Testing is limited to [***laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories***].

Results are for the identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in **[*name specimen type*]** during the acute phase of infection. Positive results

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are indicative of active infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The ***[test name]*** is intended for use by **[*include intended user, e.g., trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures*]**. The ***[test name]*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

***2) Special Conditions for Use Statements:***

For prescription use only
For in vitro diagnostic use only

***3) Special Instrument Requirements:***

The ***[test name]*** test is to be used with the [***list all RT-PCR Instruments, software requirements, automated extraction instruments***].

## H. DEVICE DESCRIPTION AND TEST PRINCIPLE

**Example text has been added under each of the sub-headings below for a fluorescence based rRT-PCR test for detection of organism RNA. If a different test principle is used by the test for the detection of a specific analyte please modify the description accordingly to capture the salient points in each of the sub-headings below. Please note that for new investigative technologies FDA may request additional detailed information so we can adequately assess the risks and benefits associated with the device.**

***1) Product Overview/Test Principle:***

**Describe the technology of the test and how this technology works to identify the measurand, the instruments employed/required to perform the test from sample collection to result (include all claimed extraction and PCR detection instruments), and the specimen types for which you claim to have specific performance characteristics as described below. If applicable, list all primer and probe sets and briefly describe what they detect. Please include the nucleic acid sequences for all primers and probes used in the test. Please indicate if the test uses biotin-Streptavidin/avidin chemistry in any of the steps for coupling reagents. Please note that an alignment with available reference genomes for different strains of the target pathogen is requested as part of the inclusivity evaluation (Section N).**

The ***[test name]*** is a real-time reverse transcription polymerase chain reaction (rRT - PCR) test. The 2019-nCoV primer and probe set(s) is designed to detect RNA from

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the 2019-nCoV in ***[list all the specimens]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated).

2) ***Description of Test Steps:***

**List and describe in detail all the steps of the test sequentially from specimen collection to detection.**

Nucleic acids are isolated and purified from ***[specimens]*** using ***[please describe the method(s) of extraction (please specify the specimen input volume for extraction and/or test, the nucleic acid elution volume and whether isolation/purification is manual and/or automated)].*** The purified nucleic acid is reverse transcribed using ***[enzyme mix/kits – please specify the input volume of purified nucleic acid added to the rRT-PCR reaction mix]*** into cDNA which is then subsequently amplified in ***[please describe the instrument(s) and enzyme mix]***. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by ***[please describe the detection instrument(s)]***.

3) ***Control Material(s) to be Used with [test name]:***

**List all control materials (provided with the test kit and/or required but not provided with the test kit and describe what they are, how they are expected to work, where in the testing process they are used, and the frequency of use. If a control is commercially available, provide supplier's name and catalog number or other identifier; if your device relies on external controls that are manufactured by a third party please note that these controls should also be validated within your analytical and clinical studies described below in Section (N).**

Controls that will be provided with the test kit include:

a) A "no template" (negative) control is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***

b) A positive template control is needed to ***[describe need]*** and is used ***[describe use – please specify the concentration of the positive control relative to the LoD of your test (note that ideally the positive control concentration should be such that it is close to the LoD of your test) and also specify frequency of use]***

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c) An extraction control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use].*** **Please note that if the no template control and positive control, are taken through the entire sample processing procedure, including the extraction, then a separate extraction control is not required**.

d) An internal control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use]***.

Controls that are required but not provided with the test kit include ***[describe control – provide recommended sources of the control materials – either a separate control kit for purchase that you the applicant develops or a control material that can be purchased from a third party].*** This/these control(s) is/are needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***.

**Please note that any control recommended to be used with your device (provided with the kit or not) needs to be validated in the context of your analytical and clinical study (i.e., you will need to run these controls as part of your studies). In instances where control material is not readily available through 3rd party vendors (which is often the case at the beginning of an outbreak) FDA may request that you include suitable control material with your device. Please note that external control materials are considered particularly important in the context of EUA devices because often GMP requirements for the manufacture of the EUA device are waived in emergency situations and reagent stability studies are limited. Hence the external controls offer some assurance of EUA test performance in the hands of the end user.**

## I. INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. **Please describe if a Ct cutoff is used as part of your testing algorithm and/or if the end user is required to review fluorescent curves for weakly positive samples before final interpretation. Although not typical for molecular-based tests, if the test result involves the use of an algorithm/calculation, for example a ratio value, when determining the final patient test result, please include a detailed description and any additional calibration materials that may be required.**

1) ***[Test name] Controls – Positive, Negative and Internal***

**Describe in detail the expected results generated, including acceptance criteria, for all the controls described in detail in Section H above. Describe the measured values (if applicable) for valid and invalid controls and outline the recommended actions the laboratory should take in the event of an invalid control result.**

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2) ***Examination and Interpretation of Patient Specimen Results:***

**Describe when clinical specimen test results should be assessed and outline the criteria for test validity**. **Example text**: Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

**Clearly indicate how to interpret numeric test values (if applicable) as positive or negative for presence of the 2019-nCoV. Indicate if the end user is required to review fluorescent curves for weakly positive samples before final interpretation and how to identify indeterminate/inconclusive results (if they exist) results and how the user should resolve them, e.g. if repeat testing may be required.**

**When applicable, provide a table clearly describing the possible combinations of test result values for each primer/probe set, and how they should be combined into a final interpretation of the result for your test. If the test produces result that will be used as part of a CDC recommended testing algorithm, please indicate what follow-up testing/process should be conducted, if applicable.**

## J. PRODUCT MANUFACTURING

**Please note that if you are developing a test for use at a single site (i.e., a laboratory developed test LDT), some of the information requested in this section may not be applicable. Please contact FDA for additional guidance for an emergency use LDT.**

The ***[test name]*** has been validated using only the components referenced in this submission and shall not be changed without prior concurrence from the FDA.

*1)* ***Overview of Manufacturing and Distribution:***

The product will be manufactured at [***manufacturer's name and FDA registration number (if applicable) or laboratory name if an LDT***] by [***manufacturer name, or laboratory name if an LDT***] personnel consistent with practices for the production of **[*types of devices*]** based on [***type of quality system****]. Material manufactured by [***manufacturer's name, or laboratory name if an LDT***] may be bottled and kitted by [***packager name***] manufacturing facility.

***Under the Emergency Use Authorization (EUA) most of the 21 CFR 820 Quality System Regulation (QSR) requirements can be waived for the duration of the EUA. FDA expects that developers follow comparable practices as much as possible and may consider previous compliance history when determining whether or not to waive certain QSR requirements for a specific product. Please note adverse events, as per 21 CFR Part 803, have to be reported for authorized devices (see Section R).**

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The current manufacturing capabilities include the ability to manufacture approximately **[*please insert the approximate number of units/products that can currently be manufactured per week at the manufacturing facility*]** products per week, however in the event of a surge in demand this could be increased to **[*please insert the approximate maximum number of units/products that could potentially be manufactured per week at the manufacturing facility if there was a surge in demand*]** product per week within a **[*please specify in weeks/months the expected timeframe required to increase product production if required*]** timeframe.

The product will be distributed by **[*please describe the distribution plan for the product and list all current distributors*]**.

2) ***Components Included with the Test***

Components manufactured by [***manufacturer's name and FDA registration number (if applicable)***] and supplied with the test include:

**List all components and reagents provided for your test, including a description of the primers and probes, volumes, concentrations, quantities, buffer components, etc.**

3) ***Components Required But Not Included with the Test***

Components required but not included with the test:

**List all components and reagents not included with the test that must be supplied by the user to perform the test, with specific supplier names and catalog numbers or other identifiers for obtaining these components and reagents. Please include here all specific consumables that were validated for use with your device, that are not interchangeable with other products and that are needed to guarantee device performance as established in the EUA validation studies listed in Section N below.**

4) ***Testing Capabilities***

**Briefly describe current sample throughput capacity, total time required to perform the test (from clinical specimen collection, specimen transport to result), and number of tests that can be performed per instrument run and per day.**

5) ***Reagent Stability:***

**Briefly describe stability test plan for *[test name]* reagents and include any accelerated stability information if available. Please note that reagent stability studies do not need to be completed at the time of EUA issuance, however the study design should be agreed upon during interactive review and the stability studies started immediately following authorization, if not before. When designing your stability study, we have some general recommendations that are outlined in Appendix B, for your consideration.**

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## K. PERFORMANCE EVALUATION

**If you plan to claim multiple target analytes to aid in differential diagnosis or you plan to claim multiple RT-PCR instruments and/or extraction methods, please refer to Appendix A and C, respectively, more information. Please note that any omission of a requested study in this document should be documented and justified.**

### *1) Analytical Sensitivity:*

a) *Limit of Detection (LoD):* **You should determine the LoD of the device utilizing the entire test system from sample preparation to detection for each clinical matrix claimed. Please note that claims for additional anticoagulants, for blood specimens, can be supported by a matrix equivalency study as outlined in Section N, subsection 3 below. The LoD is determined using dilutions of live propagated and titered 2019-nCoV stocks (CFU/mL or PFU/mL) spiked into a relevant clinical matrix. If wild-type virus is not available at the time of your validation studies, please contact FDA to discuss a potential alternative. Please note that if available please also provide Genomic Equivalent Copies (GEC)/mL units for the stock solutions used and include an explanation on how they were determined. Please note that LoD studies should be performed with live organisms, as described above. If you plan to use inactivated organism in your LoD determination you should describe how the material was inactivated and perform a study to determine whether the inactivation process impacted the LoD of the device.**

**First a tentative LoD must be established through limiting dilutions of the prepared material with 3-5 replicate measurements. Please note for all the analytical studies described in Section N that require replicate testing, one replicate equates to one independent extraction and PCR detection. Once a tentative LoD is established, the LoD should be confirmed by preparing at least 20 additional replicates at the LoD concentration and demonstrating that the organism was detected with a minimum 95% positivity (19/20). If this confirmatory study achieves a positivity of 100%, then a lower concentration needs to be tested (with 20 replicates) until <100% positivity is obtained.**

**Please use the following format when submitting LoD information and data:**

LoD studies determine the lowest detectable concentration of 2019-nCoV at which approximately 95% of all (true positive) replicates test positive. The LoD was determined by limiting dilution studies using characterized samples.

**List/describe the following in this section:**

- **Titers and strains of the 2019-nCoV stocks used for the LoD study and describe how the organism stocks were prepared and how the titers were determined.**

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- **The dilution factor and number of serial dilutions of the characterized 2019-nCoV that were tested to determine the LoD for each primer and probe set.**
- **The nucleic acid extraction/purification method.**
- **The real time PCR instrument.**

Serial dilutions of the characterized 2019-nCoV were then tested in **[*number of replicates (i.e., recommend that sample is extracted independently three-five times and each extraction tested once)*]** replicates. The lowest concentration at which all [*number of replicates*] replicates were positive was treated as the tentative LoD for each test. The LoD of each test was then confirmed by testing [*number of replicates (at least 20 recommended)*] with concentrations at the tentative limit of detection. The final LoD of each test was determined to be the lowest concentration resulting in positive detection of [*number of positive replicates (at least 19 out of 20 replicates)*]. [*Include analysis of LoD results, indicating the final LoD for each test*]

**Tentative LoD: [*Please provide a summary of the data for each strain tested]* example table 2019-nCoV stocks is provided below:**

| 2019-nCoV Strain Tested | Stock 2019-nCoV Titer | Serial 10-Fold Dilution Factor | Concentration in Dilution Tested [Include Units] | Replicate 1 $C_t$ | Replicate 2 $C_t$ | Replicate 3 $C_t$ | Replicate 4 $C_t$ | Replicate 5 $C_t$ | Call Rate | Lowest Concentration with Uniform Positivity per Analyte | Limit of Detection (LoD) per Virus Strain |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Example:*** *[analyte]* | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

b) FDA Sensitivity Evaluation: The analytical sensitivity of the test has to be further assessed by evaluating an FDA-recommended reference material using an FDA developed protocol if applicable and/or when available. Details will be provided during the Pre-EUA interactive review.

c) *Reactivity/Inclusivity:* Reactivity of the ***[test name]*** was evaluated for additional isolates of 2019-nCoV.

**Reactivity: *[test name]* example table below**

| 2019-nCoV Strain/Isolate | Source/Sample Type* | Concentration | Ct** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

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| | | | |
|---|---|---|---|
| | | | |

***Please list source of material used for wet testing and sample type tested (i.e., organism – live or inactivated, purified nucleic acid – whole genome etc.).**
**** If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**At a minimum, the strain used in your LoD evaluation should be listed here (multiple isolates of the same 2019-nCoV strain that was used for the LoD studies can also be included if available). If additional isolates are not available at the time of your validation studies, please discuss with FDA. Each isolate should be tested at or near the LoD (no more than 3x LOD) of the test, spiked into clinical matrix utilizing the entire test system, including extraction. If you plan to claim more than one type of clinical matrix, we recommend that you perform this study in the most challenging clinical matrix, testing a minimum of 3 replicates. In addition, the wet testing should be accompanied by extensive inclusivity *in silico* analysis of the test primer and probes with all known strains/isolates (past/present) of 2019-nCoV (including the strain/isolate used for wet testing).**

## 2) *Analytical Specificity:*

a) *Cross-Reactivity:* Cross-reactivity of the ***[test name]*** was evaluated using both *in silico* analysis and by testing whole organisms **[*pathogen*]** (concentration) or purified nucleic acid from other ***[describe organisms]*** (concentration/reaction).

**Cross-Reactivity: *[test name]* example table for wet tested organisms below**

| Virus/Bacteria/Parasite | Strain | Source/ Sample type | Concentration | Ct Values* |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

***If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**Cross-reactivity studies are preformed to demonstrate that the test does not react with related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen. The FDA Tables 1 and 2, below are intended to recommend simulate testing of patients having infections with organisms which cause similar symptoms to those observed at the onset of 2019-nCoV infection. The FDA Tables also include other organisms and strains which have significant genetic similarity and therefore a higher likelihood of cross-reacting with 2019-nCoV specific reagents. Also included in the FDA Tables are recommended unclaimed organisms/strains which are likely to be endemic to the currently affected area should be included in cross-reactivity testing since these organisms/strains will be an important aspect of the differential diagnosis of 2019-nCoV infection.**

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**FDA Table 1 Cross-Reactivity: List of Organisms to be wet-tested and analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens**

| Other high priority pathogens from the same genetic family | High priority organisms likely in the circulating area |
|---|---|
| Human coronavirus 229E | Adenovirus (e.g. C1 Ad. 71) |
| Human coronavirus OC43 | Human Metapneumovirus (hMPV) |
| Human coronavirus HKU1 | Parainfluenza virus 1-4 |
| Human coronavirus NL63 | Influenza A |
| SARS-coronavirus | Influenza B |
| MERS-coronavirus | Enterovirus (e.g. EV68) |
| | Respiratory syncytial virus |
| | Rhinovirus |
| | *Chlamydia pneumonia* |
| | *Haemophilus influenzae* |
| | *Legionella pneumophila* |
| | *Mycobacterium tuberculosis* |
| | *Streptococus pneumonia* |
| | *Streptococcus pyrogenes* |
| | *Bordetella pertussis* |
| | *Mycoplasma pneumoniae* |
| | *Pneumocystis jirovecii* (PJP) |
| | Pooled human nasal wash - *to represent diverse microbial flora in the human respiratory tract* |
| | |

**FDA Table 2 Cross-Reactivity: List of Organisms to be analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens:**

| Other high priority pathogens from the same genetic family | High priority organisms, including organisms commonly found in the clinical matrix |
|---|---|
| | Influenza C |
| | Parechovirus |
| | *Candida albicans* |
| | *Corynebacterium diphtheriae* |
| | *Legionella non-pneumophila* |
| | *Bacillus anthracosis* (Anthrax) |
| | *Moraxella cararrhalis* |
| | *Neisseria elongate and miningitidis* |
| | *Pseudomonas aeruginosa* |
| | *Staphylococcus epidermis* |
| | *Staphylococcus salivarius* |
| | *Leptospirosis* |

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| | |
|---|---|
| | *Chlamydia psittaci* |
| | *Coxiella burneti (Q-Fever)* |
| | *Streptococcus aureus* |
| | |

***In silico* analysis should be performed on all potentially cross-reactive organisms outlined in the FDA Tables 1 and 2 above. You should provide the result summary of the *in silico* blast analysis (tabular format) evaluating whether there is any significant amplification of non-target sequences that could either result is cross-reactivity or potentially interfere with the detectability of the actual target analyte. As such we are asking that you provide individual blast results (non-truncated alignments) for each of the primers and probes used in your device with potential cross-reacting organisms. Please provide for our review the percent sequence homology for each organism relative to the target analyte primers/probes in your test. Please use the example table below when presenting the results of *in silico* analysis in your submission:**

**Results of *In Silico* Analysis**

| Pathogen | Strain | GenBank Acc# | % Homology Test FP (i.e. 0-100%) | % Homology Test RP | % Homology Test Probe |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**The analysis should include multiple representative strains from GenBank for each organism. If *in silico* analysis reveals other potential cross-reactants (i.e., ≥80% homology between one of your primers or the probe to any of the sequences of listed potential cross reactants), you should carefully review the alignments and determine based on the positions of the homologous stretches and mismatches if additional cross-reactivity and/or interference (please refer to item b below – microbial interference studies) wet testing will be required to rule out cross-reactivity or interference of that organism that may affect the performance of your device. In these circumstances if wet-testing is omitted you should include an explanation as to why *in silico* generated data is not clinically relevant (irrelevant isolate, location/extent of match within primer/probe, etc.), or why the performance of your test would not be impacted.**

**Organisms in FDA Table 1 should be wet tested in addition to the *in silico* analysis. Omissions from wet-testing should be discussed with FDA and supported by a well-documented justification that includes a due diligence attempt to obtain the live or inactivated organisms (and/or purified nucleic acid – which is acceptable for cross reactivity evaluation for an EUA).**

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**The wet testing evaluation should reflect test specimens prepared at the highest clinically relevant level of organism (i.e., a minimum of $10^6$ CFU/ml or higher for bacteria and $10^5$ $TCID_{50}$/mL or PFU/ml or higher for viruses) and should be tested with a minimum of three replicates per organism test specimen. Test specimens can be prepared by spiking cultured isolates/inactivated organisms/ purified nucleic acids (whole genome) into negative clinical matrix and determining cross reactivity based on triplicate replicates. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix.**

**If you plan to claim non-blood or non-respiratory clinical specimen types for diagnostic use with your device, e.g., stool specimens, etc., please consult FDA for more information on additional organisms that may be recommended for cross-reactivity testing, common examples are provided below for stool specimens (FDA Table 3):**

**FDA Table 3: Organisms to be analyzed for non-blood clinical specimens:**

| **Stool** |
|---|
| *Escherichia coli* |
| *Lactobacillus* |
| *Bacillus* spp. |
| *Clostridium* Spp. |
| *Enterobacter* |
| *Enterococcus* |
| Fusobacterium |
| Bacteroidetes |
| Bifidobacterium |
| Ruminococcus |
| |

b) *Microbial Interference Studies:* **If *in silico* analysis reveals ≥ 80% homology between the cross-reactivity microorganisms and your test primers/ probe(s), we recommend that you either perform (1) a microbial interference study with 2019-nCoV and the microorganisms that your test primers/ probe(s) have homology to, (2) as an alternative to the microbial interference study, you may provide justification as to why (e.g., amount of primer(s)/ probe(s) included in your master mix) the performance of your test would not be impacted by the presence of a causative agent of a clinically significant co-infection, or (3) explain why the *in silico* results are clinically irrelevant. In the case of the microbial interference study, interference should be evaluated using samples spiked at a low 2019-nCoV concentration, at 3x LoD, and a high interferent level (either microorganisms or nucleic acids purified from them), to represent the worst-case scenario, with a minimum of 3 replicates. If you plan to claim more than**

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**one type of blood clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix. If the LoDs are similar in the blood clinical matrices the study should be performed in the most challenging matrix, i.e., whole blood. In addition, if you are claiming blood and non-blood clinical specimens you may be required to perform this study in more than one clinical matrix. If interference is observed at the level tested, an additional titration study should be performed to determine the highest microorganism interferent level the 2019-nCoV test can tolerate.**

c) *Endogenous Interference Substances Studies*: **The extent of testing for endogenous interference substances depends on the matrix that is claimed for the device as well as on the technology of the device, e.g., if a nucleic extraction procedure is performed prior to testing or not. For EUA we do not typically ask for interference studies for tests that use conventional PCR and/or well-established extraction methods prior to testing (e.g., Boom method and column-based extraction methods).**

**For extraction procedures that are new or for nucleic acid-based technologies that are different from conventional PCR (e.g., various isothermal methods), we expect testing of potential interferents. The impact of interfering substances should be evaluated over the expected clinical range of the potentially interfering substance. Potential sources of endogenous interference include, but are not limited to, the ones listed in the tables below. It is important to note that the evaluation of interference and the generation of false negative results should be done using samples containing the analyte at or near the LoD and should not exceed 3x LoD. You should test a minimum of 3 replicates per substance. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed between the different clinical matrices this may warrant this study being performed in more than one clinical matrix. Biotin interference poses a risk to laboratory tests that incorporate the free biotin-streptavidin capture method. Therefore, please review this safety communication [ HYPERLINK "https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication" ] and the following [ HYPERLINK "onenote:http://sharepoint.fda.gov/orgs/CDRH-IVD/Orgs/DMD/DMD%20OneNotes/Language/Analytical%20Studies/Interference.one" \l "DRAFT%20guidance%20-%20Testing%20for%20Biotin%20Interference%20in%20In%20Vitro%20Diagnostic%20Devices&section-id={39D67316-5AE2-4791-958F-9387D384D6FA}&page-id={9298F00C-7C39-43CB-9EBA-29E5BC08BB6E}&end" ] ([ HYPERLINK "http://sharepoint.fda.gov/orgs/CDRH-IVD/Orgs/DMD/_layouts/OneNote.aspx?id=%2Forgs%2FCDRH-IVD%2FOrgs%2FDMD%2FDMD%20OneNotes%2FLanguage&wd=target%28Analytical%20Studies%2FInterference.one%7C39D67316-5AE2-4791-958F-**

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**9387D384D6FA%2FDRAFT%20guidance%20-%20Testing%20for%20Biotin%20Interference%20in%20In%20Vitro%7C9298F00C-7C39-43CB-9EBA-29E5BC08BB6E%2F%29" ]) to determine if biotin interference testing may be warranted for your device. We also recommend you consult with FDA prior to initiating biotin interference testing, if applicable.**

**The tables below indicate the potentially interfering substances that may be found in blood and respiratory specimens. For other non-blood specimen types, such as stool, the list of substances could be expanded – please consult with FDA.**

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *positive* results:**

| Potential Interfering Substance | Concentration | Results (Detected X/3) |
|---|---|---|
| **Respiratory Specimens** | | |
| Mucin: bovine submaxillary gland, type I-S | | |
| Blood (human) | | |
| Nasal sprays or drops | | |
| Nasal corticosteroids | | |
| Nasal gel | | |
| FluMist | | |
| Homeopathic allergy relief medicine | | |
| Throat lozenges, oral anesthetic and analgesic | | |
| Anti-viral drugs | | |
| Antibiotic, nasal ointment | | |
| Antibacterial, systemic | | |
| **Blood Specimens** | | |
| Hemoglobin | 10 mg/mL* | |
| Bilirubin Conjugated | 0.4 mg/mL* | |
| Bilirubin Unconjugated | 0.4 mg/mL* | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | |
| Triglycerides | 15 mg/mL* | |
| Cholesterol | 4 mg/mL* | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | |
| Rheumatoid Factor | 2000 IU/mL* | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *negative* results:**

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| Potential Interfering Substance | Concentration* | Viral Strain Level (In multiples of LoD) | Results (Detected X/3) |
|---|---|---|---|
| **Respiratory Specimens** | | | |
| Mucin: bovine submaxillary gland, type I-S | | | |
| Blood (human) | | | |
| Nasal sprays or drops | | | |
| Nasal corticosteroids | | | |
| Nasal gel | | | |
| FluMist | | | |
| Homeopathic allergy relief medicine | | | |
| Throat lozenges, oral anesthetic and analgesic | | | |
| Anti-viral drugs | | | |
| Antibiotic, nasal ointment | | | |
| Antibacterial, systemic | | | |
| **Blood Specimens** | | | |
| Hemoglobin | 10 mg/mL* | | |
| Bilirubin Conjugated | 0.4 mg/mL* | | |
| Bilirubin Unconjugated | 0.4 mg/mL* | | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | | |
| Triglycerides | 15 mg/mL* | | |
| Cholesterol | 4 mg/mL* | | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | | |
| Rheumatoid Factor | 2000 IU/mL* | | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

### 3) *Matrix Equivalency (if applicable):*

**A matrix equivalency study may be used to support certain specimen type claims that were not evaluated during the clinical study (e.g., serum versus plasma, use of different anticoagulants, use of difference swab types or viral transport media, etc.). Please note that LoD and clinical specificity studies are required for all claimed matrices. The matrix in which the clinical studies are conducted is the comparator. All other matrices are to be shown to be equivalent to the comparator matrix. We request a minimum of 40 paired samples each obtained from individual persons; negative (10 samples), low positive (1.5-2xLoD, 20 samples), and moderate positive (5-10xLoD, 10 samples) samples should be tested. Positive samples are prepared by spiking paired negative clinical matrix with the same amount of target analyte. Please note that individual (and not pooled) samples should be used in this study.**

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4) ***Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method:***

**A comparative LoD study may be required to support use of a comparator method in your clinical evaluation that has not been validated with a specific specimen type. The comparative LoD study should be conducted testing the same dilution series using both, your test and the comparator you chose in parallel (to dilution endpoints for both tests), 3-5 replicates per dilution level are sufficient for this study.**

5) ***Specimen Stability and Fresh-frozen Testing:***

**A specimen stability study may be required to support specimen stability claims in the instructions for use outside of those typically outlined in CSLI standards. A fresh/frozen and/or freeze/thaw study may be required to support the use of frozen specimens if they are used as part of the clinical evaluation. Please consult with FDA concerning an appropriate study design prior to initiating any studies.**

6) ***Clinical Evaluation:***

**This section should describe the clinical study used to evaluate the performance of your test. Please note that the exact requirements for the clinical evaluation will be very dependent on, access to 2019-nCoV disease clinical specimens at the time of the studies and the nature of the emergency. Our general clinical study evaluation recommendations for respiratory and serum clinical specimens are outlined below. If you are interested in claiming additional specimen types, for example, stool, please contact FDA for current recommendations. Please note these clinical study recommendations may be subject to change as we continue to learn about the 2019-nCoV disease or as the risk benefit analysis changes.**

**The clinical performance in general should be evaluated for each unique claimed clinical specimen type - with the exception of claims that can be supported by a matrix equivalency study (outlined in Section 3 above). The performance characteristics should ideally be established using a clinical study with a limited number of prospective samples. If a prospective study is not feasible, an acceptable alternative would be to test retrospectively collected 2019-nCoV nucleic acid negative and positive specimens from patients, accompanied by some basic information such as, the specimen collection date, date of onset of symptoms (if present/known), tests used to identify 2019-nCoV nucleic acid positive specimens, etc. Depending on the nature of the disease, if no prospective or retrospective specimens are**

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**available at the time of your pre-EUA submission for the 2019-nCoV disease we may accept a fully contrived clinical evaluation. The clinical evaluation should be comprised of a minimum of 100 negative individually collected specimens and 50 individual positive specimens (prospective, retrospective and/or contrived). Use of pooled specimens are not acceptable for the clinical evaluation of your test. Please see FDA Table 5 for more details. Please note that if a fully contrived clinical study is used to support your Pre-EUA submission, additional clinical testing of a limited number of natural clinical positive specimens and potentially negative specimens from the endemic region, if available, may be required at the time when this Pre-EUA transitions to an EUA as a result of an Emergency declaration for 2019-nCoV disease.**

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## FDA Table 5: Clinical study Recommendations:

| Details | Study Including Prospective/ Retrospective Specimens | Fully Contrived Sample Study |
|---|---|---|
| Minimum Number of Positive Specimens | 50<br><br>The number of natural (prospective/retrospective) positive clinical specimens should be at least 25 (collected from symptomatic patients in the 2019-nCoV disease endemic region(s)) and, if necessary, may be supplemented with contrived samples to generate the total of 50 positive specimens. Contrived samples should be prepared as described in the fully contrived sample study column. | 50<br><br>The contrived positive samples should be made in individual negative clinical matrix collected from subjects from a non-endemic population (pooled matrix is not acceptable for the clinical evaluation). Please note that the negative clinical matrix used for spiking should be confirmed negative by your test device prior to spiking. Half of the contrived positive samples can be prepared by spiking the 2019-nCoV at LoD and the remaining contrived positive samples should cover the range of the test up to and not higher than 5 x LoD.<br><br>Negative respiratory specimens: Can be archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection.<br><br>Negative blood specimens: Can be collected from healthy subjects from non-endemic areas. |
| Minimum Number of Negative Specimens | 100<br><br>Note: In general, for EUA the 100 individual negative samples can be collected from; (1) archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection for respiratory specimens, and (2) healthy subjects from non-endemic areas for blood specimens, that are "expected 2019-nCoV disease negative". Note these negative specimens can be used to also prepare any contrived positive specimens used in support of the clinical evaluation of the test.<br><br>Please note this recommendation is dependent on the current outbreak situation and is subject to change as we learn more about the 2019-nCoV disease/outbreak. If the outbreak situation for 2019-nCoV disease is primarily outside of the continental U.S. (OUS) it may be beneficial to consider collecting negative specimens that represent 50% endemic and 50% non-endemic regions. If negative specimens are collected from the endemic region of the 2019-nCoV disease these should be tested with the same comparator chosen for the positive specimens (more details provided below). For non-endemic collected specimens you can compare to the expected "negative" result. | |
| Recommended Comparator Method | Positive: Positive percent agreement should be calculated in comparison to a EUA PCR test (please see the following website for the most recent list of FDA authorized 2019-nCoV | Positive: Compare to expected result.<br><br>Negative: See Minimum Number of Negative Specimens row |

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| | | |
|---|---|---|
| for percent agreement performance calculations | tests: [ HYPERLINK "https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm" ]. If no EUA test available at the time of your EUA submission, please consult with FDA about your choice of comparator method – which ideally should be a well validated PCR test with comparable sensitivity to your subject device. Please note that a well validated PCR test should include evaluation of the tests LoD, inclusivity, exclusivity, interference and any clinical testing.<br><br>Negative: See Minimum Number of Negative Specimens row | |
| Comparator Method Note 1 | Please note when using natural clinical specimens, the comparator method must be validated for the specimen type claimed – if not you should perform a Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method study, as explained above (Section 4), to support its use as a comparator method in your clinical study. | N/A |
| Comparator Method Note 2 | Any occurrences of false results should be investigated with an additional validated PCR test and/or targeted sequencing, and the results of the discordant analysis can be footnoted in your final performance table but cannot be used to change the final performance calculations. | |
| Natural Clinical Specimens IRB/Informed Consent Note | For clinical specimens collected to support the EUA request, please note that sample collection needs to adhere to all applicable rules of human subject protection; as such, sample collection needs IRB approval, which includes review of the informed consent forms. Samples need to be collected with informed consent. If leftover de-identified samples are used, FDA exercises enforcement discretion regarding the informed consent requirement if the specimen collection meets the criteria described in the FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable ([ HYPERLINK "http://www.fda.gov/cdrh/oivd/guidance/1588.pdf" ]).<br>**Note that IRB approval is still required even if leftover de-identified samples are used in your study.** | |
| Additional Studies Warning | N/A | If fully contrived samples were used in your Pre-EUA submission, additional testing of natural clinical specimens may be requested, if available, to support transition of the Pre-EUA to EUA as a result of an Emergency declaration. |
| Testing Approach Note 1 | Please note all clinical specimens (natural and contrived) should be evaluated in accordance with your proposed diagnostic algorithm, including retesting when appropriate. We understand the limited nature of natural specimens may preclude retesting. In instances were retesting is indicated but not performed, for the purposed of performance evaluation, initial results will be analyzed for performance and equivocal/indeterminate results count against your final performance. | |
| Testing Approach Note 2 | Specimens should be tested in a blinded fashion, e.g., positive and negative samples should be mixed and blinded to the end user, end user should also be blinded to the results of any comparator method testing. | |

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**When you describe your clinical study please indicate/include:**

- **How the specimens were generated/collect/sourced**
- **If the study was fully prospective, mix of prospective, retrospective and/or contrived or fully contrived**
- **The rationale for the concentrations/specimens selected (if using contrived or 3-party sourced specimens)**
- **The total number of specimens tested**
- **The specimen types (clinical matrix)**
- **A summary of the study results**

**In the case of real-time PCR tests, please provide the line data in an Excel file as part of the Pre-EUA submission for each specimen (please indicate for each specimen if it was prospective, retrospective or contrived and the clinical matrix it represents); the data should include the $C_T$ values (for the specimen and the controls) and call/result for your device and, in the case of the natural clinical specimens, the comparator method results should be included as well.**

## L. UNMET NEED ADDRESSED BY THE PRODUCT

**This section will be finalized by FDA based on the state of the emergency at the time of authorization and based on recommendations from Public Health authorities at that time. Example text is provided below but may be adapted according to the specific emergency situation that is addressed by the device and the need at the specific time of the outbreak.**

[Outline background of pathogen, disease and current outbreak]

[Outline details of the disease such as the following:

- likely sources of transmission
- likely symptoms – if any
- Prevalence of symptomatic disease (what fraction of infection results in symptomatic disease)]

Laboratories in the United States are in need of diagnostic tools for use in the 2019-nCoV emergency for rapid diagnosis of acute 2019-nCoV infection.

A public health emergency has been declared by the Secretary of Health and Human Services (HHS) on [Month Day, YEAR] justifying the authorization of emergency use of *in vitro* diagnostic tests for detection of 2019-nCoV and/or diagnosis of 2019-nCoV infection.

The ***[test name]*** can augment clinically important laboratory evidence for individuals with active infection. The 2019-nCoV nucleic acid is generally detectable in [name

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specimen type] during the acute phase of infection (approximately [7] days following onset of symptoms, if present) [and possibly for longer in other specimen types].

Under emergency use authorization (EUA), ***[applicant name]*** plans to distribute the test or accept sample for testing with the ***[test name]*** for the detection of nucleic acid from 2019-nCoV in clinical specimens collected from individuals meeting CDC's 2019-nCoV clinical and/or epidemiological criteria. This EUA request for the ***[test name]*** is intended to expand domestic readiness within the United States and its territories by expanding diagnostic testing capabilities for 2019-nCoV during public health emergency.

FDA consulted with subject matter experts within HHS on the public health needs for diagnostic devices to detect 2019-nCoV nucleic acid. It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for 2019-nCoV detection during the public health emergency.

## M. APPROVED/CLEARED ALTERNATIVE PRODUCTS

Currently no methods for the detection of the 2019-nCoV have been approved/ cleared by FDA.

## N. RISKS AND BENEFITS:

**The Risks and Benefits section should be updated according to your specific device, some example language is given below but should be tailored to the device and the disease.**

Risks

The ***[test name]*** has been designed to minimize the likelihood of false test results. However, should false results occur, they may present risks to patients:

- False positive result:
  - A false positive 2019-nCoV result could [***update based on the pathogen***].
  - A false positive result in the context of the current public health emergency could lead to misallocation of resources used for surveillance and prevention.
  - A false positive result could delay correct diagnosis and initiation of appropriate treatment for the actual cause of patient illness.
- False negative result:
  - Although a negative result does not rule out 2019-nCoV infection, a false negative has the potential to result in initiation of inappropriate treatment and a delay in correct diagnosis.
  - A false negative result can trigger a waste of health care resources, as additional evaluations are pursued in the effort to establish the true diagnosis.
  - A false negative results can contribute to further spread of the disease.

Benefits

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The primary benefit of distributing the ***[test name]*** for clinical use is that it provides a relatively fast diagnostic method for symptomatic patients, which enables faster intervention.

- True positive test results provide support for the diagnosis of a 2019-nCoV infection. The results can be used in conjunction with clinical and epidemiological information to guide patient management.
- Distribution of the factsheets can help healthcare professionals and the public learn more about 2019-nCoV disease and how to avoid acquiring it.

Risk Assessment

- Negative results may not preclude a 2019-nCoV infection. It is emphasized that the ***[test name]*** should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure must be considered pivotal to making patient management decisions. A negative test should not be interpreted as definitive, if other aspects of the patient's clinical presentation or recent epidemiologic exposures indicate such is likely, and diagnostic tests for other diseases are negative.
- False negative results due to failure of PCR are minimized by the presence of controls that monitor nucleic acid extraction and PCR efficiency.
- Risk of patient discomfort or harm during sample collection is minimal.

Risk-Benefit Assessment

The risks posed by use of the ***[test name]*** are mitigated by:

- Use of the ***[test name]*** in conjunction with other laboratory, epidemiological, and clinical evaluation tools
- Distribution of Healthcare Provider and Patient fact sheets.
- Post-market studies/reporting or conditions of Authorization.

Based on these factors, the potential benefits from the use of the ***[test name]*** are expected to outweigh the risks.

## O. FACT SHEET FOR HEALTHCARE PROVIDERS AND PATIENTS:

**Include proposed Fact Sheets for Patients and Healthcare Providers**

## P. INSTRUCTIONS FOR USE/ PROPOSED LABELING/PACKAGE INSERT:

**Include Instructions for Use, Box Labels, Vial Labels and any other proposed labeling.**

## Q. RECORD KEEPING AND REPORTING INFORMATION TO FDA:

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[***Manufacturer name***] will track adverse events and report to FDA under 21 CFR Part 803. A website is available to report on adverse events, and this website is referenced in the Fact Sheet for Health Care providers as well as through the [***Manufacturer name***] Product Support website: [***Include link to Website***]. Each report of an adverse event will be processed according to [***Manufacturer name]***'s Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the FDA as required. Through a process of inventory control, [***Manufacturer name]*** will also maintain records of device usage/purchase. [***Manufacturer name]*** will collect information on the performance of the test, and report to FDA any suspected occurrence of false positive or false negative results of which [***Manufacturer name]*** becomes aware. [***Manufacturer name]*** will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

## R. ADMINISTRATIVE INFORMATION:

**Interactive Review Log:** Please use the table below to document interactive review with FDA and include interactions initiated by either FDA or yourself

| **Date** | **Type of Interaction** (phone/ email/ formal submission-DCC) | **Brief Description** (e.g., questions asked/ feedback from FDA received / any word documents included) |
|---|---|---|
| [X] | [X] | [X] |
| | | |
| | | |

## S. FDA ADMINISTRATIVE INFORMATION:

**This section will be finalized by the FDA Lead Reviewer upon completion of the review process and documents the interactive review of this submission and any conclusions resulting from the interactive review.**

1) **Summary of Interactive Review – Lead Reviewer to use this section to highlight any major issues solved during interactive review.**
2) **Final Conclusions for Interactive Review -** It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for [pathogen] detection during the public health emergency. **Conclusion should include an outline the unique features of the device compared to currently issued EUA's under the declaration, if applicable.**
3) **Upon competition of this section the Lead Reviewer should also sign this document and save the file as the final Decision Memorandum.**

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## APPENDIX A – Multiplex Panels Under EUA:

An emergency declaration by the HHS Secretary is typically specific for a pathogen/disease (i.e., there is a publicly declared health emergency involving a particular etiologic agent). Therefore, the EUA pathway is only applicable for testing patients with signs/symptoms/risk of exposure for that single agent in a given emergency. FDA has occasionally allowed limited additional target pathogens to be claimed for EUA devices, but panel members must be relevant to the event/disease outbreak subject of the specific emergency declaration. When determining whether to issue an EUA for a multiplex panel FDA takes into consideration the utility of the test (multiplex pathogen detection as an aid in differential diagnosis), clearance/approval status of IVDs for the other panel members, whether the proposed Intended Use fits within the HHS emergency declaration and the how the multiplex panel would fit into current public health authority patient testing algorithm recommendations. We recommend you contact FDA for specific feedback if you plan to claim multiple target analytes as part of your EUA test. If it is determined that a multiplex test is beneficial to the emergency response, please note that analytical and clinical evaluations for each of the target analytes will be required.

## APPENDIX B – General Study Design Recommendations for Reagent Stability:

- For EUAs you may follow the current FDA recognized CLSI Standard EP25 – Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline when evaluating the suitability of stability study designs. If you are planning to pursue a De Novo/510(k) for your device we recommend discussing in more detail your stability design to facilitate potential use of the EUA data in your regular premarket submission.
- Please note that use of only the positive controls is not acceptable for reagent stability evaluation because controls are usually formulated at a moderate positive level. For all the stability evaluations in addition to your external positive and negative controls and the no-template control you should include for the EUA evaluation at least one sample, that should be prepared by spiking negative clinical matrix at an analyte concentration of 3-5xLoD.
- If you are claiming multiple blood clinical specimen types in which similar LoDs are determined, you should use the most challenging clinical matrix for this study.
- Please note we typically recommend your stability study design includes the evaluation of at least 5 replicates. You should also evaluate, if available, 3 different lots of reagents.
- You should design your study to provide data for a timeframe that is about 10% longer than the one to be claimed – for example; a claim of 18 months should be supported by stability data out to 20 months and a claim of 7 days should include stability data out to 8 days.
- FDA considers 15-30°C to represent room temperature conditions. Ideally you should evaluate stability at both 15°C and 30°C, however, for the purposes of the EUA evaluation at 30°C is acceptable as the worse-case scenario.
- Shelf-Life Stability- Unopened kit:
    - You should evaluate real-time kit stability studies with unopened kits stored at the claimed storage temperature for your test.

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  - Accelerated stability evaluations for unopened kits is acceptable for EUA submissions while the real-time studies are on-going. However, please note real-time stability data is required to support regular pre-market submissions and for the final claim of an EUA.
- Shipping Stability - Unopened kit: Study should evaluate the anticipated handling and shipping times and temperatures expected for unopened kits.
- In-use/Opened Kit Stability: Depending on your device your stability study design should also support in-use stability of the kit reagents once the kit has been opened, e.g., storage at 2-8 $^{o}$C for 7 days. This includes on board stability once reagents have been placed on the instrument (if applicable).
- Inverted stability (if applicable): Study should support inverted stability for of kits.
- Freeze-thaw Stability: If you recommend aliquoting the reagents to meet the end-users needs following the initial thaw this recommendation should be supported by a freeze-thaw stability study, including the specific number of allowed freeze-thaw cycles.
- FDA analysis recommendations for real time stability studies are as follows:
  - Baseline of the study (t=0 of stability study) should not exceed a month from bottling
  - Clear baselines should be described (e.g., a month from bottling) for each stability claim under each study
  - Claims should be determined based on regression analysis. Any %change (%shift) from time zero (baseline) should be calculated between the target claim and the zero-time as (Ttest-Tbaseline)/ Tbaseline*100 with 95%CI using the regression equation obtained from plotting the mean values. When formulating your acceptance criteria for evaluating the shift from baseline you should consider the reproducibility of your device. However, generally, that the shift at the target claim due to storage cannot exceed 10-15%. The target stability is the next to last tested point that was within +/- 10% of time zero.
  - Acceptance criterion may be different, depending on the test samples analyte concentration distribution in the intended use population and the risk, in other words, the impact of false results to public health.

**APPENDIX C – Claiming Multiple Instruments and/or Extraction Methods:**

If you wish to claim multiple instruments and/or extraction methods for use with your test, please review the study recommendations provided below and contact FDA for any additional feedback. Please note that these analytical and clinical evaluation recommendations are based on the assumption that the elution volumes from the extraction methods and PCR volumes on the different RT-PCR instruments are identical.

- Limit of Detection (LoD): Please note that these studies should be repeated for each clinical matrix claimed in the Intended Use. Pick one RT-PCR instrument and determine the tentative LoD (using 5 replicates in 10-fold dilution) followed by the confirmatory LoD (20 replicates spiked at tentative LoD) for each extraction method on the chosen instrument. Note: If you detect 20/20 replicates in your confirmatory LOD study you should test the next lower concentration, using a 3-fold dilution, until

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you achieve a hit rate of <20/20.

- If the different extraction methods yield the same LoD (≤3xLOD) on the RT-PCR instrument chosen for initial testing, pick one extraction method for further LoD determination on the remaining RT-PCR instruments and follow the recommendations below.
- If the extraction methods do not yield the same LoD on the chosen RT-PCR instrument, please choose the extraction method with the worst LoD for further comparison of the LoD on all RT-PCR instruments.

For all other RT-PCR instruments you should use the following adaptive LoD study design:

- Please perform a refined tentative LoD study with 5 replicates at 0.5x, 1x, and 1.5 to 2x LoD. If you detect 4/5 replicates as positive at all the tested levels, you need to include the next higher concentration (i.e., 3x LoD). If you obtain 5/5 replicates at 0.5x LoD, you need to test the next lower concentration (i.e., 0.25x LoD). You will test in this manner until you find the lowest concentration that gives you 5/5 positive results for the tested RT-PCR instrument. This concentration should be used for a confirmatory LoD study for the given RT-PCR instrument using 20 replicates.

Final reported LoD: Please list all RT-PCR instruments with their respective LoDs if different LoDs are obtained. LoDs are considered comparable if they are between 1-3xLoD. These studies should be repeated for each clinical matrix claimed in the Intended Use.

- Interference Substances Studies (if applicable): Pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Inclusivity Testing: For the inclusivity testing, pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Exclusivity Testing: For exclusivity, you can perform this study using any extraction/instrument combination.

- Clinical study: If equivalency of the RT-PCR instruments is shown in an LoD study that tests and confirms that the LoD is the same or very similar for all of the RT-PCR instruments (between 2-3xLoD), then you can pick one RT-PCR instrument for your clinical study provided that the RT-PCR instruments in question are known to FDA for other *in vitro* diagnostic devices. If you find that one or more RT-PCR instruments machines has/have a different LoD, you should pick the extraction method / RT-PCR instrument combination with the worst LoD.

Note, if there are differences in the extraction input volume, extraction elution volume

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and PCR input volume (extracted nucleic acid) then the LoD should be confirmed, for each.

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**[Date]**

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**ATTN:** Division Director: Dr. Uwe Scherf**,** OHT7-OIR/OPEQ/CDRH/FDA

**RE:** Request for Pre-Emergency Use Authorization (Pre-EUA) of the [*Name of the Assay*]

**Dear Dr. Scherf,**

[***Name of the Company***] is submitting a Pre-Emergency Use (Pre-EUA) for the [***Name of the Medical Device Product***] so we can obtain feedback from FDA concerning the studies and/or testing outlined in our Pre-Emergency Use Authorization (Pre-EUA) submission package.

The [***Name of the Medical Device Product***] is [***brief description of the device***] and [***intended use***].

Attached to this letter is the first draft of our device EUA Interactive Review Template for FDA review as a Pre-EUA. One hard copy of the signed EUA Cover Letter and one electronic copy are enclosed. Also, these documents have been sent to you via email.

In case you should have any questions regarding the information provided and/or need additional information/data from us please contact me immediately either via email [_____] or phone [_____].

Sincerely,

[***Name***]

[***Signature block***]

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 5:01:35 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

Jeff,

Additional individuals who helped us getting the documents posted immediately.

Eddie D. Seligson & Stefan Gagne

---

**From:** Scherf, Uwe
**Sent:** Tuesday, February 4, 2020 4:40 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued
**Importance:** High

Jeff,

Here is the list of individual being involved in the EUA, and also please see the email I just send out, I am terrible sorry that somehow I missed to send it you to too, getting a little tired.
Uwe

Thanks to the tireless and extraordinary work of the DMD review team over the last weeks:

- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*
- **Li Li**, Lead Reviewer, Viral Respiratory & HPV Branch,
- **Brittany Goldberg**, MD, Senior Medical Officer, and
- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, **Megan McSeveney** & **Angela Stark** (press office).

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 4:27 PM
**To:** CDRH-OIR-IVD-DMD <CDRH-OIR-IVD-DMD@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy

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<Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued
**Importance:** High

**Congratulations!**

FDA just issued the Emergency Use Authorization for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.
Thanks to the tireless and extraordinary work of the DMD review team over the last weeks:

- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*
- **Li Li**, Lead Reviewer, Viral Respiratory & HPV Branch,
- **Brittany Goldberg**, MD, Senior Medical Officer, and
- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, **Megan McSeveney** & **Angela Stark** (press office), and our senior leadership.

These have been incredible 2 weeks and words cannot describe how grateful I am for your phenomenal dedication and extraordinary hard work that made this happen. You are an exceptional team to work with unprecedented commitment to public health!

Thanks you! Thank you! Thank you!

My very kind regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/10/2020 6:34:11 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: 2/10/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/10/20 6 AM update

**Status of activities on diagnostics**:

- Issue with rapid verification and implementation of CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel in handful of public health labs:
  - CDC informed FDA yesterday afternoon that APHL has been notified that some laboratories have observed performance issues during verification testing, particularly with the N3 part of the assay showing sporadic aberrant reactivity in the negative controls. CDC is aware of these reports and is investigating.
  - Conference call with CDC has been scheduled for today 2 PM to discuss the issue and any investigation so far.

**New roadblocks/challenges/delays:**
(b) (5)

**Enclosed also the compiled activities over the weekend which have been previously communicated:**

**Status of activities on diagnostics previously reported for 2/8/20 @ 2/9/20**:

- A total of 41 IVD Developers have requested and received EUA review template, additional requests (2) are pending clarification about the device technology.

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- Conference call with CDC: CDC intends to add 2 additional automated extraction methods to their EUA (Roche MagNA Pure 96 and Roche MagNA Pure 24), to support larger number of State Public Health labs who are only using these instruments. DMD/CDC agreed on bridging study protocol and limited clinical sample testing to demonstrate performance. CDC expects to submit amendment in next 2 weeks.
- On 2/6/20 CDC started shipping CDC's 2019-nCoV PCR assay to 4 public health labs that are strategically located in US and to other public health labs in states with confirmed cases.
- CDC via their IRR (International Reagent Resource) is accepting orders for CDC's 2019-nCoV tests from qualified laboratories.
  - This includes 115 qualified U.S. laboratories [state & local public health labs and DoD labs]
  - 191 qualified international labs, such as the World Health Organization (WHO) Global Influenza Surveillance Response System (GISRS) laboratories.
  - CDC test will not be available in U.S. hospitals or other primary care settings.
- CDC's isolate from infected patient in Washington was shipped to BEI (Biodefense and Emerging Infections Research Resources Repository) on Wednesday (NR-52281). Additional viral Isolates from other patients in US are expected to arrive at BEI in the next 2 weeks. Isolate without inactivation is BSL-3 analyte. BEI will begin work on inactivating virus [For use in BSL-2 labs]. Generating inactivated virus will take 2-3 months.

- Phone call scheduled with FDA/BARDA/CDC on Monday to address issues regarding timeline for virus inactivation and availability of BSL-3 facilities for commercial developers.

- CDRH was contacted by (b) (5), (b) (4)
(b) (4), (b) (5)

  - Delicate intended use from the public health perspective in an outbreak situation
  - DMD is following up on actions taken towards apps during the Zika outbreak
  - DMD will contact app developer to get further information and clarification on the ap

**New roadblocks/challenges/delays:**

(b) (5)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/11/2020 8:27:32 AM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC:** Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Antigen template paragraph and email responses
**Attachments:** email responses 02062020.docx

Kim,

Nicely done, please see a few comments I had. Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 7:12 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** Antigen template paragraph and email responses

Dear Uwe, Tamara, Li, and Jennifer

Please find attached for your review the following:

- Draft bullet for the antigen template about accepting submissions but decision to EUA (b)(5) (b)(5)
- Draft Email response to firms of IgM and IgG tests
- Draft Email response to firms of devices not specific for 2019-nCoV

Appreciate any suggestions

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

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**Opening bullet in the Antigen EUA review template:**

(b)(5)

[redacted]

**Email response to firms with IgG and IgM tests under development:**

(b)(5)

[redacted]

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**Email response to firms with tests/devices not specific for 2019-nCoV:**

(b)(5)

[redacted]

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/4/2020 9:38:28 PM
**To:** (b) (4), (b) (6)
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; CDRH-EUA-Templates [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfb0733393d74e80a407946c10c53411-CDRH-EUA-Te]
**Subject:** RE: Request of coronavirus rapid test EUA

No problem, please request under:

CDRH-EUA-Templates@fda.hhs.gov

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** (b) (4), (b) (6)
**Sent:** Tuesday, February 4, 2020 9:35 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Request of coronavirus rapid test EUA

Hi Uwe,
Who will be the direct contact person for receiving the template and sending the EUA application? I feel bad to email you directly knowing that you have millions of other things to take care of.

Thank you.

(b) (4), (b) (6)

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 9:24 AM
**To:** (b) (4), (b) (6)
**Subject:** RE: Request of coronavirus rapid test EUA

(b) (4), (b) (6)

We assume for the (b) (4) you are interested in (b) (4), correct? I heard yesterday at a meeting that China was also interested in an antibody test.

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Please clarify

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** (b) (4), (b) (6)
**Sent:** Tuesday, February 4, 2020 7:33 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** Request of coronavirus rapid test EUA

Hi Uwe and Tamara,

It is nice to see you yesterday. The tremendous effort that your division put out to encourage the EUA product development is very appreciated.

(b) (4)

I really appreciate your support to the these tests development especially at this critical time.

Best regards,

(b) (4), (b) (6)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/11/2020 1:55:16 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/11/20 2 PM update

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/11/20 2 PM update:

**Status of activities on diagnostics**

- A total of 56 IVD Developers have requested and received the EUA review template

- DMD reached out to company advertising their **RUO** Logix Smart 2019-nCoV Kit.
- Statements made with respect to this product are inconsistent with Research Use Only (RUO) products
- Wording implies use for diagnostic/screening purposes, not laboratory research
- Requested telecom with sponsor today to take immediate action to correct statements

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 3:28:38 PM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Urgent - DMD just send the CDC EUA package to OCET & OCC for final FDA clearance

Thanks, some rest would be nice now ☺

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 3:27 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Urgent - DMD just send the CDC EUA package to OCET & OCC for final FDA clearance

Congratulations on this milestone! I know there is still much work to do, but this is something to celebrate. Perhaps with a nice nap? You must be exhausted.

Seriously, thank you for all you do for public health.

Elizabeth

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 2:03 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Caliguiri, Laura (OS) <Laura.Caliguiri@hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Urgent - DMD just send the CDC EUA package to OCET & OCC for final FDA clearance

Update: DMD just send the CDC EUA package to OCET & OCC for final FDA clearance, sorry for the delay, last minute issues needed to be resolved with CDC.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Scherf, Uwe
**Sent:** Monday, February 3, 2020 11:04 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael (Michael.Mair@fda.hhs.gov) <Michael.Mair@fda.hhs.gov>
**Cc:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Caliguiri, Laura (OS) <Laura.Caliguiri@hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Urgent - CDC EUA package received
**Importance:** High

Jeff, Denise, Anna, Tim, and Michael,

CDC just submitted their EUA package to request authorization for their 2019-Novel Coronavirus (2019-nCoV) assay. DMD staff has reviewed most of the data package already and will finish the review of the outstanding data as expeditiously as possible. I want to provide a clear update on how long that process could take and next steps once we have completed our review.
We expect that it will take us close 3-4 hours to fully review the outstanding data and prepare all the final documents for clearance in the review division. If the data is acceptable, we plan to send the EUA approval package to OCET & OCC tomorrow morning around 11 AM for final FDA clearance before it goes to Denise for authorization. We have been closely coordinating with OMA and they already have drafted a press release so that we are ready to make an announcement if an EUA can be issued tomorrow.
I will keep this group updated.

Thank you all in advance for your patience and help.

Best,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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CDRH | Food and Drug Administration
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uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/10/2020 4:50:37 PM
**To**: Hwang, Leroy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5da97657ec944cebf943616bd848105-Leroy.Hwang]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Action needed tomorrow - FW: RUO coronavirus tests

**Importance**: High

Leroy,

Just spoke with Ellen. We need to call the company tomorrow and asked them to take their announcement down.

They requested an EUA template and know they need EUA authorization, so they must take these statements down.

Let's touch base tomorrow morning. Thanks, Uwe

It looks like there is another company mentioned as well in the bottom Novacyt.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 1:46 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RUO coronavirus tests

**Uwe -- Did you see this? – Ellen**

7 February 2020
News
**Co-Diagnostics launches RUO test for new coronavirus**

US-based Co-Diagnostics has launched a research use only (RUO) CoPrimer test for new coronavirus (2019-nCoV).
The company launched the product just weeks after it completed principle design work for the test to address the growing need for testing designs to detect the presence of coronavirus.
To date, the coronavirus outbreak killed 638 people, with a total of 31,428 infection cases now confirmed.
The Logix Smart 2019-nCoV coronavirus test is now available for sale to laboratories, hospitals and institutions.

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Designed leveraging the company's CoDx Design software system, the test helps in identifying the most optimal target on the 2019-nCoV genome for a PCR assay.
Co-Diagnostics expects that the test will ensure greater accuracy in detecting the presence of the coronavirus.
Co-Diagnostics CEO Dwight Egan said: "Leveraging our proprietary design process and software has allowed us to quickly move this product from design into commercialisation, and to do so with the confidence that our high-quality product meets our goal of providing an effective, much-needed global diagnostic solution in an emergency situation."
"As a result of our rapid development, we have already received requests from customers in countries across the world to purchase tests.
"Sales and shipments of products will be fulfilled from our Utah headquarters to customers who have the capacity to utilise RUO products to slow the spread of this epidemic."
Last week, Novacyt's molecular diagnostics division Primerdesign launched a molecular RUO test for 2019-nCoV.

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/15/2020 12:41:46 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: EUA Questions

Jeff,

(b)(5) [redacted]

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 9:49 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: EUA Questions

Yes, thank you!

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 15, 2020 at 9:33:37 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: EUA Questions

(b)(5) [redacted]

(b)(5) [redacted]

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 9:05:29 AM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** EUA Questions

I have two questions and no rush in responding. I prepping for an upcoming press roundtable on CoV.

(b)(5) [redacted]

Jeff

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/12/2020 6:38:17 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/12/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/12/20 6 AM update:

**Status of activities on diagnostics**

- A total of 56 IVD Developers have requested and received EUA review template

- Held conference call with company advertising their Logix Smart 2019-nCoV Kit as an RUO test. Labeling and advertising implied diagnostic and screening testing.
- Explained RUO labeling regulation 809.10(c)(i) - and the requirement that all labeling bears the statement, prominently placed: **"For Research Use Only. Not for use in diagnostic procedures."**
- Pointed out and requested correction of specific claims and statements on their website and in news releases that implied performance and use of their device for diagnostic/screening testing.
- Firm acknowledged that they are not in compliance with RUO labeling regulation.
- Firm agreed to take immediate corrective action to resolve the identified concerns regarding the product labeling and advertising.
- Agreed on deadline for complete list of all planned action of 2/14/20.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*
OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/7/2020 6:50:40 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/7/20 6 AM

Today **No additional updates** on activities communicated yesterday's at ~4 PM. For your convenience here the reported activity from yesterday:

**nCoV Diagnostic EUA Activity**

- Additional IVD Developers have requested and received EUA review template [(b) (4) Roche Diagnostics (Shanghai), (b) (4) , (b) (4) University of Washington (LDT)] total 40 to date, additional requests (2) are pending clarification about the device technology.

- Responded to various EUA template requestor questions regarding access to viral materials and clinical specimens

- CDRH met with (b) (4) nd determined their device was not eligible for an EUA. We encouraged a Q-sub.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/4/2020 9:28:20 PM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: CDC Documents related to Corona Virus

Susanne, got in contact with Dr. Odle from CDC. She will deliver the package to me tomorrow at 8:30 AM. Issue resolved.
Uwe

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 4, 2020 at 9:13:12 PM EST
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: CDC Documents related to Corona Virus

Suzanne, received the contact information of the CDC individual in possession of the documents who is in the DC area. Left voice and text request to contact me to arrange successful delivery of documents tomorrow. The security guards were also requested to call me if the carrier returns to Building 1 tomorrow.
Uwe

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 4, 2020 at 8:28:35 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC Documents related to Corona Virus

Uwe,

Per our conversation, please call (b)(6) to speak with Kim Gardner, our FDA Emergency OPs Coordinator.

She can put you in touch with The CDC POC, Brian Taylor, so that you can give him specific instructions for the document delivery tomorrow.

I will call her right now and let her know you will be reaching out,

Suzanne
Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration

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Office: 301-796-6937
Mobile: (b) (6)

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 4, 2020 at 8:13:01 PM EST
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC Documents related to Corona Virus

Suzanne,
We do not need the documents tonight, but need to make sure the carrier can deliver the documents to CDRH tomorrow. They are the hard copies of the EUA request we already received electronically earlier today and approved with the issuance of CDC's EUA.

Please give me a call at (b)(6)
so we can assure to be prepare with the Emergency OP's coordinator to be ready to accept the documents tomorrow.

Uwe

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 4, 2020 at 7:04:41 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: CDC Documents related to Corona Virus

The CDC person said that the CDC group is in the DC area and they will have the courier return the document to them this evening and the CDC will deliver it themselves tomorrow.

Uwe: feel free to call me directly or I can put you in touch with the Emergency OPs Coordinator. I'm not sure if you are waiting at WO for these documents tonight.

Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b) (6)

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 4, 2020 at 6:58:47 PM EST
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: CDC Documents related to Corona Virus

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I am in the office if that helps.

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 6:57 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC Documents related to Corona Virus
**Importance:** High

Uwe,

I just received a call from FDA's Emergency OPs Coordinator that there's a courier with documents from CDC at the Bldg 1 entrance but doesn't have a POC to deliver it to. It is supposed to go to CDRH.

Brian Taylor is the CDC contact that our OPs Coordinator spoke to.

I don't know if you are expecting documents for an EUA?

In any case, the CDC contact said they will re-deliver them tomorrow.

Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b) (6)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/13/2020 1:53:35 PM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; CDRH-EUA-Templates [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfb0733393d74e80a407946c10c53411-CDRH-EUA-Te]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Pre-EUA IVD template request

Agree, this has lower priority. Uwe

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 1:52 PM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Pre-EUA IVD template request

Kim,

It may be easier to send them the older format template at this time since we do not have the time to update it. We can update the language later if they submit an EUA, as long as the required studies are correct.

Thanks,

Tamara

---

**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 1:47 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Pre-EUA IVD template request

Dear Uwe and Tamara,

The EUA is still active for (b)(5) [redacted] - it is in the older format at this point.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993

AMERICAN OVERSIGHT

Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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**From:** (b) (4), (b) (6)
**Sent:** Thursday, February 13, 2020 1:26 PM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** (b) (4), (b) (6)
**Subject:** Pre-EUA IVD template request

(b) (4), (b) (6)

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(b) (4)



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/10/2020 10:01:56 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]
**Subject**: RE: IMG meeting this morning

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov
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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 9:27 AM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IMG meeting this morning

Thanks very much Heather

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 9:24 AM

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**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IMG meeting this morning

Hi Kim and Uwe,

Nothing came up during the 9:00 am call.

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: (b) (6)
Email: Heather.Agler@fda.hhs.gov

---

**From:** Sapsford, Kim E
**Sent:** Monday, February 10, 2020 8:46 AM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** IMG meeting this morning

Heather – Uwe and I are both in a meeting this morning and cant attend the IMG call, can you let me know if any diagnostic issues come up?

Cheers
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/15/2020 5:55:23 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: CDC and potential enforcement discretion issue

Confidential / Deliberative / Predecisional

Dear Uwe,

Jeff asked me to start drafting potential enforcement discretion language for the cut-off issue. I don't have all the facts so I need your help to fill them in. Also, I was not sure whether this had to cover both the N1 and N3, or only N1. We can have a call to discuss this matter if that would be easier. I am available at (b)(6)

Thanks,
Ellen

Confidential Draft / Predecisional:

(b)(5)

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/8/2020 3:06:36 PM
**To:** Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** Fwd: (b) (4) (b) (4) screening for Coronavirus

Kris, who from the (b) (4), (b) (5)
(b)(5)
[redacted]

Uwe

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Date:** February 8, 2020 at 2:10:54 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Krueger, Angela C <Angela.Krueger@fda.hhs.gov>
**Subject:** Re: (b) (4) - (b) (4) screening for Coronavirus

Jeff,
I think this would be in OHT7's DMD. Looping in Tim and Uwe to confirm.
Bill

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 8, 2020 at 12:35:19 PM EST
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** Fwd: (b) (4) - (b) (4) screening for Coronavirus

Bill,

A small start up is looking to create a (b) (5), (b) (4)
(b) (5), (b) (4)

I'm including Bakul and Suzanne for awareness.

Jeff

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**From:** Ajintha Pathmanathan (b) (6)
**Date:** February 8, 2020 at 11:18:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** (b) (4) - (b) (4) screening for Coronavirus

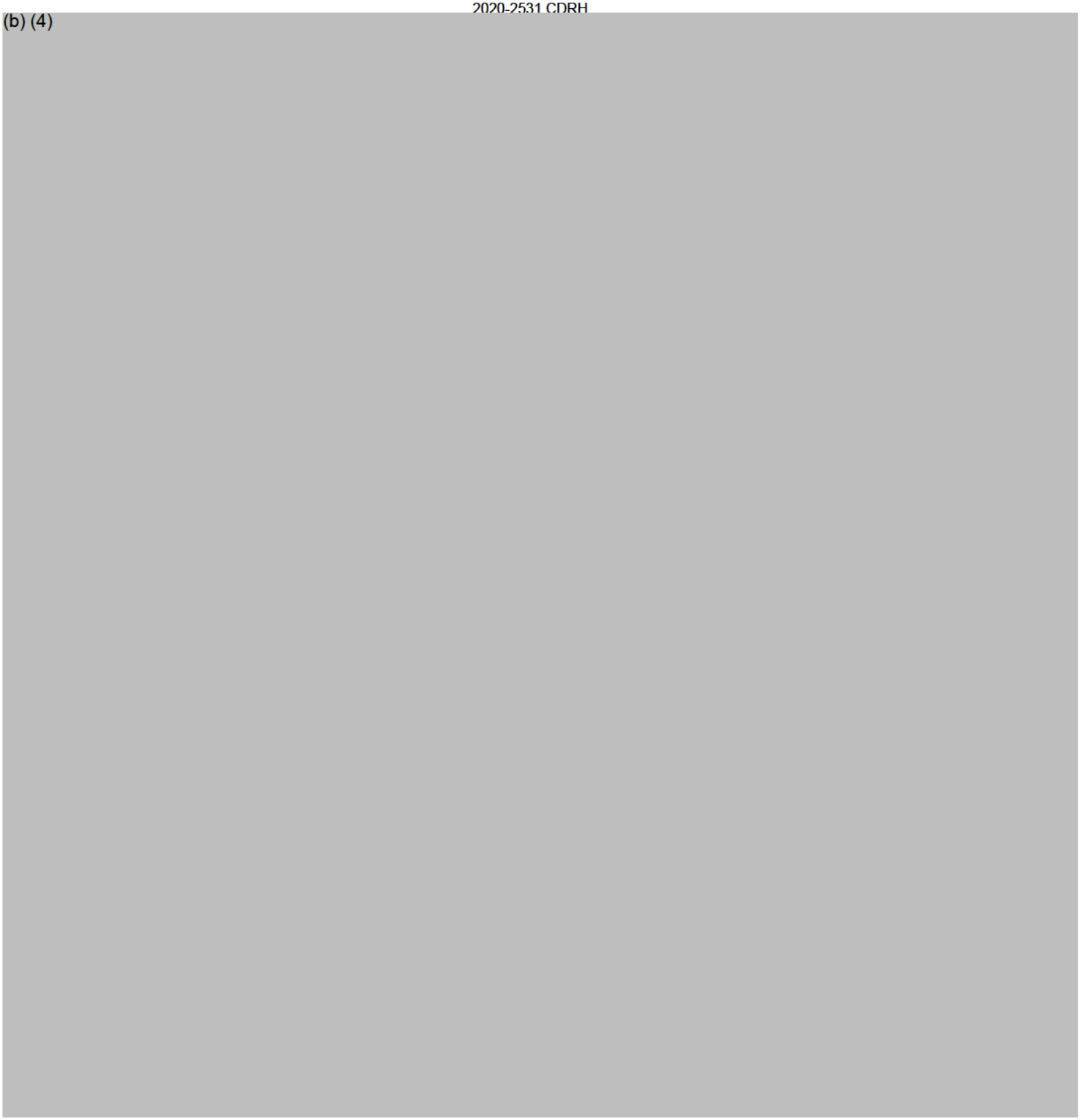
Hi Jeff,

Thank you for the interest. In terms of more information;

(b) (4)

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(b) (4)

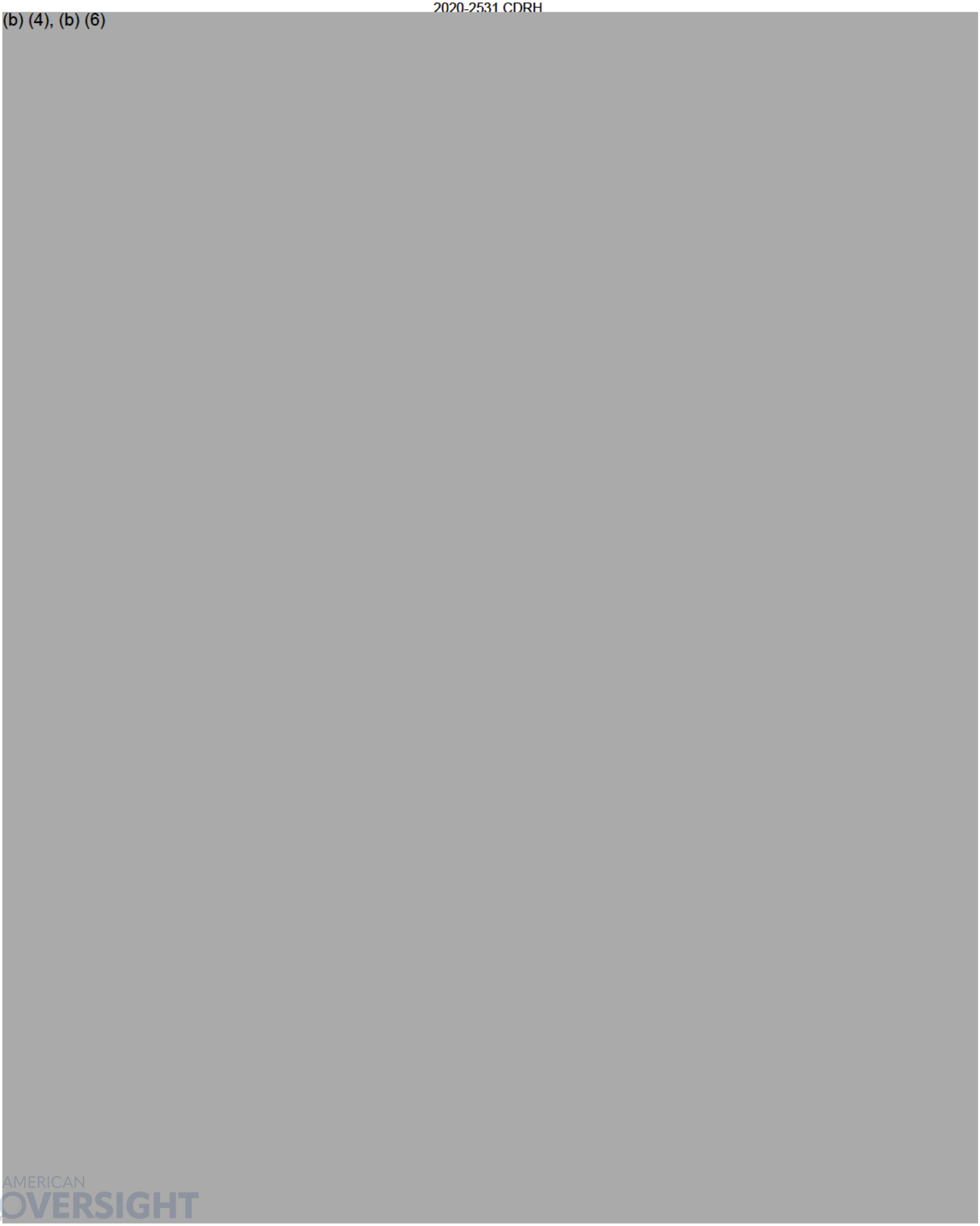


Thanks

(b) (4), (b) (6)

AMERICAN OVERSIGHT

(b) (4), (b) (6)



AMERICAN OVERSIGHT

**From:** Shuren, Jeff
**Sent:** Saturday, 8 February 2020 4:13 AM
**To:** Ajintha Pathmanathan
**Subject:** Re: (b) (4) (b) (4) screening for Coronavirus

Hi Ajintha,

It's good to hear from you. Thank you for reaching out to me.

(b) (4)

Jeff

---

**From:** Ajintha Pathmanathan (b) (6)
**Date:** February 7, 2020 at 10:15:52 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** (b) (4) - (b) (4) screening for Coronavirus

Hi Jeff,

(b) (4), (b) (6)

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Please find attached overview deck.

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/14/2020 12:20:57 PM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Mielech, Anna (Anna.Mielech@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: High Level Info on current pre-EUAs

**Importance**: High

Li, Himani & Anna,

I tried to capture at a very high level info about the pre-EUAs that we have received by now into Tamara's table.

Could you please made any corrections/update and add the info for the outstanding pre-EUAs.

Please provide this information COB today.

Thanks, Uwe

(b) (5)

[redacted]

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

AMERICAN OVERSIGHT

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/13/2020 10:20:33 AM
**To**: Lovell, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a4cfa4fc4094bbf8fac0e16bf710049-SXL]
**Subject**: nCoA activities

Steve here some points for the report. Uwe

- A total of 56 IVD Developers have requested and received EUA review template - DMD provides interactive feedback even before pre-EUA submission.

- DMD received four pre-EUA submissions: BioFire Defense for their BioFire 2019-nCov Test, Inbios Inc. for their Smart *Detect*™ 2019-nCOV rRT-PCR kit, Roche Molecular Systems for their cobas 2019-nCoV test for use on the 6800/8800 Systems and Vela Diagnostics' for their ViroKeyTM SA201 2019-nCoV RT-PCR Test. The submissions request FDA feedback on the planned studies. DMD's review team started review and will provide responses interactively.

- CDC reported issues with test verification in 26 U.S. Public health labs that received the CDC test. These labs could not verify assay due to false positive results of the N-3 component with negative controls. CDC concluded being a manufacturing issue, re-manufactured component and will replace component. The risk to patients is low, since no patient samples have been tested at the labs who could not verify the CDC test. Further investigation of root cause under way. DMD is receiving updates when available.

- DMD held conference call with company advertising RUO product with implied diagnostic/screening claims. Firm agreed to take immediate corrective action to resolve the identified concerns regarding the product labeling and advertising.

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/15/2020 12:19:26 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** FW: Urgent - Action needed

**Importance:** High

Heads up. Important issue that came up today.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 12:16 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Urgent - Action needed
**Importance:** High

Jeff and Ellen,

I want you to give you a heads up on this. I received a call from CDC (b)(5)
(b)(5)

(b)(5)

(b)(5)

I will let you know as soon as I receive CDC's formal request. I can be reached at (b)(6)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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**Sent:** 2/14/2020 4:15:03 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: CDC EUA

Great thanks, enjoy your trip, might need to call you. ☺

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 4:11 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC EUA

(b) (4), (b) (5)

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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Kim.Sapsford@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 4:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC EUA

Thanks, and we got (b) (4) in as well correct?

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 4:05 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC EUA

AMERICAN OVERSIGHT

Dear Uwe,

60 – see attached

Best regards
Kim

PS this is the updated I sent OCET earlier:

**CDRH Diagnostics SITREP Friday Feb 14, 2020**

| Diagnostic Pipeline | | | |
|---|---|---|---|
| **Sponsor** | **Product** | **Regulatory Status** | **Notes** |
| CDC | CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel | EUA | |
| Inbios | Molecular DX | Pre-EUA | |
| Roche Molecular Systems | Molecular DX | Pre-EUA | |
| BioFire Defense | Molecular DX | Pre-EUA | |
| Cepheid | Molecular DX | Pre-EUA | |
| Vela Diagnostics | Molecular DX | Pre-EUA | |

- EUA template for antigen-based tests has been finalized and is being shared with IVD Developers
- Additional IVD Developers have requested and received the appropriate EUA review template (b) (5) (b) (5) total 60 to date.
- Interactions with CDC to informally discuss the proposed outline of a community transmission surveillance activity and to identify regulatory strategy options CDC can consider to ensure the surveillance activity is conducted in compliance with FDA law and regulation.

- Tri-agency Taskforce for Emergency Diagnostics had call to give agency updates on activities around EUA and Pre-EUA diagnostics.

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 4:02 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC EUA

Thanks, quick question, how many EUA request do we have now?

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 4:00 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** CDC EUA

Dear Uwe, Tamara and Li,

I think we can go ahead and close the CDC EUA – I have forwarded as many emails as it docman will let me – it is sending anything with an attachment back to me now!! I captured all the major feedback emails I think. I also included a CTS note that the document was received after the EUA was issued. The final authorized package is also uploaded in the reviewer documents.
I will not have my computer with me in Florida but I will have my work phone to monitor email – just FYI ☺
Have a good weekend
Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/4/2020 8:18:26 PM
**To:** Sally A Hojvat [sally.hojvat@gmail.com]
**CC:** Sally A. Hojvat [sally.hojvat@gmail.com]
**Subject:** Re: FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic

Thanks, took some heavy lifting. Uwe

---

**From:** Sally A Hojvat <sally.hojvat@gmail.com>
**Date:** February 4, 2020 at 7:50:45 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sally A. Hojvat <sally.hojvat@gmail.com>
**Subject:** Fwd: FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic

Well done !

Begin forwarded message:

**From:** "U.S. Food and Drug Administration" <fda@info.fda.gov>
**Subject: FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic**
**Date:** February 4, 2020 at 6:39:39 PM EST
**To:** sally.hojvat@gmail.com
**Reply-To:** "U.S. Food and Drug Administration" <fdago-reply@fda.hhs.gov>

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FDA U.S. FOOD & DRUG ADMINISTRATION

# FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic

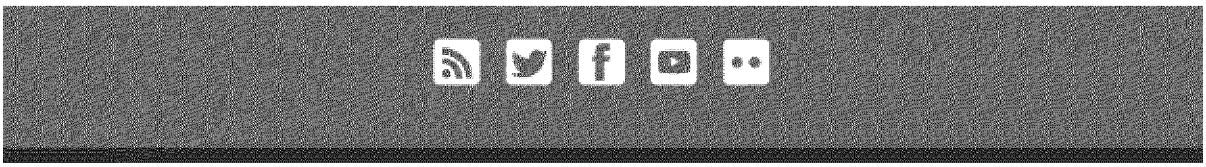
*Critical Milestone Reached in Response to this Outbreak*

AMERICAN OVERSIGHT

Today, the U.S Food and Drug Administration issued an emergency use authorization (EUA) to enable emergency use of the Centers for Disease Control and Prevention's (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel. To date, this test has been limited to use at CDC laboratories; today's authorization allows the use of the test at any CDC-qualified lab across the country.

**"Since this outbreak first emerged, we've been working closely with our partners across the U.S government and around the globe to expedite the development and availability of critical medical products to help end this outbreak as quickly as possible. This continues to be an evolving situation and the ability to distribute this diagnostic test to qualified labs is a critical step forward in protecting the public health," said FDA Commissioner Stephen M. Hahn, M.D. "Our collaboration with the CDC has been vital to rapidly developing and facilitating access to this diagnostic test. The FDA remains deeply committed to utilizing our regulatory tools and leveraging our technical and scientific expertise to advance the availability of critical medical products to respond to this outbreak in the most expeditious, safe and effective manner possible."**

Read More



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1-888-INFO-FDA (1-888-463-6332)
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AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/12/2020 10:50:50 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/13/20 6 AM update - FDA ACTION REQUIRED

**Importance**: High

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/13/20 6 AM update, a number of issues came about this afternoon:

**Status of activities on diagnostics**

- As previously reported on Monday CDC has issues with test verification in a number of labs that received the CDC test: this has now be **reported in press this afternoon**
- Initially only 10, but now 26 U.S. Public health labs out of ~100 that received the CDC test cannot verify assay due to positive results of the N-3 component with negative controls.
- CDC concluded this being a manufacturing problem.
- CDC has re-manufactured the components for the N3 portion of the assay.
- New lot passed newly established QC testing. New product will be lyophilized and send out asap.
- Further investigation of root cause under way. DMD is receiving updates when they become available.

- CDC informed FDA about their updated Patient Under Investigation (PUI) definition and footnote. The following statement was added: ***For severely ill individuals, testing can be considered when exposure history is equivocal (e.g., uncertain travel or exposure, or no known exposure) and another etiology has not been identified.***

AMERICAN OVERSIGHT

DMD agreed with this updated definition, but requested going forward to be informed ahead of time if any PUI updates are planned so FDA can provide input.

- CDC is planning several public health activities to address the SARS-CoV-2 outbreak (previously called 2019-nCoV)
- **Investigation of contacts of confirmed SARS-CoV-2 cases: FDA ACTION REQUIRED**
  - Serial respiratory specimens are being collected from close contacts of confirmed cases every other day until 14 days after the close contact's last exposure to the confirmed case.
  - **ACTION REQUIRED:** (b) (5) [redacted]
  - In the interest of public health during this outbreak with uncertainty regarding infection and transmission DMD recommend allowing the report of positive result.

- **Sentinel surveillance to detect non-travel related SARS-CoV-2 Infections in the community: FDA ACTION REQUIRED**
  - The intended use restricts testing to persons with severe illness, recent travel to China or known contact with a confirmed SARS-CoV-2 case, and precludes identification of mild illness in persons who did not travel to China.
  - Knowing whether there is community transmission without ties to travel or confirmed cases is critical to shaping future response activities including testing criteria, quarantine guidance, investigation protocols, and additional public health preparedness measures.
  - CDC communicated that they will established initially a limited number (5) of sentinel surveillance sites [and if necessary will expanded in the future].
  - Most sites will use ongoing outpatient surveillance specimens that have tested negative for influenza and other respiratory viruses.
  - CDC is currently working with the 5 initial states to determine a protocol if a positive test result is found.

**ACTION REQUIRED:** (b) (5) [redacted]

- **Study to understand the natural history of SARS-CoV-2 Infection**:
  - Serial specimens collection from confirmed cases throughout the course of infection. Information will directly inform guidance on diagnostics, infection prevention and control and the need for isolation.

- **Updated information from BEI regarding possible availability of SARS-CoV-2 genomic RNA and inactivated viruses:**
- If no issues arise genomic RNA and inactivated viruses may become available in the next 4-6 weeks
- Novel Coronavirus 2019-nCoV/USA-WA1/2020 (culture) is available now, but requires BSL-3 facility

- DMD received the (b) (4) pre-EUA submission from Vela Diagnostics' for their ViroKeyTM SA201 2019-nCoV RT-PCR Test.

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**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/10/2020 12:50:59 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject:** RE: 2/10/20 6 AM update

Absolutely, Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 12:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: 2/10/20 6 AM update

Uwe,

Thank you. Please let me know what comes out of the 2 PM call with CDC. I have a call with administration folks today at 4:30 PM on devices/diagnostics.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 11:46 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/10/20 6 AM update

Tim,

(b)(5)
[redacted]

Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 8:40 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J.

AMERICAN OVERSIGHT

<don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: 2/10/20 6 AM update

Thank you Uwe for the continued excellent updates. (b)(5)
(b)(5)

(b)(5)

(b)(5)

(b)(5)

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Office of Product Evaluation and Quality

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 6:34 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/10/20 6 AM update

AMERICAN OVERSIGHT

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/10/20 6 AM update

**Status of activities on diagnostics**:

- Issue with rapid verification and implementation of CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel in handful of public health labs:
  - CDC informed FDA yesterday afternoon that APHL has been notified that some laboratories have observed performance issues during verification testing, particularly with the N3 part of the assay showing sporadic aberrant reactivity in the negative controls. CDC is aware of these reports and is investigating.
  - Conference call with CDC has been scheduled for today 2 PM to discuss the issue and any investigation so far.

**New roadblocks/challenges/delays:**

(b) (5)

**Enclosed also the compiled activities over the weekend which have been previously communicated:**

**Status of activities on diagnostics previously reported for 2/8/20 @ 2/9/20**:

- A total of 41 IVD Developers have requested and received EUA review template, additional requests (2) are pending clarification about the device technology.
- Conference call with CDC: CDC intends to add 2 additional automated extraction methods to their EUA (Roche MagNA Pure 96 and Roche MagNA Pure 24), to support larger number of State Public Health labs who are only using these instruments. DMD/CDC agreed on bridging study protocol and limited clinical sample testing to demonstrate performance. CDC expects to submit amendment in next 2 weeks.
- On 2/6/20 CDC started shipping CDC's 2019-nCoV PCR assay to 4 public health labs that are strategically located in US and to other public health labs in states with confirmed cases.
- CDC via their IRR (International Reagent Resource) is accepting orders for CDC's 2019-nCoV tests from qualified laboratories.
  - This includes 115 qualified U.S. laboratories [state & local public health labs and DoD labs]
  - 191 qualified international labs, such as the World Health Organization (WHO) Global Influenza Surveillance Response System (GISRS) laboratories.
  - CDC test will not be available in U.S. hospitals or other primary care settings.
- CDC's isolate from infected patient in Washington was shipped to BEI (Biodefense and Emerging Infections Research Resources Repository) on Wednesday (NR-52281). Additional viral Isolates from other patients in US are expected to arrive at BEI in the next 2 weeks. Isolate without inactivation is BSL-3 analyte. BEI will begin work on inactivating virus [For use in BSL-2 labs]. Generating inactivated virus will take 2-3 months.

- Phone call scheduled with FDA/BARDA/CDC on Monday to address issues regarding timeline for virus inactivation and availability of BSL-3 facilities for commercial developers.

- CDRH was contacted by (b) (4), (b) (5)

(b) (4), (b) (5)

AMERICAN OVERSIGHT

  - Delicate intended use from the public health perspective in an outbreak situation

- DMD is following up on actions taken towards apps during the Zika outbreak
- DMD will contact app developer to get further information and clarification on the ap

**New roadblocks/challenges/delays:**

(b) (5)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/9/2020 8:28:52 PM
**To:** Patel, Bakul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ce7d58d8b9c473c8ba4d6fcb8b02b5a-BYP]
**Subject:** RE: (b) (4) screening for Coronavirus

Bakul,

Thanks, it Is likely we need some feedback from you team. Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>
**Sent:** Sunday, February 9, 2020 6:00 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>
**Subject:** RE: (b) (4) screening for Coronavirus

Thanks Uwe, let me know if my team could be of help.

*Bakul*

**Director, Digital Health**
**Center for Devices and Radiological Health (CDRH)**
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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 08, 2020 3:00 PM
**To:** Maisel, William <William.Maisel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: (b) (4) screening for Coronavirus

AMERICAN OVERSIGHT

Bill, Jeff,
I confirm this belongs to DMD. We had similar apps for the Zika outbreak and will find out how those request were handled. (b) (5)
(b)(5) DMD will follow up with a phone call to the sponsor.
Uwe

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Date:** February 8, 2020 at 2:10:54 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Krueger, Angela C <Angela.Krueger@fda.hhs.gov>
**Subject:** Re: (b) (4) screening for Coronavirus

Jeff,
I think this would be in OHT7's DMD. Looping in Tim and Uwe to confirm.
Bill

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 8, 2020 at 12:35:19 PM EST
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** Fwd (b) (4) (b) (4) screening for Coronavirus

Bill,

A small start up is looking to (b) (4)
(b) (4)
(b) (4) s there an appropriate person in OPEQ who can speak with them about FDA expectations, depending on what they specifically want to claim, including the merits of a Qsub? They may modify what they do based on the feedback.

I'm including Bakul and Suzanne for awareness.

Jeff

---

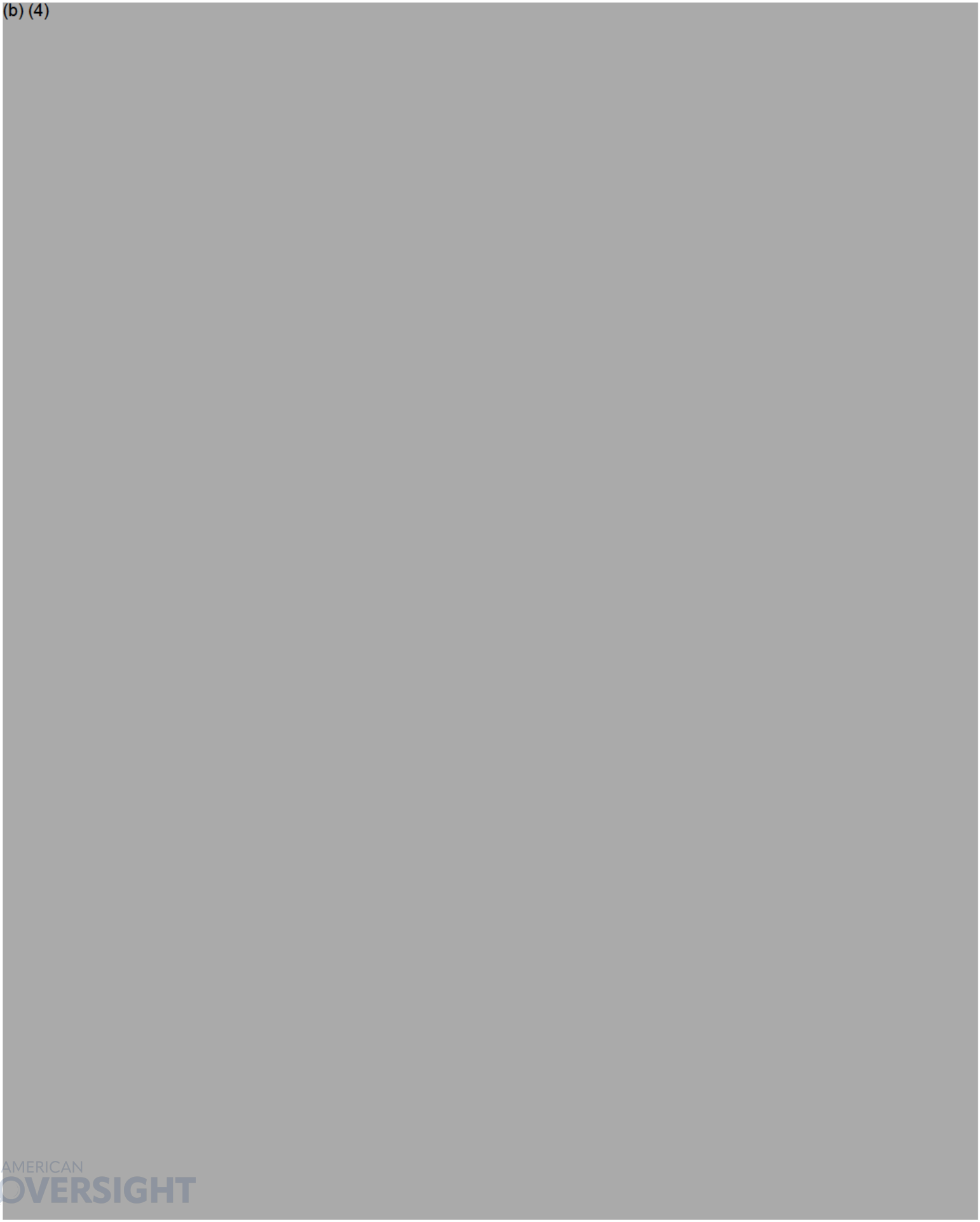
**From:** Ajintha Pathmanathan (b) (6)
**Date:** February 8, 2020 at 11:18:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** (b) (4) (b) (4) screening for Coronavirus

Hi Jeff,

Thank you for the interest. In terms of more information;

AM OVERSIGHT

(b) (4)



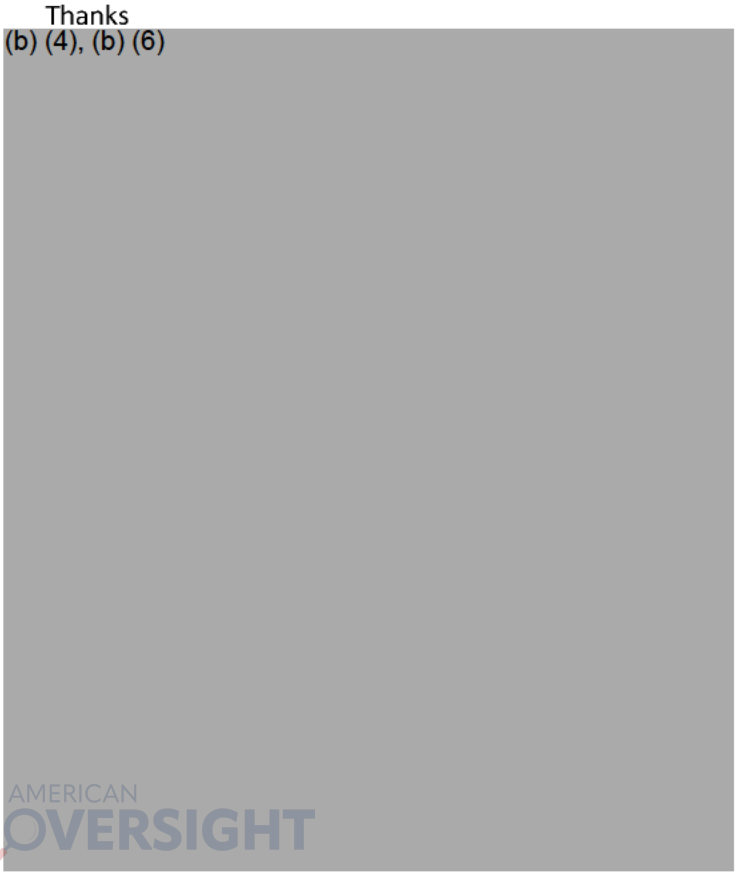
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(b) (4)



Thanks

(b) (4), (b) (6)



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(b) (4), (b) (6)



**From:** Shuren, Jeff
**Sent:** Saturday, 8 February 2020 4:13 AM
**To:** Ajintha Pathmanathan
**Subject:** Re: (b) (4) screening for Coronavirus

Hi Ajintha,

It's good to hear from you. Thank you for reaching out to me.

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

Jeff

---

**From:** Ajintha Pathmanathan (b) (6)
**Date:** February 7, 2020 at 10:15:52 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** (b) (4) screening for Coronavirus

Hi Jeff,

(b) (4)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/12/2020 9:44:26 AM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Lias, Courtney H [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98a0fa6159ce418898b4b97381a76112-CDL]; Ochs, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78dd64e6b3ff4c9894037d63ede4edc8-RAO]; Rubinstein, Wendy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3712ebbe444401c81a2a44df908c345-Wendy.Rubin]; Brenner, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5916ba05b26e4fd0a602fc0049eb382b-Sara.Brenne]; Sauer, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5fe780aaf3a4448fb18efde5e29621d6-Robert.Saue]
**Subject**: FW: DUE WED NOON – solutions to advance US production capabilities for N95 and other key devices essential for prevention and patient care related to nCoV

Tim,

As discussed yesterday and in response to Courtney's email this morning, enclosed below in the table some solutions to respond to the 2012-nCoV outbreak important for DMD.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 4:27 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** FW: DUE WED NOON – solutions to advance US production capabilities for N95 and other key devices essential for prevention and patient care related to nCoV
**Importance:** High

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Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 4:13 PM
**To:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>
**Cc:** Maisel, William <William.Maisel@fda.hhs.gov>
**Subject:** FW: DUE WED NOON – solutions to advance US production capabilities for N95 and other key devices essential for prevention and patient care related to nCoV
**Importance:** High

Hi Linda and Katie, Here are some initial ideas from me. Best, Tim

(b)(5)



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(b)(5)

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(b)(5)

[redacted]

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Jennifer.Campbell@fda.hhs.gov

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**From:** O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 1:42 PM
**To:** CDRH Leadership Team <CDRHLeadershipTeam@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** DUE WED NOON – solutions to advance US production capabilities for N95 and other key devices essential for prevention and patient care related to nCoV
**Importance:** High

Dear SLT,

(b)(5)



**Kathryn M. O'Callaghan**
*Deputy Division Director*

**Center for Devices and Radiological Health**
**Office of Strategic Partnerships and Technology Innovation (OST)**
**Division of All Hazards Response, Science and Strategic Partnerships (DARSS)** – *formerly Science & Strategic Partnerships*
**U.S. Food and Drug Administration**
Tel: 301-796-6349
kathryn.ocallaghan@fda.hhs.gov






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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/4/2020 3:03:25 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** FW: CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel
**Attachments:** 1-Cover Letter CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel EUA Request Letter.pdf; 2-CDC 2019-nCoV Letter of Authorization DRAFT 02042020.doc; 3-CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel HCP FS 02042020.docx; 4-CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Patient FS 02042020.docx; 5a-CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Instructions for Use 02042020.docx; 5b-CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel PIS and VR 02042020.pdf; 6-EUA Review Memo for the CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel 04FEB2020 DMD.doc

**Importance:** High

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Scherf, Uwe
**Sent:** Tuesday, February 4, 2020 2:03 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel
**Importance:** High

Dear Jennifer, Liz, Dennis, Marcy and Michael,

Please find attached the formal EUA request package for the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel with the following documents for OCET and OCC's review and clearance:

Please find attached the EUA request package for the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel:

1) CDC Cover Letter - pdf
2) Draft EUA Letter of Authorization – with some notes for OCET/OCC – MS word
3) CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel HCP Fact Sheet – MS word

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4) CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Patient Fact Sheet – MS word
5) CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Labeling
a. Instructions for Use – MS word – [note CDC are having technical issues making this a pdf- will submit later – to combine with the labeling in b]
b. Product Information Sheet and Verification Requirements - pdf
6) DMD EUA Lead Memo for CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel – MS word

CDRH considers these documents as cleared.

Thank you so much for your collaboration and help getting this first EUA for 2019-nCoV authorized so expeditiously!

Best regards
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

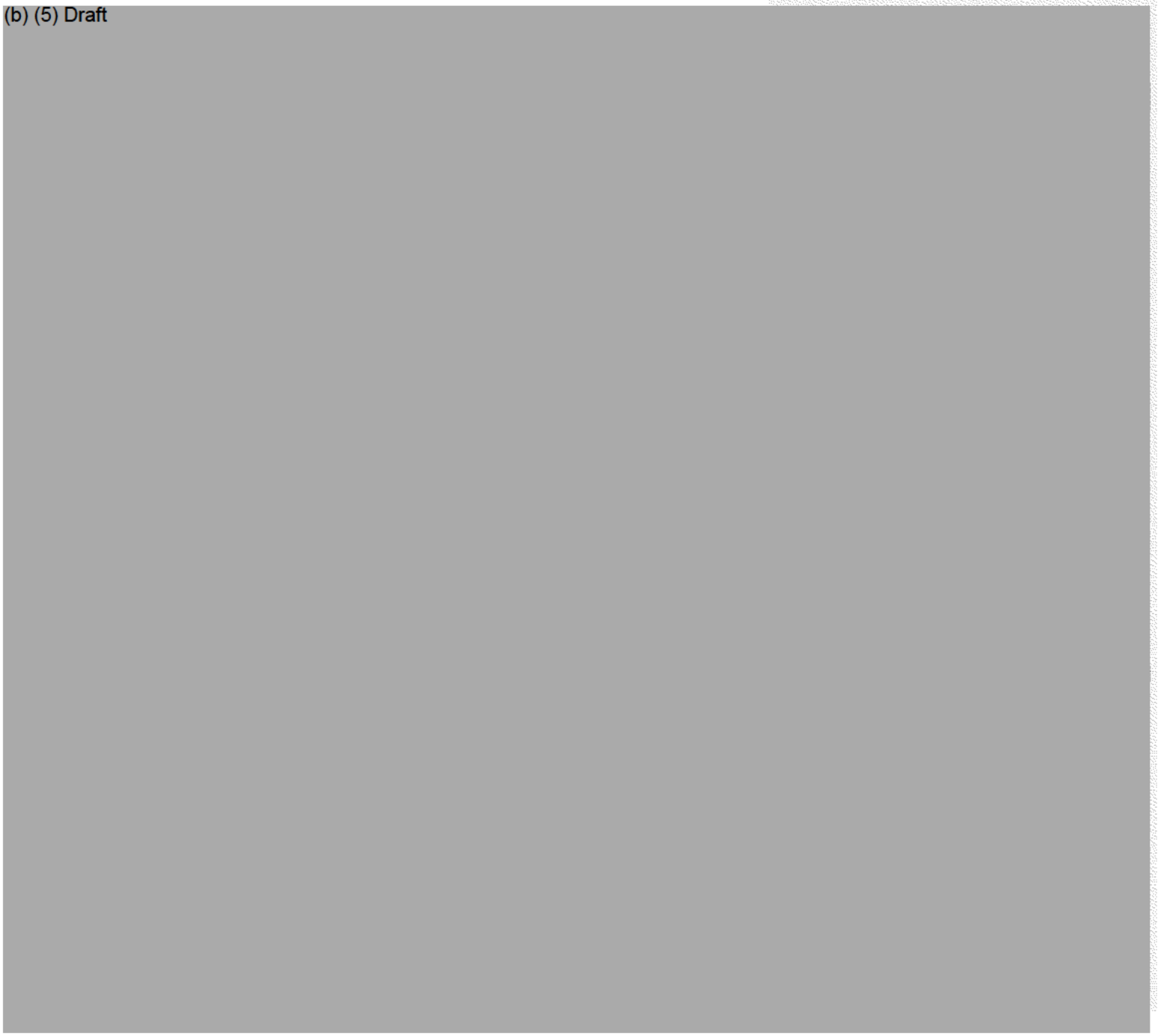
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

(b) (5) Draft



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(b) (5) Draft

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# FDA REVIEW MEMORANDUM FOR EMERGENCY USE AUTHORIZATION (EUA) OF THE CDC 2019 Novel CORONAVIRUS (2019-nCoV) REAL-TIME RT-PCR DIAGNOSTIC PANEL

## A. EXECUTIVE SUMMARY (as of 01/31/2020)

An outbreak of pneumonia caused by a novel coronavirus (2019-nCoV) in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019. Chinese health officials have reported thousands of infections with 2019-nCoV in China, with the virus reportedly spreading from person-to-person in many parts of that country. As of January 31, there were six confirmed cases of 2019-nCoV in the United States with one confirmed instance of person-to-person transmission. On January 31, 2020, Health and Human Services Secretary Alex M. Azar II declared a public health emergency (PHE) for the United States to aid the nation's healthcare community in responding to 2019-nCoV.

The Centers for Disease Control and Prevention (CDC) continues to closely monitor the outbreak of the 2019-nCoV. CDC has established an Incident Management System to coordinate a domestic and international public health response. As part of its response activities CDC has developed a molecular *in vitro* diagnostic test, the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, to aid in the diagnosis of patients being evaluated with acute febrile, respiratory illness who meet the CDC clinical criteria for a 2019-nCoV patient under investigation (PUI).

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 4:39:46 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

**Importance**: High

Jeff,

Here is the list of individual being involved in the EUA, and also please see the email I just send out, I am terrible sorry that somehow I missed to send it you to too, getting a little tired.
Uwe

Thanks to the tireless and extraordinary work of the DMD review team over the last weeks:

- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*
- **Li Li**, Lead Reviewer, Viral Respiratory & HPV Branch,
- **Brittany Goldberg**, MD, Senior Medical Officer, and
- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, **Megan McSeveney** & **Angela Stark** (press office).

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 4:27 PM
**To:** CDRH-OIR-IVD-DMD <CDRH-OIR-IVD-DMD@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued
**Importance:** High

**Congratulations!**

FDA just issued the Emergency Use Authorization for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.
Thanks to the tireless and extraordinary work of the DMD review team over the last weeks:

- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*

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- **Li Li**, Lead Reviewer, Viral Respiratory & HPV Branch,
- **Brittany Goldberg**, MD, Senior Medical Officer, and
- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, **Megan McSeveney** & **Angela Stark** (press office), and our senior leadership.

These have been incredible 2 weeks and words cannot describe how grateful I am for your phenomenal dedication and extraordinary hard work that made this happen. You are an exceptional team to work with unprecedented commitment to public health!

Thanks you! Thank you! Thank you!

My very kind regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/13/2020 9:51:56 AM
**To:** Lovell, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a4cfa4fc4094bbf8fac0e16bf710049-SXL]
**Subject:** Compliance

**Status of activities on diagnostics**

- A total of 56 IVD Developers have requested and received EUA review template.

- Held conference call with company advertising their Logix Smart 2019-nCoV Kit as an RUO test. Advertising implied diagnostic and screening testing.
- Explained RUO labeling regulation 809.10(c)(i) - and the requirement that all labeling bears the statement, prominently placed: **"For Research Use Only. Not for use in diagnostic procedures."**
- Pointed out and requested correction of specific claims and statements on their website and in news releases that implied performance and use of their device for diagnostic/screening testing.
- Firm acknowledged that they are not in compliance with RUO labeling regulation.
- Firm agreed to take immediate corrective action [update their website] to resolve the identified concerns regarding the product labeling and advertising.
- Agreed on deadline for complete list of all planned action of 2/14/20.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/9/2020 7:53:48 PM
**To**: Robert Di Tullio (b) (6)
**CC**: Gitterman, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4747486679444f24aa8d1086cca27390-SRG]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: EUA

Dear Robert,

I assume your client has requested and received the EUA Template and followed the recommendation in that document.

If not, please ask the company to request the EUA Template at:

CDRH-EUA-Templates@fda.hhs.gov

Kind regards. Uwe

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

-----Original Message-----
From: Robert Di Tullio (b) (6)
Sent: Sunday, February 9, 2020 7:22 PM
To: Gitterman, Steven <Steven.Gitterman@fda.hhs.gov>
Cc: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: EUA

Greetings friends
I hope you' re doing well. I have a client who is an emerging IVD company in Australia who is interested in a EUA for their coronavirus test. I have read the guidance and intend to send in a letter beginning the authorization process but wondered if you have any advice upfront. Thanks!

My best regards

Robert

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/10/2020 3:39:36 PM
**To**: Cynthia Phillips, PhD [Cynthia.Phillips@BioFireDefense.com]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Maher, Carmen T CIV USARMY DOD JPEO CBRND (USA) [carmen.t.maher.civ@mail.mil]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: BioFire 2019-nCoV Test - Request for Interactive EUA Review

Dear Cynthia,

I confirm the receipt of the electronic Pre-Emergency Use Authorization (Pre-EUA) of the BioFire 2019-nCov Test.

DMD is looking forward to working with you and your team on this submission.

Kind regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Cynthia Phillips, PhD <Cynthia.Phillips@BioFireDefense.com>
**Sent:** Monday, February 10, 2020 1:30 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Maher, Carmen T CIV USARMY DOD JPEO CBRND (USA) <carmen.t.maher.civ@mail.mil>
**Subject:** RE: BioFire 2019-nCoV Test - Request for Interactive EUA Review

10 February 2020

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
**ATTN:** Division Director: Dr. Uwe Scherf, OHT7-OIR/OPEQ/CDRH/FDA

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**RE:** Request for Pre-Emergency Use Authorization (Pre-EUA) of the BioFire 2019-nCov Test

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Dear Dr. Scherf,

BioFire Defense, LLC is submitting a Pre-Emergency Use (Pre-EUA) for the BioFire 2019-nCov Test to obtain feedback from FDA concerning the studies and/or testing outlined in our Pre-Emergency Use Authorization (Pre-EUA) submission package. BioFire Defense is respectfully requesting early interactive review to ensure the test plans are acceptable to the US FDA prior to testing and EUA submission. Assay design is not complete, testing has not yet been initiated, and the EUA template is in draft form (BioFire Defense proposed sections are in blue).

The U.S. Department of Defense (DoD) NGDS contract with BioFire Defense is likely to be used to support this project to pursue authorization for 2019-nCoV testing on the U.S. DoD diagnostic system of record (FilmArray 2.0). While a contract is not yet in place for this work, the U.S. DoD has requested that BioFire Defense pursue the fastest route to authorization for the BioFire 2019-nCoV Test.

**Proposed Intended Use**

BioFire 2019-nCoV Test is a nested multiplexed real-time RT-PCR test intended for the qualitative detection of nucleic acid from the 2019-nCoV in nasopharyngeal swabs in Viral Transport Media (and sputum) from individuals meeting CDC 2019-nCoV clinical criteria (e.g., clinical signs and symptoms associated with 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated). Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity tests, or by similarly qualified non-U.S. laboratories.

Attached to this letter is the first draft of our device EUA Interactive Review Template for FDA review as a Pre-EUA. Hard copies comprising this submission (including a signed hard copy of this cover letter) are listed below. An eCopy is included for this submission. **The eCopy is an exact duplicate of the paper copy.** Also, these documents have been sent to you via email.

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Documents comprising the submission:

001_ CoverLetter_PreEUA_BioFire_2019-nCov Test
002_Form3514
003_ EUA Template_FilmArray_2019-nCoV_Test_20200209

In case you should have any questions regarding the information provided and/or need additional information/data from us please contact me immediately either via email or phone.

Sincerely,

Cynthia Phillips, Ph.D.
VP of Regulatory, Quality, and Clinical Affairs
BioFire Defense, LLC
Phone: 801-262-3592 ext 1370
Cell Phone: (b) (6)
Email: Cynthia.phillips@biofiredefense.com

---

**Cynthia Phillips, PhD**
*VP of Regulatory, Quality and Clinical Affairs*
**BioFire Defense**
Phone: 801-262-3592 x1370

**From:** Sapsford, Kim E [mailto:Kim.Sapsford@fda.hhs.gov]
**Sent:** Sunday, February 09, 2020 7:54 PM
**To:** Cynthia Phillips, PhD <Cynthia.Phillips@BioFireDefense.com>
**Cc:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: BioFire 2019-nCoV Test - Request for Interactive EUA Review

Dear Cynthia,

Thank you for the draft EUA Template for the BioFire 2019-nCoV test. We request that in addition to this email you submit this same template to our document control center as a Pre-EUA submission – I have attached a draft cover letter and the instructions are below:

Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft you sent with your email
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under type of submission please check "other" and specify Pre-EUA.

One hard copy of the signed EUA Cover Letter and one electronic copy of you Pre-EUA submission package (including the EUA Review Template - MS word document) should be enclosed in your Pre-EUA submission to FDA.

We will review the BioFire Defense proposed section in blue in the EUA template you submitted and let you know if we have any questions.

We look forward to working with you on this submission
Best regards
Kim

AMERICAN OVERSIGHT

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Cynthia Phillips, PhD <Cynthia.Phillips@BioFireDefense.com>
**Sent:** Sunday, February 09, 2020 8:32 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Subject:** BioFire 2019-nCoV Test - Request for Interactive EUA Review

Hello Kim,

Attached is a draft EUA Template for a BioFire 2019-nCoV Test. BioFire Defense is respectfully requesting early interactive review to ensure the test plans are acceptable to the US FDA prior to testing and EUA submission. Assay design is not complete, testing has not yet been initiated, and the EUA template is in draft form (BioFire Defense proposed sections are in blue).

Background: The US Department of Defense (DoD) NGDS contract with BioFire Defense is likely to be used to support this project to pursue authorization for 2019-nCoV testing on the US DoD diagnostic system of record (FilmArray 2.0). While a contract is not yet in place for this work, the US DoD has requested that BioFire Defense pursue the fastest route to authorization for the BioFire 2019-nCoV Test.

Please let us know if we have sent this to the right office, if you would like us to submit formally through the document mail center, if there is an updated template, whether it is possible to do this kind of interactive review, and whatever other information we need to begin. We are always available for questions. As I am rarely in my office; my cell phone (b) (6) or email are the best ways to reach me.

Thank you,
Cynthia

---

AMERICAN OVERSIGHT



**Cynthia Phillips, PhD**
*VP of Regulatory, Quality and Clinical Affairs*
**BioFire Defense**
79 W 4500 S Suite 14 | Salt Lake City, Utah 84107 USA
Office: 801-262-3592 x1370
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/15/2020 8:17:45 AM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Mielech, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Urgent - Request to have conference call today at 4 PM

All,

I have been thinking about the pre-EUA comments to be send to the sponsor. We are getting a lot of pressure from all sides.

Sorry to interrupt your weekend, but we need to get the comments to the sponsors asap and not wait until Tuesday as I originally wanted to.

As discussed with Tamara, let have a group teleconference today at 4 PM. Tamara will send out the WebEx for the group.

We will go over the following items and any additional items identified by Anna and Himani.

(b) (5)



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(b) (5)

[redacted]

Thank you all for your dedication and hard work!!

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/11/2020 6:43:57 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]
**Subject**: 2/11/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/11/20 6 AM update:

**Status of activities on diagnostics**

- DMD received the first three pre-EUA submissions: one from BioFire Defense for their BioFire 2019-nCov Test, the 2nd from Inbios Inc. for their Smart *Detect*™ 2019-nCOV rRT-PCR kit, and the 3rd from Roche Molecular Systems for their cobas 2019-nCoV test for use on the cobas 6800/8800 Systems. The submissions primarily request FDA feedback on the planned studies and only have very limited data. DMD's review team started review and will provide responses interactively.

- A total of 45 IVD Developers have requested and received EUA review template - DMD provides interactive feedback even before pre-EUA submission.

- Contacted (b) (4), (b) (5) . Received additional information, under review, follow up call scheduled for this week.

- CDC issue with verification in around 10% of labs receiving the CDC test:
- Official email on this issue received by FDA. DMD agreed to best option for immediate resolution: Manufacturing of a new primer/probe set for the N3 assay and selective N3 component replacement only. The primer/probe set of the other 2 targets of the assay did not show any false positive issues and will not be replaced.

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**Recap from yesterday afternoon 3 PM:**

- FDA/BARDA/CDC call to address issues regarding timeline for virus inactivation and availability of BSL-3 facilities for commercial developers
- BEI inactivating of virus [For use in BSL-2 labs] will take 2-3 month
- Alternative option: NIH has contract with UTMB to generate live virus, UTMB timeline for growing and inactivation was communicated to NIH to be shorter [optimal case (b) (4) weeks, if complications occur (b) (4) weeks] NIH is following up with UTMB to confirm these timelines.
- (b) (5)
- (b) (5) is not a viable option

- CDC issue with verification in a some labs:
- Around 100 labs received CDC assay, 10% cannot verify assay due to N3 false positive results
- CDC concluded that the observed reactivity with the N3 part of the assay is a manufacturing issue and not a technical error in laboratories
- CDC will manufacture N3 assay component with higher QC specs. Will also contract to commercial vendor for external manufacturing
- CDC proposed N3 component replacement [not the whole test] for labs failing the verification first followed by the other lab. A false N3 signal triggers inconclusive results requiring sample to be retested at CDC in Atlanta.
- Official report on this issue will be sent to FDA today. DMD is in support of the proposal of the N3 component replacement.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**EMERGENCY USE AUTHORIZATION (EUA)**

**EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (2019-nCoV)**

(b) (5) Draft



AMERICAN OVERSIGHT

(b) (5) Draft

AMERICAN OVERSIGHT

(b) (5) Draft

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(b) (5) Draft

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**Sent**: 2/12/2020 1:21:56 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/12/20 2 PM update

Nothing to report for the 2 PM update. Uwe

---

**From:** Scherf, Uwe
**Sent:** Wednesday, February 12, 2020 6:38 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** 2/12/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/12/20 6 AM update:

**Status of activities on diagnostics**

- A total of 56 IVD Developers have requested and received EUA review template
- Held conference call with company advertising their Logix Smart 2019-nCoV Kit as an RUO test. Labeling and advertising implied diagnostic and screening testing.

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- Explained RUO labeling regulation 809.10(c)(i) - and the requirement that all labeling bears the statement, prominently placed: **"For Research Use Only. Not for use in diagnostic procedures."**
- Pointed out and requested correction of specific claims and statements on their website and in news releases that implied performance and use of their device for diagnostic/screening testing.
- Firm acknowledged that they are not in compliance with RUO labeling regulation.
- Firm agreed to take immediate corrective action to resolve the identified concerns regarding the product labeling and advertising.
- Agreed on deadline for complete list of all planned action of 2/14/20.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/6/2020 5:20:12 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Are RUO Tests Allowed?

Great, thanks, Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, February 6, 2020 5:20 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Are RUO Tests Allowed?

They have it already Uwe – was sent 02/01/2020

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 06, 2020 5:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Are RUO Tests Allowed?

Kim,

I just got this, we should send them the EUA template and invite them to submit their data.

Uwe

---

**From:** Jeff Fischer <jeff@lhnvd.com>
**Sent:** Thursday, February 6, 2020 4:40 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** Are RUO Tests Allowed?

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Co-Diagnostics, Inc. (Nasdaq: CODX), a molecular diagnostics company with a unique, patented platform for the development of diagnostic tests, announced today that its research use only (RUO) CoPrimer™ test for the 2019-nCoV coronavirus is ready for sale to appropriate laboratories, hospitals, and institutions in need of a solution to the current coronavirus epidemic.

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/8/2020 7:28:19 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/8/20 8 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/8/20 8 AM update

**Status of activities on diagnostics**:

- A total of 41 IVD Developers have requested and received EUA review template, additional requests (2) are pending clarification about the device technology.
- Conference call with CDC: CDC intends to add 2 additional automated extraction methods to their EUA (Roche MagNA Pure 96 and Roche MagNA Pure 24), to support larger number of State Public Health labs who are only using these instruments. DMD/CDC agreed on bridging study protocol and limited clinical sample testing to demonstrate performance. CDC expects to submit amendment in next 2 weeks.
- On 2/6/20 CDC started shipping CDC's 2019-nCoV PCR assay to 4 public health labs that are strategically located in US and to other public health labs in states with confirmed cases.
- CDC via their IRR (International Reagent Resource) is accepting orders for CDC's 2019-nCoV tests from qualified laboratories.
  - This includes 115 qualified U.S. laboratories [state & local public health labs and DoD labs]
  - 191 qualified international labs, such as the World Health Organization (WHO) Global Influenza Surveillance Response System (GISRS) laboratories.
  - CDC test will not be available in U.S. hospitals or other primary care settings.
- CDC's isolate from infected patient in Washington was shipped to BEI (Biodefense and Emerging Infections Research Resources Repository) on Wednesday (NR-52281). Additional viral Isolates from other patients in US are expected to arrive at BEI in the next 2 weeks. Isolate without inactivation is BSL-3 analyte. BEI will begin work on inactivating virus [For use in BSL-2 labs]. Generating inactivated virus will take 2-3 months.
- Phone call scheduled with FDA/BARDA/CDC on Monday to address issues regarding timeline for virus inactivation and availability of BSL-3 facilities for commercial developers.

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**New roadblocks/challenges/delays:**

(b) (5)

[redacted]

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/5/2020 6:55:56 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2/5/20 6AM update

2/5/20 6AM update

**Status of activities on diagnostics**:

- Issued Emergency Use Authorization for CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel
- Provided feedback on diagnostic 1 pager briefing document for the White House Task Force – currently scheduled to meet at 4pm on Thursday
- A total of 29 IVD Developers have requested and received EUA review template.

**New roadblocks/challenges/delays:**

- None

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/8/2020 7:20:15 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Quick questions

Great, thanks, I will include Heather and Julie as well until we figure out the setting. Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 8, 2020 7:18 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Quick questions

Looks good Uwe, could you also include Heather and Julie (Marders) on the email to Jeff also. I am trying to figure out with them exactly whom we should be sending updates to now. Now this IMG group has been set up it is a bit confusing, and I know Heather and Julie are updating Jeff also. We can chat next week

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 08, 2020 7:13 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Quick questions

Kim,

I am planning to send the following to Jeff et all this morning, do you think it is too detailed?

**Status of activities on diagnostics**:

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- A total of 41 IVD Developers have requested and received EUA review template, additional requests (2) are pending clarification about the device technology.
- Conference call with CDC: CDC intends to add 2 additional automated extraction methods to their EUA (Roche MagNA Pure 96 and Roche MagNA Pure 24), to support larger number of State Public Health labs who are only using these instruments. DMD/CDC agreed on bridging study protocol and limited clinical sample testing to demonstrate performance. CDC expects to submit amendment in next 2 weeks.
- On 2/6/20 CDC started shipping CDC's 2019-nCoV PCR assay to 4 public health labs that are strategically located in US and to other public health labs in states with confirmed cases.
- CDC via their IRR (International Reagent Resource) is accepting orders for CDC's 2019-nCoV tests from qualified laboratories.
  - This includes 115 qualified U.S. laboratories [state & local public health labs and DoD labs]
  - 191 qualified international labs, such as the World Health Organization (WHO) Global Influenza Surveillance Response System (GISRS) laboratories.
  - CDC test will not be available in U.S. hospitals or other primary care settings.
- CDC's isolate from infected patient in Washington was shipped to BEI (Biodefense and Emerging Infections Research Resources Repository) on Wednesday (NR-52281). Additional viral Isolates from other patients in US are expected to arrive at BEI in the next 2 weeks. Isolate without inactivation is BSL-3 analyte. BEI will begin work on inactivating virus [For use in BSL-2 labs]. Generating inactivated virus will take 2-3 months.

- Phone call scheduled with FDA/BARDA/CDC on Monday to address issues regarding timeline for virus inactivation and availability of BSL-3 facilities for commercial developers.

**New roadblocks/challenges/delays:**

(b) (5)

[redacted]

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/7/2020 4:25:21 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2019 nCoV DMD EUA MCM Hours_01-22-2020.xlsx

**Importance**: High

Kim, LI, and Tamara,

Could you please fill in the number of our you worked on nCoV for the following time periods:

| |
|---|
| 1/1/20 - 2/1/20 |
| 2/2/20 - 2/8/20 |

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/14/2020 11:08:50 AM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject:** FW: Assigned Lead Reviewers for nCoV pre-EUAs

Li, could you please give me a quick call? Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 11:02 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>
**Subject:** Assigned Lead Reviewers for nCoV pre-EUAs

Dear All,

Below is the table with current EUA/pre-EUA assignments.

| | | | | |
|---|---|---|---|---|
| PEU200001 | InBios | Smart Detect 2019-nCoV | 2/11/2020 | Li |
| PEU200002 | Roche Molecular | cobas 2019-nCoV on cobas 6800/8800 Systems | 2/11/2020 | Li |
| PEU200003 | BioFire Defense | BioFire 2019-nCoV Test | 2/11/2020 | Li |
| PEU20000x | ScienCell Research Laboratories | SARS-Cov-2 RT-PCR Detection Kit | 2/13/2020 | Himani |
| PEU20000x | Novacyt | Primerdesign 2019- nCoV | 2/14/2020 | Himani |
| PEU20000x | Cepheid | Xpert SARS-CoV-2 test | 2/13/2020 | Anna |
| PEU20000x | Vela Diagnostics | ViroKeyTM SA201 2019-nCoV RT-PCR Test | 2/11/2020 | Anna |

Kim,

Please include Anna and Himani on the nCoV internal meeting invite. Next time we should discuss questions/issues raised by Li that will affect all pre-EUAs. I copied the questions from Li's e-mail:

(b) (5)

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(b) (5)

[redacted]

Best regards,

Tamara

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 8:08 AM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** RE: Need assigned Lead Reviewers - not in CTS yet

Thanks Tamara

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 7:47 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** RE: Need assigned Lead Reviewers - not in CTS yet

I was waiting for them to show up in CTS but I will assign the reviewer today and then record in CTS when the pre-EUAs are logged in.

Tamara

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 14, 2020 7:37 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Need assigned Lead Reviewers - not in CTS yet

Dear Uwe and Tamara,

Can we assign Lead Reviewers to the following – I send the submissions as separate email files:

- Cepheid Xpert SARS-CoV-2 test
- ScienCell Research Laboratories - SARS-Cov-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit
- Primerdesign **2019- nCoV**

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/5/2020 9:55:20 AM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject:** RE: Request of coronavirus rapid test EUA

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Wednesday, February 5, 2020 9:55 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Request of coronavirus rapid test EUA

Here it is

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 1:25 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Request of coronavirus rapid test EUA

Attached please find the first draft of the EUA template for an antigen-based 2019-nCoV test for discussion.
Li

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 8:54 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Request of coronavirus rapid test EUA

Li and Tamara,

Can you please start working on drafting a template for the rapid antigen test. Uwe

---

**From:** (b) (4), (b) (6)
**Sent:** Tuesday, February 4, 2020 7:33 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>

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**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** Request of coronavirus rapid test EUA

Hi Uwe and Tamara,

It is nice to see you yesterday. The tremendous effort that your division put out to encourage the EUA product development is very appreciated.

(b) (4)

I really appreciate your support to the these tests development especially at this critical time.

Best regards,

(b) (4), (b) (6)

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/6/2020 12:57:22 PM
**To:** eventsregistration@gatesfoundation.org
**Subject:** decline

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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---

**From:** Bill & Melinda Gates Foundation Events Team <eventsregistration@gatesfoundation.org>
**Sent:** Thursday, February 6, 2020 12:28 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Reminder - Invitation to the Global Research and Innovation Forum: Towards a Roadmap for the 2019 Novel Coronavirus

World Health Organization

GLOPID-R
Global Research Collaboration for Infectious Disease Preparedness

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – www.who.int

Uwe Scherf

Dear Uwe Scherf,

WHO R&D Blueprint

*for action to prevent epidemics:*

**Global research and innovation forum: towards a roadmap for the 2019 novel Coronavirus**
**WHO Executive Boardroom, 11-12 February 2020, Geneva, Switzerland**

On behalf of the World Health Organization (WHO), and the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), we have pleasure in inviting you, as a participant, to attend the above-mentioned 2-day in-person meeting to be held in Geneva, Switzerland, 11-12

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February 2020. We plan to live-stream the plenary sessions for participants unable to travel.

The purpose of the forum is to bring together a group of key experts, partners and stakeholders to finalize the development of a *roadmap for the 2019 novel Coronavirus* in order to enable the conduct of research, product development and innovation. Such a roadmap will include an analysis of current capacities and ongoing efforts in affected countries and globally, and a review of the steps that the community should take to accelerate critical research. This meeting will assess the status of research and product development to fight the 2019 novel Coronavirus epidemic; including diagnostics, therapeutics, and prophylactics products as well as regulatory, ethical, social sciences, animal health, data / sample sharing and other considerations; to align on a cross-functional strategy to advance the countermeasures necessary to treat patients and control transmission.

The forum will be structured in a series of plenary and group sessions, the three main overall objectives being to

- *enable the joint identification of the main knowledge gaps and research priorities;*
- *foster an acceleration of the generation of scientific information; and*
- *promote the development and generation of priority medical countermeasures to control the 2019-nCoV emergency, through an effective collaborative approach.*

*The main expected outcome will be to generate a concerted global research agenda, including priorities and frameworks for global coordination and implementation.*

A complete set of the background documents will be available on your arrival in Geneva. The working language of the consultation will be English.

Please find a Declaration of Interests Form which we kindly request you to complete and return, as soon as possible and upload directly to the event registration site or email eventsregistration@gatesfoundation.org with document attached prior to the meeting.

Please **register here no later than Tuesday, February 3, 2020.** If you will not be able to attend and would no longer like to receive emails please respond to this message with "decline".

Please note the following requirements for each registration:

**WHO reg:**

- Minimum of 15 min
- Create an account – then activate through email
- Cannot register with phone, must be on computer
- Need photo
- Need passport number

**DOI:**

- Be prepared to have an e-signature or print, sign, and scan the document

Should you require further details on the technical content of the consultation, please do not hesitate to contact Ms. Ximena Riveros Balta, email: lauriex@who.int. For any administrative queries related to this meeting, please contact Ms Neddy Mafunga, e-mail: mafungan@who.int or Peyton.Wall@GatesFoundation.org.

We look forward to hearing from you with regard to your participation.

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Yours sincerely,

| | | |
|---|---|---|
| Dr. Soumya Swaminathan<br>WHO Chief Scientist | Dr. Mike Ryan<br>WHO Executive Director<br>Health Emergencies | Prof. Yazdan Yazhanpanah<br>GloPID-R Chair |

منظمة الصحة العالمية • 世界卫生组织

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**Sent**: 2/13/2020 9:15:30 AM
**To**: Sauer, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5fe780aaf3a4448fb18efde5e29621d6-Robert.Saue]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Lias, Courtney H [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98a0fa6159ce418898b4b97381a76112-CDL]; Ochs, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78dd64e6b3ff4c9894037d63ede4edc8-RAO]; Rubinstein, Wendy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3712ebbe444401c81a2a44df908c345-Wendy.Rubin]; Brenner, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5916ba05b26e4fd0a602fc0049eb382b-Sara.Brenne]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: DUE WED NOON – solutions to advance US production capabilities for N95 and other key devices essential for prevention and patient care related to nCoV

Robert,

Enclosed please find the estimates for these solutions see below in red. Thanks for converting the FTEs into $.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**From:** Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 1:37 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Ochs, Robert <Robert.Ochs@fda.hhs.gov>; Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>
**Subject:** RE: DUE WED NOON – solutions to advance US production capabilities for N95 and other key devices essential for prevention and patient care related to nCoV

Yes. Uwe, do you have cost estimates for these solutions? For those that involve FTE, just let me know how many and I'll convert that to $$.

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Thanks,

Rob

**Robert Sauer**
Deputy Director
DPOM: Division of Program Operations and Management | OHT7: Office of In Vitro Diagnostics and Radiological Health
CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 3434 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-3580
Robert.A.Sauer@fda.hhs.gov

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 10:37 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Ochs, Robert <Robert.Ochs@fda.hhs.gov>; Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>
**Subject:** RE: DUE WED NOON – solutions to advance US production capabilities for N95 and other key devices essential for prevention and patient care related to nCoV

Thanks Uwe! ☺ The additions are excellent. I have added your name for those you added and to one that I had previously listed….I will pass these on shortly.

Rob, Can we add these to the separate 2021 budget request list too?

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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CDRH | Food and Drug Administration
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Jennifer.Campbell@fda.hhs.gov

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 9:44 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Ochs, Robert <Robert.Ochs@fda.hhs.gov>; Rubinstein, Wendy

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<Wendy.Rubinstein@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>
**Subject:** FW: DUE WED NOON – solutions to advance US production capabilities for N95 and other key devices essential for prevention and patient care related to nCoV

Tim,

As discussed yesterday and in response to Courtney's email this morning, enclosed below in the table some solutions to respond to the 2012-nCoV outbreak important for DMD.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 4:27 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** FW: DUE WED NOON – solutions to advance US production capabilities for N95 and other key devices essential for prevention and patient care related to nCoV
**Importance:** High

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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Jennifer.Campbell@fda.hhs.gov

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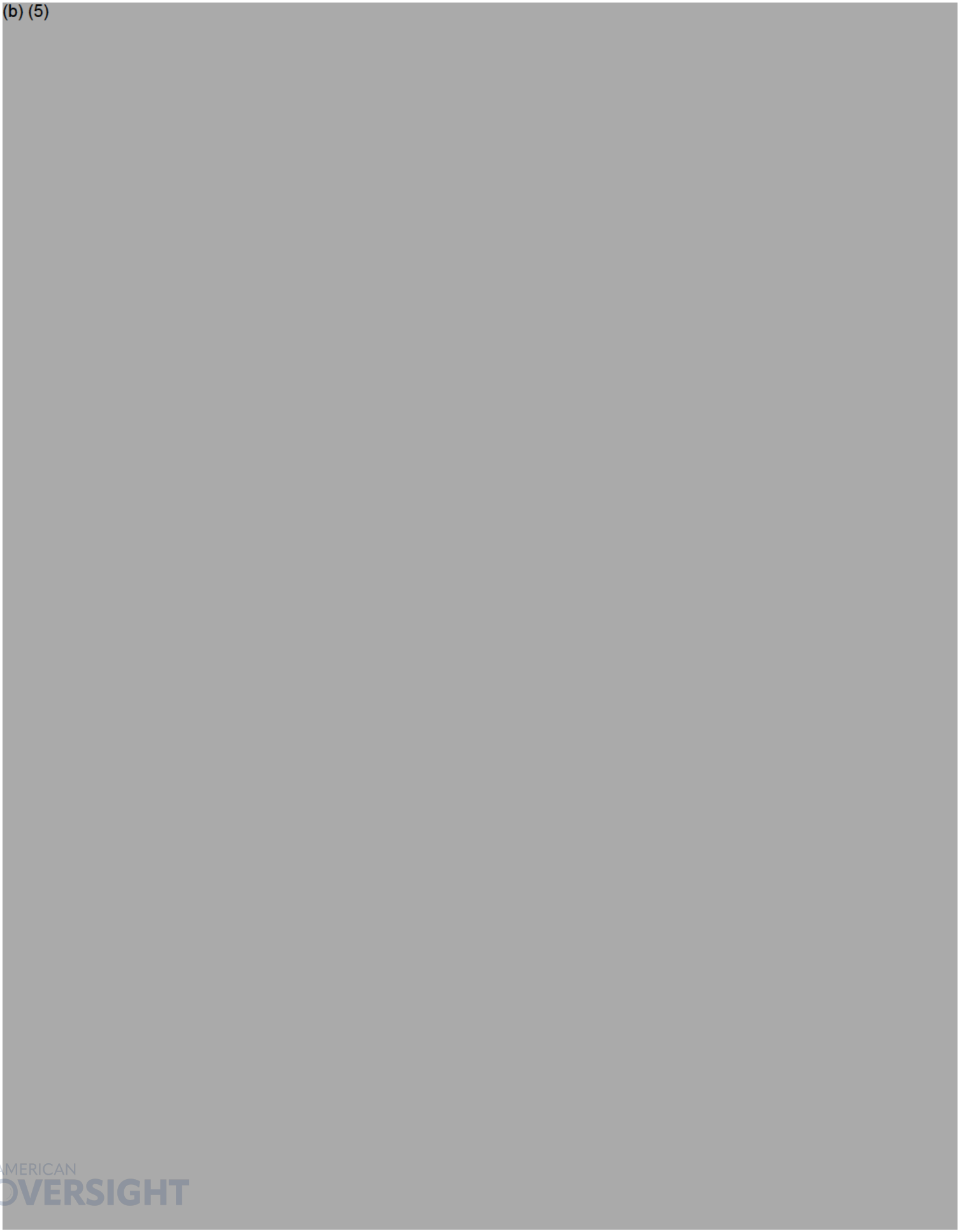
**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 4:13 PM
**To:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>
**Cc:** Maisel, William <William.Maisel@fda.hhs.gov>
**Subject:** FW: DUE WED NOON – solutions to advance US production capabilities for N95 and other key devices essential for prevention and patient care related to nCoV
**Importance:** High

Hi Linda and Katie, Here are some initial ideas from me. Best, Tim

| Solution | Problem it would solve / what we could do better if we had it | Example and/or relevant context to appreciate significance | Solution category (policy/authority, resource, market-based incentives, etc.) | Source Office / POC |
|---|---|---|---|---|
| (b) (5) | | | | |

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(b) (5)



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(b) (5)



Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
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**From:** O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 1:42 PM
**To:** CDRH Leadership Team <CDRHLeadershipTeam@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** DUE WED NOON – solutions to advance US production capabilities for N95 and other key devices essential for prevention and patient care related to nCoV
**Importance:** High

Dear SLT,

As Jeff discussed earlier today, pls identify potential solutions that could further incentivize and/or enable on-shore production capabilities of N-95 masks, PPE and other key devices essential for prevention and patient care related to nCoV. Pls send to Linda Ricci and Katie O'Callaghan by NOON WED. Response template provided below. Thanks in advance for the quick response.

Potential Ideas:

(b) (5)

| Solution | Problem it would solve / what we could do better if we had it | Example and/or relevant context to appreciate significance | Solution category (policy/authority, resource, market-based incentives, etc.) | Source Office / POC |
|---|---|---|---|---|
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| | | | | |
| | | | | |
| | | | | |

**Kathryn M. O'Callaghan**
*Deputy Division Director*

**Center for Devices and Radiological Health**
**Office of Strategic Partnerships and Technology Innovation (OST)**
**Division of All Hazards Response, Science and Strategic Partnerships (DARSS)** – *formerly Science & Strategic Partnerships*
**U.S. Food and Drug Administration**
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kathryn.ocallaghan@fda.hhs.gov






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**Sent**: 2/10/2020 11:45:57 AM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: 2/10/20 6 AM update

Tim,

Clarification for the use of extracted nucleic acid from viral isolate. (b) (5) [redacted] The availability of BSL-3 labs plays a big role here and we are trying to find out in the call today what the landscape of BSL-3 labs is.

Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 8:40 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: 2/10/20 6 AM update

Thank you Uwe for the continued excellent updates. Regarding getting viral isolates into the hands of developers, for safety reasons and timeliness reasons, I like the idea of the last bullet as we discussed last week, see below:

- Discuss resource needs and timing to generate extracted nucleic acid from viral isolate. Extracted nucleic acid can be used in BSL-2 labs, if material is certified being non-infective. (b) (5) [redacted]]

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Of course, you are know all this, just thinking out loud. The downside of this approach may be (b) (5) [redacted]

Finally, do we have an idea of (b) (5) [redacted].

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 6:34 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/10/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/10/20 6 AM update

**Status of activities on diagnostics**:

- Issue with rapid verification and implementation of CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel in handful of public health labs:
  - CDC informed FDA yesterday afternoon that APHL has been notified that some laboratories have observed performance issues during verification testing, particularly with the N3 part of the assay showing sporadic aberrant reactivity in the negative controls. CDC is aware of these reports and is investigating.

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- Conference call with CDC has been scheduled for today 2 PM to discuss the issue and any investigation so far.

**New roadblocks/challenges/delays:**

(b) (5)

**Enclosed also the compiled activities over the weekend which have been previously communicated:**

**Status of activities on diagnostics previously reported for 2/8/20 @ 2/9/20**:

- A total of 41 IVD Developers have requested and received EUA review template, additional requests (2) are pending clarification about the device technology.
- Conference call with CDC: CDC intends to add 2 additional automated extraction methods to their EUA (Roche MagNA Pure 96 and Roche MagNA Pure 24), to support larger number of State Public Health labs who are only using these instruments. DMD/CDC agreed on bridging study protocol and limited clinical sample testing to demonstrate performance. CDC expects to submit amendment in next 2 weeks.
- On 2/6/20 CDC started shipping CDC's 2019-nCoV PCR assay to 4 public health labs that are strategically located in US and to other public health labs in states with confirmed cases.
- CDC via their IRR (International Reagent Resource) is accepting orders for CDC's 2019-nCoV tests from qualified laboratories.
  - This includes 115 qualified U.S. laboratories [state & local public health labs and DoD labs]
  - 191 qualified international labs, such as the World Health Organization (WHO) Global Influenza Surveillance Response System (GISRS) laboratories.
  - CDC test will not be available in U.S. hospitals or other primary care settings.
- CDC's isolate from infected patient in Washington was shipped to BEI (Biodefense and Emerging Infections Research Resources Repository) on Wednesday (NR-52281). Additional viral Isolates from other patients in US are expected to arrive at BEI in the next 2 weeks. Isolate without inactivation is BSL-3 analyte. BEI will begin work on inactivating virus [For use in BSL-2 labs]. Generating inactivated virus will take 2-3 months.

- Phone call scheduled with FDA/BARDA/CDC on Monday to address issues regarding timeline for virus inactivation and availability of BSL-3 facilities for commercial developers.

- CDRH was contacted by (b) (4), (b) (5)

(b) (4), (b) (5)

  - Delicate intended use from the public health perspective in an outbreak situation
  - DMD is following up on actions taken towards apps during the Zika outbreak
  - DMD will contact app developer to get further information and clarification on the ap

**New roadblocks/challenges/delays:**

(b) (5)

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- Will determine whether BEI has 'BSL-3 suites' that developers could use for evaluating their device with the viral isolate if sponsor has no access to BLS-3 lab (b) (5)
- Discuss resource needs and timing to generate extracted nucleic acid from viral isolate. Extracted nucleic acid can be used in BSL-2 labs, if material is certified being non-infective. (b) (5) (b) (5)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**Sent:** 2/3/2020 8:42:48 AM
**To:** Schlottmann, Silke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e336124318b94b659ff7a2c244ce4c18-Silke.Schlo]; Garcia, Mayra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7db05677732d4023bcdf772ee0474055-GarciaM]; Garcia, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ec44354adae4472a61ac05123d291d3-Maria.Garci]
**Subject:** RE: Urgent - Question possible coming up tomorrow at the late panel meeting

Thanks

---

**From:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>
**Date:** February 3, 2020 at 7:29:37 AM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>, Garcia, Maria <Maria.Garcia@fda.hhs.gov>
**Subject:** RE: Urgent - Question possible coming up tomorrow at the late panel meeting

Problems:
(b) (5)

**Silke Schlottmann**
*Scientific Reviewer*

Hepatitis and General Virology Branch
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR) | OHT7

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Silke.Schlottmann@fda.hhs.gov






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**From:** Schlottmann, Silke
**Sent:** Monday, February 03, 2020 7:26 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>
**Subject:** RE: Urgent - Question possible coming up tomorrow at the late panel meeting

Mayra covered it all (market vs. cost of development, clinical trial, sample availability.)
I adding the following:

(b) (5)

Thanks
SIlke

**Silke Schlottmann**
*Scientific Reviewer*

Hepatitis and General Virology Branch
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR) | OHT7

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 02, 2020 8:40 PM
**To:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>; Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>
**Subject:** RE: Urgent - Question possible coming up tomorrow at the late panel meeting

Thanks, this is great material.

An specifically what were the problem our companies had who went for De Novo

**From:** Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 8:33 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>
**Subject:** RE: Urgent - Question possible coming up tomorrow at the late panel meeting

Uwe,

This topic was discussed in the WHO meeting in Geneva I attended a couple of years ago. The main points that come up to my mind from our experience and this particular meeting are:

-Barrier 1: Perception of length/burden of regulatory process and cost. For example 510k is too "expensive" (e.g., (b) (4) especially regarding the clinical trials. For the EUA we allowed about half of the molecular samples to be contrived, but for the 510k more natural samples were needed and therefore, prospective expensive studies were necessary.
*Solutions: 1) (b) (5)

-Barrier 2: Limited ability to interact with regulatory agencies
*Solution: (b) (5)

-Barrier 2: Lack of enough samples to complete 510k requirement, especially during Ebola.
*Solutions: 1) (b) (5)

-Barrier 3: Lack of market incentive, market not big enough. After the Zika outbreak, few cases have been seen as to justify further investment of money, time, and effort to get a 510K.
*Solutions: (b) (5)

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-Barrier 4: Small companies, limited resources. Some companies like (b) (4) also explained to us they are a small company, reg people are limited and very busy. (b) (5)

*Solution: (b) (5)

-Barrier 5 (global): Duplicative application processes. Companies need to prepare multiple applications to different parts of the world, so they need to select sometimes where to apply.
*Solution: (b) (5)

-Barrier 6 (global): Lack of standardization amongst regulatory agencies and lack of guidance and recommendations in regulatory approval process specially outside US. Companies need to prepare different applications to different parts of the world.
*Solutions: (b) (5)

We can see what other points are presented tomorrow.

Regards,

Mayra

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 02, 2020 7:02 PM
**To:** Schlottmann, Silke <Silke.Schlottmann@fda.hhs.gov>; Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>
**Subject:** RE: Urgent - Question possible coming up tomorrow at the late panel meeting

Better phrase of the question:
**what** did FDA learn from the few Ebola and Zika EUA-510k examples we have been through about barriers which may have contributed to Industry's lack of interest in following through an EUA with an 510k and are you able to start to explore ideas based on what you hear tomorrow and that are possible within the current regs

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From:** Scherf, Uwe
**Sent:** Sunday, February 2, 2020 6:59 PM
**To:** Schlottmann, Silke (Silke.Schlottmann@fda.hhs.gov) <Silke.Schlottmann@fda.hhs.gov>; Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>
**Subject:** Urgent - Question possible coming up tomorrow at the late panel meeting

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Silke, Mayra, and Ines

Since you have been closest to Ebola and Zika:
For Ebola and Zika EUA-510k examples what were the about barriers which may have contributed to Industry's lack of interest in following through an EUA with an 510k.

Please let me know by tomorrow morning. Thanks Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/5/2020 12:04:27 PM
**To:** Donald Henton [donald.henton@veladx.com]
**Subject:** RE: Following-up on EUA request for coronavirus EUA template request

Mr. Henton,

I followed up and received confirmation that the template was sent to your organization this morning at 9:30 AM. Please let me know if it did not arrive.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Donald Henton <donald.henton@veladx.com>
**Sent:** Wednesday, February 5, 2020 11:31 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Subject:** Following-up on EUA request for coronavirus EUA template request

Hello Dr. Scherf,

I'm not sure if your group is handling the EUA requests and reviews for diagnostic tests to detect the coronavirus that the agency published the EUA notice for last week? I requested the template / information on behalf of Vela Diagnostics on Monday and have not yet gotten a reply. My development team is moving forwarding with qualification activities and we are wanting to make sure we understand what information the agency is looking for us to include upfront as we plan these activities.

Thank you for time and help. If your group aren't the ones tasked with this EUA review, can you help point me to the right group?

Sincerely,
Donald Henton
Sr. Dir. Regulatory Affairs North America
Vela Diagnostics USA
353C US Route 46 West Suite 250
Fairfield, NJ 07004
973-369-3578
donald.henton@veladx.com

AMERICAN OVERSIGHT

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secrets, protected health or personal information, privileged or otherwise confidential information. Unauthorized review, forwarding, printing, copying, distributing, or using such information is strictly prohibited and may be unlawful. If you are not an intended recipient, you are hereby notified that you received this email in error, and that any review, dissemination, distribution or copying of this email and any attachment is strictly prohibited. If you have received this email in error, please contact the sender and delete the message and any attachment from your system.

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 11:03:53 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]
**Subject**: RE: Meeting Today on Coronavirus

Yes, I will. Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 9:44 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** Meeting Today on Coronavirus

Uwe, ARC,

I have a meeting at 3 PM today on coronavirus. Can you each (Uwe and ARC) give me an update early this afternoon before the meeting on the status of the EUA and of possible shortages respectively? The Administration's focus is starting to turn to the latter so expect requests for frequent updates from several parties.

Thank you.

Jeff

**Jeffrey Shuren, MD, JD**
*Director*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Email: jeff.shuren@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/11/2020 4:33:03 PM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Draft email about IVTs and gblock materials - for your review

Looks good, just one edit in green, see blow.

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 2:18 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Draft email about IVTs and gblock materials - for your review

It looks good to me. I don't have any comments/edits.
Li

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 1:34 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** RE: Draft email about IVTs and gblock materials - for your review

Kim,

I made a couple of minor edits in the e-mail below. Otherwise looks good.

Thanks,

Tamara

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 1:09 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Draft email about IVTs and gblock materials - for your review

**Email regarding test validation materials – virus and/or clinical specimens –** (b) (5), (b) (4)

(b) (5), (b) (4)

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(b) (5), (b) (4)

[redacted]

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/5/2020 12:03:07 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Following-up on EUA request for coronavirus EUA template request

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, February 5, 2020 12:03 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Following-up on EUA request for coronavirus EUA template request

I sent it to him this morning at 9:30 am

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 05, 2020 12:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Following-up on EUA request for coronavirus EUA template request

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Kim,

Got this, and he called me up too. Could you send him the template, thanks, Uwe

---

**From:** Donald Henton <donald.henton@veladx.com>
**Sent:** Wednesday, February 5, 2020 11:31 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Subject:** Following-up on EUA request for coronavirus EUA template request

Hello Dr. Scherf,

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Thank you for time and help. If your group aren't the ones tasked with this EUA review, can you help point me to the right group?

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/13/2020 11:47:45 AM
**To**: Mielech, Anna (Anna.Mielech@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]
**Subject**: FW: 2019-nCoV EUA Interactive Review Template – Molecular-based for Pre-EUA on ViroKeyTM SA201 2019-nCoV RT-PCR Test from Vela Diagnostics
**Attachments**: ATT00001.htm; f5c5c091-9c1f-59ed-f50a-b6c76f476476.zip

Anna,

Here the electronic file. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Donald Henton <donald.henton@veladx.com>
**Sent:** Tuesday, February 11, 2020 6:54 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; John Panzera <john.panzera@veladx.com>
**Subject:** 2019-nCoV EUA Interactive Review Template – Molecular-based for Pre-EUA on ViroKeyTM SA201 2019-nCoV RT-PCR Test from Vela Diagnostics

Dr. Kim Sapsford-Medintz, Ph.D.,

You will find a copy of the initial Pre-EUA eCopy for the Vela Diagnostics' ViroKeyTM SA201 2019-nCoV RT-PCR Test and cover letter with questions we would like to seek FDA input on as we approach the verification and validation activities on this particular assay. I have also included the redline version of the Word document template as Eugene Wee (lead scientist) and I have gone through it.

The hardcopy is being forwarded to the document center as a Pre-EUA.

My team looks forward to your initial feedback as we refine the testing we expect to begin in roughly 10-14 days.

Sincerely,
Donald Henton
Sr. Dir. Regulatory Affairs North America
Vela Diagnostics USA
353C US Route 46 West Suite 250
Fairfield, NJ 07004
973-369-3578
donald.henton@veladx.com

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# EMERGENCY USE AUTHORIZATION (EUA)

## EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (2019-nCoV)

## GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow *[Text]* should be completed by the IVD developer (sponsor) as applicable to their specific test. Text in **bold** outlines the Food and Drug Administration (FDA) suggestions and clarifications for the sponsors' consideration when completing the required information in a specific section.

- This is a EUA interactive review template for Pre-EUA/EUA submissions concerning molecular-based single target tests for detection of 2019 Novel Coronavirus (2019-nCoV), Wuhan, China. If you are developing a multiplex molecular-based assay for the detection and differentiation of nucleic acids from a panel of microorganisms, please review Appendix A for FDA recommendations.

- This is a EUA interactive review template for Pre-EUA/EUA submissions and not a guidance document. The template is subject to change as we learn more about the 2019-nCoV disease and its risk-benefit profile. Recipients will receive notice and updated templates as they become available.

- This EUA interactive review template is an FDA internal document and any proprietary information provided within the template and during the interactive review process will remain confidential as it does in a regular FDA premarket submission.

- Feedback provided by FDA during the interactive review of your pre-EUA/EUA is subject to change as we learn more about the 2019-nCoV disease and the risk-benefit profile evolves to address unmet public health needs.

- Prior to a potential authorization FDA will require developers of molecular-based tests to assess traceability of their test to an FDA-recommended reference material panel if available at the time. Specific details about the traceability study and the FDA-recommended reference material panel will be provided by the Lead Reviewer assigned to the Pre-EUA submission once the analytical and clinical evaluation data has been reviewed and found to be acceptable.

- Please be reminded that tests for the detection of 2019-nCoV or 2019-nCoV infection must not be distributed and/or used for clinical diagnoses without premarket clearance, approval, or EUA by the FDA. Clinical samples for 2019-nCoV testing should be sent to the appropriate public health laboratories until the IVD device subject of this Pre-EUA submission has received authorization from the FDA.

- Clinical specimens may be required to support the EUA request. Furthermore, please note that applicable regulations for human subject protection do apply under the



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EUA. Please refer to the Clinical Evaluation section of this document for more details.

- If authorized, the EUA means that this 2019-nCoV IVD is temporarily authorized for use until the public health emergency is terminated or the EUA is revoked by the FDA.
    - FDA recommends that you consider registration and listing your EUA product once you have been issued an EUA. If this is problematic, please notify the Agency during your Pre-EUA.
    - The EUA is not a pathway to permanent marketing of your device. Therefore, we strongly recommend that you consider, in addition to an EUA, a traditional premarket submission for your IVD so that your device can still be legally marketed after termination of the emergency declaration. We recommend that you identify as soon as possible in the Pre-EUA review process any consideration of moving your product forward towards De Novo/510(k) clearance. If so some of our feedback to you may take such a long-term goal into consideration in order to prevent additional testing where it may not be needed. Therefore, please consider submitting a Pre-Submission to inquire what studies would be required for a premarket approval/ clearance of your 2019-nCoV IVD. Details on how to submit a Pre-Submission to the Agency are outlined in the FDA guidance document: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.* [ HYPERLINK "https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program" ]

**A. EXECUTIVE SUMMARY (as of X/XX/20XX)**

(b) (4)



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# EMERGENCY USE AUTHORIZATION (EUA)

# EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (2019-nCoV)

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- This is a EUA interactive review template for Pre-EUA/EUA submissions concerning molecular-based single target tests for detection of 2019 Novel Coronavirus (2019-nCoV), Wuhan, China. If you are developing a multiplex molecular-based assay for the detection and differentiation of nucleic acids from a panel of microorganisms, please review Appendix A for FDA recommendations.

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- Feedback provided by FDA during the interactive review of your pre-EUA/EUA is subject to change as we learn more about the 2019-nCoV disease and the risk-benefit profile evolves to address unmet public health needs.

- Prior to a potential authorization FDA will require developers of molecular-based tests to assess traceability of their test to an FDA-recommended reference material panel if available at the time. Specific details about the traceability study and the FDA-recommended reference material panel will be provided by the Lead Reviewer assigned to the Pre-EUA submission once the analytical and clinical evaluation data has been reviewed and found to be acceptable.

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- Clinical specimens may be required to support the EUA request. Furthermore, please note that applicable regulations for human subject protection do apply under the

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FDACDRH-p6-AO-000725

MULTI-HHS-20-0522-B, 20-0523-A-001994

EUA. Please refer to the Clinical Evaluation section of this document for more details.

- If authorized, the EUA means that this 2019-nCoV IVD is temporarily authorized for use until the public health emergency is terminated or the EUA is revoked by the FDA.

    - FDA recommends that you consider registration and listing your EUA product once you have been issued an EUA. If this is problematic, please notify the Agency during your Pre-EUA.
    - The EUA is not a pathway to permanent marketing of your device. Therefore, we strongly recommend that you consider, in addition to an EUA, a traditional premarket submission for your IVD so that your device can still be legally marketed after termination of the emergency declaration. We recommend that you identify as soon as possible in the Pre-EUA review process any consideration of moving your product forward towards De Novo/510(k) clearance. If so some of our feedback to you may take such a long-term goal into consideration in order to prevent additional testing where it may not be needed. Therefore, please consider submitting a Pre-Submission to inquire what studies would be required for a premarket approval/ clearance of your 2019-nCoV IVD. Details on how to submit a Pre-Submission to the Agency are outlined in the FDA guidance document: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

## A. EXECUTIVE SUMMARY (as of X/XX/20XX)

(b) (4)



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FDACDRH-p6-AO-000726

MULTI-HHS-20-0522-B, 20-0523-A-001995

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Vela Diagnostics USA Inc.
353C Route 46 West
Suite 250
Fairfield, NJ 07004
Phone : +1 (973) (b) (4)
Email: infoUSA@veladx.com
www.veladx.com

February 11, 2020

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

**Re: Pre-EUA Pre-EUA Submission Review of ViroKey™ SA201 2019-nCoV RT-PCR Test** (b) (4)

**Contents: Pre-EUA eCopy Cover Letter**
**1 Hardcopy of signature page and current draft 2019-nCoV EUA Interactive Review Template – Molecular-based**
**One USB eCopy– the eCopy is the exact duplicate of the paper copy**

Dear Dr. Kim Sapsford-Medintz, Ph.D.:

Enclosed you will find the initial Pre-EUA submission on behalf of Vela Diagnostics for it's ViroKey™ SA201 2019-nCoV RT-PCR Test (b) (4) currently under qualification as an *in vitro* diagnostic test intended for the qualitative detection of ribonucleic acids (RNA) from 2019-nCoV coronavirus in nasal swabs, nasopharyngeal swabs and serum. The test is intended as an aid to diagnose 2019-nCoV virus infection in symptomatic individuals and/or individuals who are suspected to have been exposed to the 2019-nCoV virus based on epidemiological criteria.

Please note, Vela is submitting one paper copy and one eCopy as requested following FDA's December 3, 2015 Guidance "*eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff*", **and the eCopy is an exact duplicate of the paper copy.** In addition, a paper copy with the handwritten signature is attached to the electronic copy.

We have questions we would like to address during the Pre-EUA:

(b) (4)

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(b) (4)

This submission contains trade secret and confidential commercial information that should be protected in accordance with 21 CPR Part 20.

If you should have any questions related to the content of this submission, please contact me directly at 973-369-3578. Alternatively, please contact John Panzera at (b) (6) or via email at (b) (6)

Sincerely,

Donald Henton
Dir. Regulatory Affairs North America
353C US Route 46 West, Suite 250
Fairfield, NJ 07004
donald.henton@veladx.com

enclosure

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/11/2020 1:01:14 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Hwang, Leroy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5da97657ec944cebf943616bd848105-Leroy.Hwang]
**CC**: Thornton, Keith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb8dc153f5d1427d8cec4ecde00213a1-Keith.Thorn]
**Subject**: RE: RUO Logix Smart 2019-nCoV Kit - request for teleconference

Leroy, Kim,

Looks great. Now we just need to get a hold of them. Thanks for exploring other contact routes. Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 12:07 PM
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Thornton, Keith <Keith.Thornton@fda.hhs.gov>
**Subject:** RE: RUO Logix Smart 2019-nCoV Kit - request for teleconference

Minor edit and comment – otherwise looks great Leory

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 11:59 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Thornton, Keith <Keith.Thornton@fda.hhs.gov>
**Subject:** RE: RUO Logix Smart 2019-nCoV Kit - request for teleconference

Please find my prep notes for the teleconference with Co-Diagnostics. I haven't heard a response from them yet.

Leroy

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**From:** Hwang, Leroy
**Sent:** Tuesday, February 11, 2020 9:53 AM
**To:** 'c.hutchins@codiagnostics.com' <c.hutchins@codiagnostics.com>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RUO Logix Smart 2019-nCoV Kit - request for teleconference

Ms. Hutchins,

In review of your firm's website and News release statements regarding the Research Use Only (RUO) Logix Smart 2019-nCoV coronavirus test, we have some concerns regarding your firm's statements which have been made regarding this product in the context of the current HHS Emergency Use Authorization (EUA) declaration. We would request a teleconference this afternoon to discuss our concerns. We are available between the hours of 12.30pm and 3.00pm EST. Please let us know your availability for this discussion.

Sincerely,

**Leroy N. Hwang, Ph.D.**
*Team Lead, Post-market Compliance Group*

Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3266 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (240) 402-6427
leroy.hwang@fda.hhs.gov






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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/12/2020 5:22:04 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: Public health labs report problems with coronavirus test

Thanks, Uwe

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 5:21 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Public health labs report problems with coronavirus test

Hi Uwe,

I have been following your reports on this, and thanks for them. Just wanted you to be aware that the issue is now making headlines.

Best,
Ellen

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 4:41 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Public health labs report problems with coronavirus test

Ellen,
We reported about it before on Monday [on Monday they reported 10 labs] but got update today that 26 labs had problems verifying their test. This verification step is an important assessment of how the test works before it is used on clinical samples. These labs did not run any clinical samples.

CDC manufactured a new lot of their for the N3 assay component which passed their now more stringent QC criteria. CDC will send out the new reagent lot to labs in a few days.

Their root cause analysis is ongoing. We are receiving updates when they are available.

Uwe

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 4:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Public health labs report problems with coronavirus test
**Importance:** High

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Heads up – news reporting on problems with CDC EUA test --

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>
**Sent:** Wednesday, February 12, 2020 4:22 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Public health labs report problems with coronavirus test

**Public health labs report problems with coronavirus test**

By David Lim

02/12/2020 04:21 PM EST

At least 25 public health laboratories around the country say they're unable to test for cases of the coronavirus originating in Wuhan because a test kit distributed by the CDC is delivering inconclusive results.

Some labs that began doing quality checks on the test last weekend found one of three reagents in the kit was ineffective, according to Kelly Wroblewski, director of infectious diseases at the Association of Public Health Laboratories. More labs started reporting similar issues on Monday and Tuesday. None of the diagnostic kits were used to test actual clinical specimens.

The kits allow states and localities to test patients, eliminating the need to confirm cases by sending samples to the CDC's headquarters in Atlanta. CDC is developing replacement tests it can send to the labs.

"Some of the states identified some inconclusive laboratory results, but we're working closely with them to correct the issues," Nancy Messonnier, director of the CDC's Center for the National Center for Immunization and Respiratory Diseases, said Wednesday.

There are 13 confirmed cases of coronavirus in the United States with 60 other people under investigation whose samples are waiting to be tested, according to CDC. More than 44,500 cases and 1,100 deaths are confirmed in China, according to the World Health Organization.

CDC initially made 200 of the diagnostic kits available to U.S. labs last week after receiving emergency use authorization from the FDA on Feb. 4.

"Of course I hoped that this week every state would be up and running," Messonnier said. "How long will that take? I can't tell you that for sure."

A "very small number of labs" in the U.S. have successfully verified the diagnostic test, according to Wroblewski. But states will continue to send all clinical specimens to CDC headquarters in Atlanta as a "backstopping" measure, according to Messonnier.

"Although this is sort of an unfortunate development and nobody wanted to see this happen, this is why there are quality control steps in place," Wroblewski said.

*To view online*:
https://subscriber.politicopro.com/health-care/article/2020/02/public-health-labs-report-problems-with-coronavirus-test-1879161

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/9/2020 10:12:54 AM
**To:** Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: (b) (4) screening for Coronavirus

Thanks. (b) (4), (b) (5)

Talk more tomorrow. Uwe

---

**From:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Sent:** Sunday, February 9, 2020 8:45 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE (b) (4) screening for Coronavirus

Hi Uwe,
I'd like to put Ricky on it. Will follow up on Monday. (b) (4), (b) (5)

Kris

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 08, 2020 3:07 PM
**To:** Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Fwd: (b) (4) screening for Coronavirus

Kris, who from the (b) (5)
(b) (4), (b) (5). Had similar cases for Zika and need to revisit them.
Looks to me it could be a (b) (4), (b) (5).
Uwe

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Date:** February 8, 2020 at 2:10:54 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Krueger, Angela C <Angela.Krueger@fda.hhs.gov>
**Subject:** Re: (b) (4) screening for Coronavirus

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Jeff,
I think this would be in OHT7's DMD. Looping in Tim and Uwe to confirm.
Bill

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 8, 2020 at 12:35:19 PM EST
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** Fwd: (b) (4) screening for Coronavirus

Bill,

A small start up is looking to create (b) (4), (b) (5) (b) (4), (b) (5). (b) (5) Is there an appropriate person in OPEQ who can speak with them about FDA expectations, depending on what they specifically want to claim, including the merits of a Qsub? They may modify what they do based on the feedback.

I'm including Bakul and Suzanne for awareness.

Jeff

---

**From:** Ajintha Pathmanathan (b) (6)
**Date:** February 8, 2020 at 11:18:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** (b) (4) screening for Coronavirus

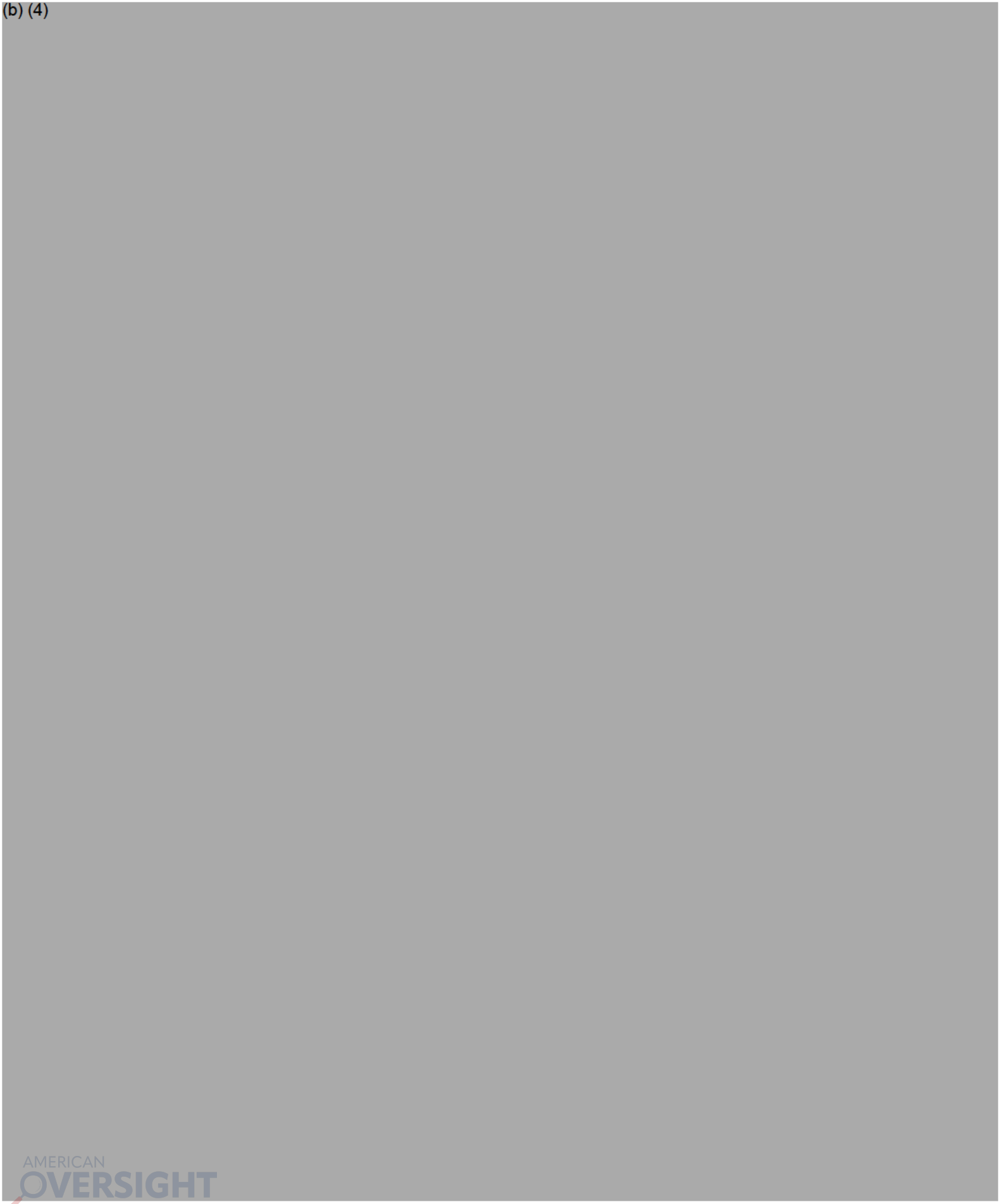
Hi Jeff,

Thank you for the interest. In terms of more information;

(b) (4)

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(b) (4)



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(b) (4)

Thanks

(b) (6)

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(b) (6)

[redacted]

**From:** Shuren, Jeff
**Sent:** Saturday, 8 February 2020 4:13 AM
**To:** Ajintha Pathmanathan
**Subject:** Re: (b) (4) screening for Coronavirus

Hi Ajintha,

It's good to hear from you. Thank you for reaching out to me.

I reviewed your slide deck and saw the video. It would help me to have a little more information. Can you please describe what the tool is intended to be used for (b) (4) who you intend the (b) (4) to be used by (b) (4) the specific inputs it would use, and the specific outputs ((b) (4) .

Jeff

---

**From:** Ajintha Pathmanathan (b) (6)
**Date:** February 7, 2020 at 10:15:52 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** (b) (4) screening for Coronavirus

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(b) (4), (b) (6)



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/10/2020 8:16:52 AM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Garcia, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ec44354adae4472a61ac05123d291d3-Maria.Garci]; Shawar, Ribhi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13f72f9309324e6cb65162140a348cca-RYS]; Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Hwang, Leroy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5da97657ec944cebf943616bd848105-Leroy.Hwang]; Lovell, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a4cfa4fc4094bbf8fac0e16bf710049-SXL]; Steven Gitterman (Steven.Gitterman@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4747486679444f24aa8d1086cca27390-SRG]
**CC**: Proctor, Tremyl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35056b97ee224343b77af6a0973d5d61-Tremyl.Proc]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2019 nCoV DMD EUA MCM Hours_Template.xlsx
**Attachments**: 2019 nCoV DMD EUA MCM Hours_Template.xlsx

All,

We have been asked to report hour worked on nCoV at the end of each week. Please use this excel template to report back to me and cc Tremyl. Please add additional staff members as needed.

Thanks, Uwe

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 22-Dec | 23-Dec | 24-Dec | 25-Dec | 26-Dec | 27-Dec | 28-Dec | Week Total 1 | 29-Dec | 30-Dec | 31-Dec | 1-Jan | 2-Jan | 3-Jan | 4-Jan | Week Total 2 | 5-Jan | 6-Jan | 7-Jan | 8-Jan | 9-Jan | 10-Jan | 11-Jan | Week Total 3 | 12-Jan | 13-Jan | 14-Jan | 15-Jan | 16-Jan | 17-Jan | 18-Jan | Week Total 4 | Period Total |
| **2019-nCoV HOURS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Scherf, Uwe** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Feldblyum, Tamara** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Roth, Kris** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Sapsford, Kim** | | | | | | | | 0 | | | | | | | | 0 | | | | | 3 | 3 | | 6 | | 0.5 | 2.5 | 2.5 | 3 | 4 | 4 | 16.5 | 22.5 |
| **Li, Li** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Garcia, Mayra** | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Total** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **6** | | | | | | | | **16.5** | **22.5** |

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## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 19-Jan | 20-Jan | 21-Jan | 22-Jan | 23-Jan | 24-Jan | 25-Jan | Week Total 1 | 26-Jan | 27-Jan | 28-Jan | 29-Jan | 30-Jan | 31-Jan | 1-Feb | Week Total 2 | 2-Feb | 3-Feb | 4-Feb | 5-Feb | 6-Feb | 7-Feb | 8-Feb | Week Total 3 | 9-Feb | 10-Feb | 11-Feb | 12-Feb | 13-Feb | 14-Feb | 15-Feb | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | H | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 16-Feb | 17-Feb | 18-Feb | 19-Feb | 20-Feb | 21-Feb | 22-Feb | Week Total 1 | 23-Feb | 24-Feb | 25-Feb | 26-Feb | 27-Feb | 28-Feb | 29-Feb | Week Total 2 | 1-Mar | 2-Mar | 3-Mar | 4-Mar | 5-Mar | 6-Mar | 7-Mar | Week Total 3 | 8-Mar | 9-Mar | 10-Mar | 11-Mar | 12-Mar | 13-Mar | 14-Mar | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 15-Mar | 16-Mar | 17-Mar | 18-Mar | 19-Mar | 20-Mar | 21-Mar | Week Total 1 | 22-Mar | 23-Mar | 24-Mar | 25-Mar | 26-Mar | 27-Mar | 28-Mar | Week Total 2 | 29-Mar | 30-Mar | 31-Mar | 1-Apr | 2-Apr | 3-Apr | 4-Apr | Week Total 3 | 5-Apr | 6-Apr | 7-Apr | 8-Apr | 9-Apr | 10-Apr | 11-Apr | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 12-Apr | 13-Apr | 14-Apr | 15-Apr | 16-Apr | 17-Apr | 18-Apr | Week Total 1 | 19-Apr | 20-Apr | 21-Apr | 22-Apr | 23-Apr | 24-Apr | 25-Apr | Week Total 2 | 26-Apr | 27-Apr | 28-Apr | 29-Apr | 30-Apr | 1-May | 2-May | Week Total 3 | 3-May | 4-May | 5-May | 6-May | 7-May | 8-May | 9-May | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 10-May | 11-May | 12-May | 13-May | 14-May | 15-May | 16-May | Week Total 1 | 17-May | 18-May | 19-May | 20-May | 21-May | 22-May | 23-May | Week Total 2 | 24-May | 25-May | 26-May | 27-May | 28-May | 29-May | 30-May | Week Total 3 | 31-May | 1-Jun | 2-Jun | 3-Jun | 4-Jun | 5-Jun | 6-Jun | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 7-Jun | 8-Jun | 9-Jun | 10-Jun | 11-Jun | 12-Jun | 13-Jun | Week Total 1 | 14-Jun | 15-Jun | 16-Jun | 17-Jun | 18-Jun | 19-Jun | 20-Jun | Week Total 2 | 21-Jun | 22-Jun | 23-Jun | 24-Jun | 25-Jun | 26-Jun | 27-Jun | Week Total 3 | 28-Jun | 29-Jun | 30-Jun | 1-Jul | 2-Jul | 3-Jul | 4-Jul | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 5-Jul | 6-Jul | 7-Jul | 8-Jul | 9-Jul | 10-Jul | 11-Jul | Week Total 1 | 12-Jul | 13-Jul | 14-Jul | 15-Jul | 16-Jul | 17-Jul | 18-Jul | Week Total 2 | 19-Jul | 20-Jul | 21-Jul | 22-Jul | 23-Jul | 24-Jul | 25-Jul | Week Total 3 | 26-Jul | 27-Jul | 28-Jul | 29-Jul | 30-Jul | 31-Jul | 1-Aug | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 2-Aug | 3-Aug | 4-Aug | 5-Aug | 6-Aug | 7-Aug | 8-Aug | Week Total 1 | 9-Aug | 10-Aug | 11-Aug | 12-Aug | 13-Aug | 14-Aug | 15-Aug | Week Total 2 | 16-Aug | 17-Aug | 18-Aug | 19-Aug | 20-Aug | 21-Aug | 22-Aug | Week Total 3 | 23-Aug | 24-Aug | 25-Aug | 26-Aug | 27-Aug | 28-Aug | 29-Aug | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 30-Aug | 31-Aug | 1-Sep | 2-Sep | 3-Sep | 4-Sep | 5-Sep | Week Total 1 | 6-Sep | 7-Sep | 8-Sep | 9-Sep | 10-Sep | 11-Sep | 12-Sep | Week Total 2 | 13-Sep | 14-Sep | 15-Sep | 16-Sep | 17-Sep | 18-Sep | 19-Sep | Week Total 3 | 20-Sep | 21-Sep | 22-Sep | 23-Sep | 24-Sep | 25-Sep | 26-Sep | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 27-Sep | 28-Sep | 29-Sep | 30-Sep | 1-Oct | 2-Oct | 3-Oct | Week Total 1 | 4-Oct | 5-Oct | 6-Oct | 7-Oct | 8-Oct | 9-Oct | 10-Oct | Week Total 2 | 11-Oct | 12-Oct | 13-Oct | 14-Oct | 15-Oct | 16-Oct | 17-Oct | Week Total 3 | 18-Oct | 19-Oct | 20-Oct | 21-Oct | 22-Oct | 23-Oct | 24-Oct | Week Total 4 | Period Total |
| **2019-nCoV HOURS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| **Total** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 25-Oct | 26-Oct | 27-Oct | 28-Oct | 29-Oct | 30-Oct | 28-Dec | Week Total 1 | 29-Oct2 | 30-Oct2 | 31-Oct | 1-Nov | 2-Nov | 3-Nov | 4-Nov | Week Total 2 | 5-Nov | 6-Nov | 7-Nov | 8-Nov | 9-Nov | 10-Nov | 11-Nov | Week Total 3 | 12-Nov | 13-Nov | 14-Nov | 15-Nov | 16-Nov | 17-Nov | 18-Nov | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

## *2019-nCoV Hours*

| | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | Sun | Mon | Tue | We | Thu | Fri | Sa | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name | 22-Nov | 23-Nov | 24-Nov | 25-Nov | 26-Nov | 27-Nov | 28-Nov | Week Total 1 | 29-Nov | 30-Nov | 1-Dec | 2-Dec | 3-Dec | 4-Dec | 5-Dec | Week Total 2 | 6-Dec | 7-Dec | 8-Dec | 9-Dec | 10-Dec | 11-Dec | 12-Dec | Week Total 3 | 13-Dec | 14-Dec | 15-Dec | 16-Dec | 17-Dec | 18-Dec | 19-Dec | Week Total 4 | Period Total |
| 2019-nCoV HOURS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Scherf, Uwe | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Feldblyum, Tamara | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Roth, Kris | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Sapsford, Kim | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Li, Li | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Garcia, Mayra | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | | | | | | | | 0 | 0 |
| Total | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | | | | | | | | **0** | **0** |

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/10/2020 8:06:18 PM
**To:** Brenner, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5916ba05b26e4fd0a602fc0049eb382b-Sara.Brenne]; Ochs, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78dd64e6b3ff4c9894037d63ede4edc8-RAO]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** 2019-nCoV highlights

Sara,

Attached some activities around the 2019-nCoV. Sorry for the late response. Uwe

- CDRH approved the Emergency Use Authorization (EUA) for CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel on 2/4/2020. https://www.fda.gov/news-events/press-announcements/fda-takes-significant-step-coronavirus-response-efforts-issues-emergency-use-authorization-first

- CDC is distributing the kits to ~100 public health and DoD labs. Training and verification of the test under way. The test is also available internationally under the IRR (International Reagent Resource) program. This includes 191 qualified international laboratories, such as the World Health Organization (WHO) Global Influenza Surveillance Response System (GISRS) laboratories.

- A total of 45 IVD Developers have requested and received EUA review template - DMD provides interactive feedback even before pre-EUA submission.

- DMD received the first two pre-EUA submissions: one from BioFire Defense for their BioFire 2019-nCov Test, and the 2nd from Inbios Inc. for their Smart *Detect*™ 2019-nCOV rRT-PCR kit. The submissions are lacking performance data, but DMD's review team started review and will provide responses interactively.

- CDC's isolate from infected patient in Washington available at BEI (Biodefense and Emerging Infections Research Resources Repository) (NR-52281). Live virus isolate requires BSL-3 facility. Generating inactivated virus will take 2-3 months, so alternative options are explored with NIH and BARDA.

- Dr. Brittany Goldberg, Senior Medical Officer in DMD (b) (5)

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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AMERICA'S OVERSIGHT

**From:** Brenner, Sara <Sara.Brenner@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 2:43 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ochs, Robert <Robert.Ochs@fda.hhs.gov>
**Subject:** RE: Two in a row

No worries and thanks Uwe. Can be super brief, just a couple high level sentences would be fine.

Thanks!

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 10, 2020 at 2:04:07 PM EST
**To:** Brenner, Sara <Sara.Brenner@fda.hhs.gov>, Ochs, Robert <Robert.Ochs@fda.hhs.gov>
**Subject:** RE: Two in a row

Sara,

I will send you some items later today, might be early evening. Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Brenner, Sara <Sara.Brenner@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 1:32 PM
**To:** Ochs, Robert <Robert.Ochs@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Two in a row

Thanks so much, Robert. I'm cc'ing Uwe, as I believe the most urgent topic OIR is dealing with at the moment is Coronavirus. Uwe, do you have anything OIR should highlight at the OPEQ Senior Staff meeting tomorrow?

---

**From:** Ochs, Robert <Robert.Ochs@fda.hhs.gov>
**Date:** February 10, 2020 at 8:36:43 AM EST
**To:** Brenner, Sara <Sara.Brenner@fda.hhs.gov>
**Subject:** RE: Two in a row

No problem. Do you have any announcements for around the table? I don't have anything for the RadHealth side at the moment.
-Robert

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**Robert Ochs, PhD**
*Deputy Director for Radiological Health*
**FDA | CDRH | OPEQ | OHT7: Office of In Vitro Diagnostics and Radiological Health**
Tel: 301-796-6661
robert.ochs@fda.hhs.gov

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---

**From:** Brenner, Sara <Sara.Brenner@fda.hhs.gov>
**Sent:** Sunday, February 09, 2020 3:27 PM
**To:** Ochs, Robert <Robert.Ochs@fda.hhs.gov>
**Subject:** Two in a row

Hi Robert, I'm going to be 15-30 min late for the OPEQ Senior Staff meeting this week Tues 2/11, due to an overlapping meeting. I believe Don will still be out; wondering if you're able to make it and take notes until I get there again? Sorry!

Sara

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 10:19:54 PM
**To**: STRÖHER, Ute [stroheru@who.int]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Vielen Dank fuer Deinen Besuch

Dear Ute,

Thank you so much for your visit today. We had a great conversation.

Sorry for being available only for such a short period of time.

Attached the reason. Please let stay in touch.

Herzlichst, Uwe

https://www.fda.gov/news-events/press-announcements/fda-takes-significant-step-coronavirus-response-efforts-issues-emergency-use-authorization-first

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 4:57:02 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; McFarland, Scott [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=218c5dc8be76494e96a57dedad1f5509-SMF]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Hinton, Kesha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8fa467f60d1f4f12969fc6f3d1b5e10c-Kesha.Hinto]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Russ, Wanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2900752acf81445785fb0f5b23c728c8-WRuss]; Spillar, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f168f1576aff405297694b4435f2bde8-Patricia.Sp]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
**Subject**: RE: FYI - Signed copy: CDC 2019-nCoV EUA

Kim, thank you for getting the up and live so quickly. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*
OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 4:43 PM
**To:** Finnen, April <April.Finnen@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
**Subject:** RE: FYI - Signed copy: CDC 2019-nCoV EUA

It's live

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
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Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

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**From:** Sapsford, Kim E
**Sent:** Tuesday, February 04, 2020 4:41 PM
**To:** Finnen, April <April.Finnen@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda

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<Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
**Subject:** RE: FYI - Signed copy: CDC 2019-nCoV EUA

Dear all,

I need to leave – but the CDRH website should go live in the next 30 minutes:

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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---

**From:** Finnen, April <April.Finnen@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 3:45 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
**Subject:** RE: FYI - Signed copy: CDC 2019-nCoV EUA

Would suggest not issuing press release until we are able to update the EUA web pages that are referenced. CDRH posts first, then we'll link to it from the OCET EUA page and nCoV page.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 3:38 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

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**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
**Subject:** RE: FYI - Signed copy: CDC 2019-nCoV EUA

We will let you know as soon as we hear back from CDC.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
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Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 3:31 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
**Subject:** RE: FYI - Signed copy: CDC 2019-nCoV EUA

Hi – Kim would probably like to alert CDC first.

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Thanks,

Jennifer

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 3:30 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
**Subject:** RE: FYI - Signed copy: CDC 2019-nCoV EUA

Hi Jennifer, do we need to wait on anything before issuing the press release or can that be issued ASAP from a OCET/procedural perspective? Thank you !

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 3:28 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Subject:** FYI - Signed copy: CDC 2019-nCoV EUA

Hello,

Please find attached the pdf and Word documents of the EUA package for CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel

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- Letter (Signed pdf and Word)

- Fact Sheet for Healthcare Providers (Word and pdf)
- Fact Sheet for Patients (Word and pdf)
- Instructions for Use (Word only)
- PIS and VR (pdf only)

A hard copy is being sent to CDC via UPS today.

Thanks,

Jennifer

**Jennifer Ross, PhD, JD**
*Senior Regulatory Counsel*

**Office of Counterterrorism and Emerging Threats**
**Office of the Chief Scientist / U.S. Food and Drug Administration**
Tel: 240-402-8155
Jennifer.Ross@fda.hhs.gov




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(b) (5)



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]

**Sent**: 2/4/2020 4:48:58 PM

**To**: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; CDRH-OIR-IVD-DMD [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=27c86ad6f7c54139b01f0af234168ac7-CDRH-OIR-IV]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]

**CC**: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]

**Subject**: RE: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

AMERICAN OVERSIGHT

Anna, thank you very much for your kind words.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**Sent:** Tuesday, February 4, 2020 4:31 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; CDRH-OIR-IVD-DMD <CDRH-OIR-IVD-DMD@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
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**Subject:** RE: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

Your dedication to protecting and promoting public health is inspiring!

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**Date:** February 4, 2020 at 4:29:44 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, CDRH-OIR-IVD-DMD <CDRH-OIR-IVD-DMD@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>, Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>, Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Stark, Angela <Angela.Stark@fda.hhs.gov>
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**Subject:** RE: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

Kudos to the team…CDRH especially!!!

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**Sent:** Tuesday, February 4, 2020 4:27 PM
**To:** CDRH-OIR-IVD-DMD <CDRH-OIR-IVD-DMD@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
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**Subject:** CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued
**Importance:** High

**Congratulations!**

FDA just issued the Emergency Use Authorization for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.
Thanks to the tireless and extraordinary work of the DMD review team over the last weeks:

- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*
- **Li Li**, Lead Reviewer, Viral Respiratory & HPV Branch,
- **Brittany Goldberg**, MD, Senior Medical Officer, and
- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, **Megan McSeveney** & **Angela Stark** (press office), and our senior leadership.

These have been incredible 2 weeks and words cannot describe how grateful I am for your phenomenal dedication and extraordinary hard work that made this happen. You are an exceptional team to work with unprecedented commitment to public health!

Thanks you! Thank you! Thank you!

My very kind regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**Sent**: 2/4/2020 4:47:36 PM
**To**: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; CDRH-OIR-IVD-DMD [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=27c86ad6f7c54139b01f0af234168ac7-CDRH-OIR-IV]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]
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**Subject**: RE: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

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Denise,

Thanks you so much!

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**Sent:** Tuesday, February 4, 2020 4:41 PM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; CDRH-OIR-IVD-DMD <CDRH-OIR-IVD-DMD@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
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I (we) appreciate all of you for your tireless efforts in working collaboratively to protect and promote public health, both domestically and abroad. We can't thank you enough!

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<Lyndsay.Meyer@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 4:27 PM
**To:** CDRH-OIR-IVD-DMD <CDRH-OIR-IVD-DMD@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued
**Importance:** High

**Congratulations!**

FDA just issued the Emergency Use Authorization for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Thanks to the tireless and extraordinary work of the DMD review team over the last weeks:

- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*
- **Li Li**, Lead Reviewer, Viral Respiratory & HPV Branch,
- **Brittany Goldberg**, MD, Senior Medical Officer, and

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- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, **Megan McSeveney** & **Angela Stark** (press office), and our senior leadership.

These have been incredible 2 weeks and words cannot describe how grateful I am for your phenomenal dedication and extraordinary hard work that made this happen. You are an exceptional team to work with unprecedented commitment to public health!

Thanks you! Thank you! Thank you!

My very kind regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/12/2020 9:45:49 AM
**To:** McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
**Subject:** RE: Flagging - tight turnaround - CMSCLEARANCE_0137: CMS Coronavirus News Alert

Megan,

I cannot not make this, will be on a call now until 11. Sorry, Uwe

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 9:37 AM
**To:** 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
**Subject:** Flagging - tight turnaround - CMSCLEARANCE_0137: CMS Coronavirus News Alert

Hi all – apologies for the tight turnaround. Does the IMG have any comments on the attached? While the deadline has passed – I will ask HHS to give us until 10:15 am. Thank you! Megan

**EXPEDITED REVIEW—Comments due by 9:30AM Wednesday, February 12, 2020 (apologies for the tight turnaround)**

**All: For your review and input. Concurrent HHS/CMS review.**

**Title:** Coronavirus News Alert

**Agency/Office:** CMS

**Subject/Description:**
CMS is alerting providers that a HCPCS code for the 2019 Novel Coronavirus Real Time RT-PCR Diagnostic test panel has been created.

**COMMs Materials for Rollout:**

- News Alert

**Deadline for comments: 9:30AM Wednesday, February 12, 2020**

**Release date: Wednesday, February 12.**

Simone Myrie, MPS
Public Affairs Specialist
Office of the Assistant Secretary for Public Affairs
US Department of Health & Human Services
(b) (6) o)
c)

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**Sent:** 2/12/2020 10:23:31 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: Follow up from briefing: any update on EUA test?

Sorry, I had something already prepared for Jeff so I used it. Hope capture the main issues. Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 10:22 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Follow up from briefing: any update on EUA test?

Thanks Uwe – you beat me to it ☺

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 10:20 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Follow up from briefing: any update on EUA test?

Michael,

(b) (5)

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Uwe

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 8:14 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Fwd: Follow up from briefing: any update on EUA test?
**Importance:** High

Hi - can u assist? Thx

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
**Date:** February 12, 2020 at 7:50:19 PM EST
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Follow up from briefing: any update on EUA test?
**Importance:** High

**What can we say about FDA's part in the reported problems with the CDC test—are we confident we did everything right? How do we explain the problems and is FDA doing anything to help resolve?**

**Please send those answers to be asap tonight.**

**Public health labs report problems with coronavirus test**

By David Lim

02/12/2020 04:21 PM EST

At least 25 public health laboratories around the country say they're unable to test for cases of the coronavirus originating in Wuhan because a test kit distributed by the CDC is delivering inconclusive results.

Some labs that began doing quality checks on the test last weekend found one of three reagents in the kit was ineffective, according to Kelly Wroblewski, director of infectious diseases at the Association of Public Health Laboratories. More labs started reporting similar issues on Monday and Tuesday. None of the diagnostic kits were used to test actual clinical specimens.

The kits allow states and localities to test patients, eliminating the need to confirm cases by sending samples to the CDC's headquarters in Atlanta. CDC is developing replacement tests it can send to the labs.

"Some of the states identified some inconclusive laboratory results, but we're working closely with them to correct the issues," Nancy Messonnier, director of the CDC's Center for the National Center for Immunization and Respiratory Diseases, said Wednesday.

There are 13 confirmed cases of coronavirus in the United States with 60 other people under investigation whose samples are waiting to be tested, according to CDC. More than 44,500 cases and 1,100 deaths are confirmed in China, according to the World Health Organization.

CDC initially made 200 of the diagnostic kits available to U.S. labs last week after receiving emergency use authorization from the FDA on Feb. 4.

"Of course I hoped that this week every state would be up and running," Messonnier said. "How long will that take? I can't tell you that for sure."

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A "very small number of labs" in the U.S. have successfully verified the diagnostic test, according to Wroblewski. But states will continue to send all clinical specimens to CDC headquarters in Atlanta as a "backstopping" measure, according to Messonnier.

"Although this is sort of an unfortunate development and nobody wanted to see this happen, this is why there are quality control steps in place," Wroblewski said.

*To view online*:
https://subscriber.politicopro.com/health-care/article/2020/02/public-health-labs-report-problems-with-coronavirus-test-1879161

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**Sent:** 2/3/2020 2:30:55 PM
**To:** Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
**Subject:** RE: update pre-eua diagnostic developers

26

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 1:05 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** update pre-eua diagnostic developers

Hello,

Could someone please update the current EUA number ?

Hi To assist diagnostic developers, we have developed an Emergency Use Authorization review template for tests to detect the novel coronavirus, which outlines the data requirements for a Pre-EUA package, which is available to developers upon request…and have already sent it to xxxx diagnostic developers.

Thank you,
Prakash

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/11/2020 1:39:52 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; 2019-nCoV FDA IMG [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1303ad17cce4c95b45c63ac5c0c31df-2019-nCoV F]; CDER-ER-OPS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4aa67416e2b4b80b0ea03681b334525-CDER-ER-OPS]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
**CC**: Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Urgent - coronavirus review requested by 1:45

No additional comments.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 1:25 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
**Subject:** RE: Urgent - coronavirus review requested by 1:45

Suggested edits attached

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Tuesday, February 11, 2020 1:09 PM
**To:** 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
**Subject:** Urgent - coronavirus review requested by 1:45

Hi all – requesting urgent concurrent IMG review before sending this document to Anna Abram and then back to HHS. You only need to review yellow and green highlighted information. Green information is completely new and primarily on shortages. Generally, info has been pulled from other documents you all have helped cleared today. Apologies on the short turnaround. Thank you!

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/3/2020 2:30:54 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** FW: Rath, Prakash (FDA) sent you a message in Skype for Business

Kim, what is the latest number? (b) (5)

---

**From:** Rath, Prakash (FDA) <prakash.rath@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 1:03 PM
**To:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Rath, Prakash (FDA) sent you a message in Skype for Business

**Rath, Prakash (FDA) 1:00 PM:**

Hi Uwe, would you be able to confirm the updated pre-eua number for today? To assist diagnostic developers, we have developed an Emergency Use Authorization review template for tests to detect the novel coronavirus, which outlines the data requirements for a Pre-EUA package, which is available to developers upon request…and have already sent it to xxxx diagnostic developers.

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**Sent:** 2/12/2020 10:12:21 PM
**To:** Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Follow up from briefing: any update on EUA test?

Michael,

Here information on the CDC issues:

- CDC initially reported on Monday about issue with test verification in a number of labs that received the CDC test: this has now be **reported in press this afternoon.** Since the assay verification failed, the labs did not use the test for any clinical sample testing
- Initially only 10, but now 26 U.S. Public health labs out of ~100 that received the CDC test cannot verify assay due to positive results of the N-3 component with negative controls.
- Upon internal investigation CDC concluded that issues is due to manufacturing problem.
- CDC has re-manufactured the components for the N3 portion of the assay.
- New lot passed newly established QC testing. New product will be lyophilized and send out shortly.
- Further investigation of root cause is under way. DMD is receiving updates when they become available.

I hope this helps.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 8:14 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Fwd: Follow up from briefing: any update on EUA test?
**Importance:** High

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Hi - can u assist? Thx

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
**Date:** February 12, 2020 at 7:50:19 PM EST
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Follow up from briefing: any update on EUA test?
**Importance:** High

**What can we say about FDA's part in the reported problems with the CDC test—are we confident we did everything right? How do we explain the problems and is FDA doing anything to help resolve?**

**Please send those answers to be asap tonight.**

**Public health labs report problems with coronavirus test**

By David Lim

02/12/2020 04:21 PM EST

At least 25 public health laboratories around the country say they're unable to test for cases of the coronavirus originating in Wuhan because a test kit distributed by the CDC is delivering inconclusive results.

Some labs that began doing quality checks on the test last weekend found one of three reagents in the kit was ineffective, according to Kelly Wroblewski, director of infectious diseases at the Association of Public Health Laboratories. More labs started reporting similar issues on Monday and Tuesday. None of the diagnostic kits were used to test actual clinical specimens.

The kits allow states and localities to test patients, eliminating the need to confirm cases by sending samples to the CDC's headquarters in Atlanta. CDC is developing replacement tests it can send to the labs.

"Some of the states identified some inconclusive laboratory results, but we're working closely with them to correct the issues," Nancy Messonnier, director of the CDC's Center for the National Center for Immunization and Respiratory Diseases, said Wednesday.

There are 13 confirmed cases of coronavirus in the United States with 60 other people under investigation whose samples are waiting to be tested, according to CDC. More than 44,500 cases and 1,100 deaths are confirmed in China, according to the World Health Organization.

CDC initially made 200 of the diagnostic kits available to U.S. labs last week after receiving emergency use authorization from the FDA on Feb. 4.

"Of course I hoped that this week every state would be up and running," Messonnier said. "How long will that take? I can't tell you that for sure."

A "very small number of labs" in the U.S. have successfully verified the diagnostic test, according to Wroblewski. But states will continue to send all clinical specimens to CDC headquarters in Atlanta as a "backstopping" measure, according to Messonnier.

"Although this is sort of an unfortunate development and nobody wanted to see this happen, this is why there are quality control steps in place," Wroblewski said.

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/10/2020 3:34:30 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Clarifying request for 2019 nCoV Fraud Products Task Force

Yes, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 2:54 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Clarifying request for 2019 nCoV Fraud Products Task Force

Should we include Leroy and Keith in this task force if it gets stood up?

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Glover, Mark <Mark.Glover@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 12:42 PM
**To:** Humbert, Jason <Jason.Humbert@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
**Subject:** RE: Clarifying request for 2019 nCoV Fraud Products Task Force

AMERICAN OVERSIGHT

In response to the request for personnel CVM submits the following personnel for the Fraud Products task force.
Vic Boddie- Vic.Boddie@fda.hhs.gov
Jenny Gabb - Jennifer.Gabb@fda.hhs.gov
Cheryl Souders - Cheryl.Souders@fda.hhs.gov
Dr. Scott Melton - Scott.Melton@fda.hhs.gov

Thanks

*CDR Mark R. Glover RN BSN* USPHS
Veterinary Lead/OPS
2019 Novel Coronavirus (nCoV) IMG
**Emergency Response Coordinator**
Complaint, Emergency, Recall Team(CERT)
Center for Veterinary Medicine/Office of Surveillance and Compliance/Division of Compliance
FDA, Food and Drug Protection Division
1070 Mail Service Center
Raleigh NC. 27699-1070
Cell (913) -387-9581
Mark.Glover@fda.hhs.gov
This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at Mark.Glover@fda.hhs.gov.

GO MIZZOU *TIGERS*
*Always know you are not always right. Other people's opinions are meaningful and useful – Steve Mangan*
*Failure happens. It's what you do in response to it that matters – Ken Bockwinkle*

---

**From:** Humbert, Jason <Jason.Humbert@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 9:43 AM
**To:** 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
**Subject:** Clarifying request for 2019 nCoV Fraud Products Task Force

Good morning,

Over the weekend I sent a request to colleagues I typically work with on health fraud matters to help organize a nCoV task force to gather information for sharing/reporting to the IMG.

This request should have gone to the IMG leads and out to the various centers. My apologies for any trouble or confusion. Since fraud products cut across commodities and involve a variety of offices within the agency, the goal was to organize how information was reported to IMG leadership.

As we have done in the past, the fraud products task force would include representatives from various Centers/programs – CBER, CFSAN, CDER, CDRH, CVM, OCI, OCC and ORA.

I want to ensure the IMG is aware of the request and happy to clarify our intention in developing this task force.

AMERICAN OVERSIGHT

Again, sorry for any trouble/confusion.

Jason

**Jason Humbert**
*Captain, U.S. Public Health Service*

Director, Health Fraud Branch/ORA
IMG Fraudulent Products Section Lead
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Office: 301-796-4670
Mobile: 240-731-8952
jason.humbert@fda.hhs.gov






AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/3/2020 4:26:31 PM
**To:** McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
**Subject:** Re: Pinging OCC: Review requested - Tweets- coronavirus - FDA- MDIC meeting today - Advancing Emergency Use Diagnostic Products Toward Full Marketing Status

Do you need anything from me

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Date:** February 3, 2020 at 4:25:24 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>, Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, OC OCC Device Team Requests <OCOCCDeviceTeamRequests@fda.hhs.gov>
**Subject:** Pinging OCC: Review requested - Tweets- coronavirus - FDA- MDIC meeting today - Advancing Emergency Use Diagnostic Products Toward Full Marketing Status

Hi – OCC are we good with these? Thank you!

1. Today, FDA cohosted a public workshop with @MDIConline on Advancing Emergency Use Diagnostic Products Toward Full Marketing Status. Planned well before the #coronavirus outbreak, it's especially timely now. http://bit.ly/36WxpC2 **[PHOTO]**

2. The workshop explored key considerations for using real world evidence to transition EUA authorized devices to full marketing status. We're continuing our collaborative work across the public and private sector to prepare, mitigate and respond to this outbreak.

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell(b) (6)
Megan.McSeveney@fda.hhs.gov




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**From:** McSeveney, Megan
**Sent:** Monday, February 03, 2020 3:25 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; OC OCC Device Team Requests <OCOCCDeviceTeamRequests@fda.hhs.gov>
**Subject:** RE: Review requested - Tweets- coronavirus - FDA- MDIC meeting today - Advancing Emergency Use Diagnostic Products Toward Full Marketing Status

Will make that edit – thank you! I (b) (5)

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cel(b) (6)
Megan.McSeveney@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 03, 2020 3:23 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; OC OCC Device Team Requests <OCOCCDeviceTeamRequests@fda.hhs.gov>
**Subject:** RE: Review requested - Tweets- coronavirus - FDA- MDIC meeting today - Advancing Emergency Use Diagnostic Products Toward Full Marketing Status

Megan, please see comments below. (b) (5)

AMERICAN OVERSIGHT

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 3:09 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; OC OCC Device Team Requests <OCOCCDeviceTeamRequests@fda.hhs.gov>
**Subject:** Review requested - Tweets- coronavirus - FDA- MDIC meeting today - Advancing Emergency Use Diagnostic Products Toward Full Marketing Status

Hi all - requesting a quick concurrent review of these draft tweets for FDA's main account on today's FDA-MDIC workshop and tying it a bit to our work on coronavirus. Please review by 4:30pm today if possible. CCing a large group for awareness. Thank you all!

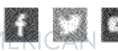
1. Today, FDA cohosted a public workshop with @MDIConline on Advancing Emergency Use Diagnostic Products Toward Full Marketing Status. Planned well before the #coronavirus outbreak, it's especially timely now. http://bit.ly/36WxpC2 **[PHOTO]**

2. The workshop explored key considerations for using real world evidence to transition EUA authorized devices to full marketing status. We're continuing our collaborative work across the public and private sector to prepare, mitigate and respond to this outbreak.

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cel(b) (6)
Megan.McSeveney@fda.hhs.gov



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/3/2020 9:55:43 PM
**To**: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject**: RE: CDC wants to distribute coronavirus diagnostic test by end of week

Ana,

Are continuously in contact with CDC, they just informed us that they might send the package tonight. My team is on standby to start the final review.

Uwe

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 9:53 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

Thanks, Uwe. Any further update since you sent your last update? Thanks so much.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 3:56 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

DMD has not received the package from CDC. The review team is in stand by. We expect we will 3-4 hours for our final review. Than it goes to OCET/OCC.
Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 3, 2020 at 3:46:56 PM EST
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

Maybe they are referring to plans for distribution. We are still awaiting the outstanding analytical validity data/EUA package. I called Uwe to confirm before I sent my reply email to you.

Adding Uwe for any additional clarity.

AMERICAN OVERSIGHT

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 3, 2020 at 3:42:03 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

So this line is not accurate "our plans were submitted to them today,"?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 2:47 PM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

We haven't received any data today. We're still waiting for the EUA package.

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 3, 2020 at 2:24:25 PM EST
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

When I last asked Michael about this a few hours ago I understood that we had received more data, but not all of it. Jeff?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 2:11 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** FW: CDC wants to distribute coronavirus diagnostic test by end of week

Do we have what we need from CDC? Or are we still waiting on data? What is our turnaround time?

---

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>
**Sent:** Monday, February 3, 2020 2:09 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** CDC wants to distribute coronavirus diagnostic test by end of week

**CDC wants to distribute coronavirus diagnostic test by end of week**

By David Lim, Sarah Owermohle

02/03/2020 02:08 PM EST

The CDC wants the FDA to quickly grant an emergency authorization to use its Wuhan coronavirus diagnostic test so it can distribute it to laboratories across the country later this week.

"The process is extremely expedited and our colleagues at FDA have been working with us closely — our plans were submitted to them today, and I expect that means we should be able to start sending them out by the end of the week barring complications," Nancy Messonnier, director of the National Center for Immunization and Respiratory Diseases, said on a press call.

For the FDA to grant emergency authorization for the test, HHS Secretary Alex Azar first must declare that circumstances exist that justify its use — a step that appears imminent after Azar declared the virus a public

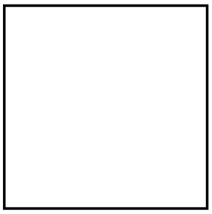
AMERICAN OVERSIGHT

health emergency late last week. CDC has already sent the test to the International Reagent Resource so states can begin ordering it, according to Messonnier.

*To view online*:
https://subscriber.politicopro.com/health-care/whiteboard/2020/02/cdc-wants-to-distribute-coronavirus-diagnostic-test-by-end-of-week-3976275

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Arlington, VA 22209
USA

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/6/2020 8:31:44 AM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: 2019-nCoV Launch

Yes, please add me as a back up. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, February 6, 2020 7:14 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: 2019-nCoV Launch

Dear Uwe,

FYI – Michael Mair has put me as the point of contact for this – for diagnostics. They have set up twice dialing meetings – one at 9 am and one at 4 pm. Are you okay if I request you are added as back-up – or Tamara? I should be fine – except Monday mornings.

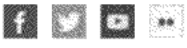
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Wednesday, February 05, 2020 1:41 PM
**To:** Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hall, Valerie <Valerie.Hall@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Lucas, Tanisha <Tanisha.Lucas@fda.hhs.gov>; Gutierrez, Sacha <Sacha.Gutierrez@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Harrison, Tina <Tina.Harrison@fda.hhs.gov>; Arsenault, Sam <Samuel.Arsenault@fda.hhs.gov>; Measer, Gregory <Gregory.Measer@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
**Cc:** Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Russo, Mark <Mark.Russo@fda.hhs.gov>
**Subject:** 2019-nCoV Launch

Dear 2019-nCoV IMG members,

Hi. First off, many thanks for all of the awesome work you have been doing to respond to the 2019-nCoV outbreak…and all of the work you will continue to do. And thank you for agreeing to be a team member on the 2019-nCoV IMG.

I would have liked to have a held a kick off meeting in person, but everyone is so busy that I thought a virtual kick off would be better for folks.

The overall over all objectives of the 2019-nCoV IMG are to:

- Facilitate internal coordination and support overall Agency activities
- Facilitate external coordination with US government partners and other stakeholders
- Promote situational awareness across the Agency
- Identify policy and resource issues for consideration by the AEG
- Facilitate timely communications

I have attached the current org chart , and we'll be updating this as members rotate in or out of the IMG, or the structure itself changes as we move forward.

We are not requesting that IMG members work from the FDA EOC, due to multiple priorities and varied locations you are free to work 'virtually'. That said, the EOC is available should co-locating there be useful for facilitating activities. Each section will determine how best to manage their respective work flow…section chiefs will work with their respective teams to optimize and manage process as works best. Our intent is to maximize efficiency.

I will add you all to the request for information for the daily FDA SITREP. So keep an eye out for that.

In addition, the AEG will be having a daily call (at least for the next few weeks) at 5:15 – 5:30 PM. Given that, I will be scheduling a daily call at 4:00-4:30 PM with IMG staff to touch base in advance of the AEG call. I will be looking to the Section Chiefs primarily to report out, but am including everyone on the invite to listen in and/or provide information as necessary. I realize how busy you all are, but please join when you can.

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Please do not hesitate to contact me and Tom Mignone (Deputy AIC) if there is anything that you need from us, or with ideas or concerns you have as we get up to full speed.

Thx again. - michael

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]

**Sent**: 2/3/2020 3:23:27 PM

**To**: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Gibney, Jaycie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=390bd4f246ee4a97ada93d146d6d7276-Jaycie.Gibn]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]

**CC**: Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; OC OCC Device Team Requests [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8a2ec9bd04349c39553083f88d2587d-OCOCCDevice]

**Subject**: RE: Review requested - Tweets- coronavirus - FDA- MDIC meeting today - Advancing Emergency Use Diagnostic Products Toward Full Marketing Status

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Megan, please see comments below. (b) (5)

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
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**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 3:09 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; OC OCC Device Team Requests <OCOCCDeviceTeamRequests@fda.hhs.gov>
**Subject:** Review requested - Tweets- coronavirus - FDA- MDIC meeting today - Advancing Emergency Use Diagnostic Products Toward Full Marketing Status

Hi all - requesting a quick concurrent review of these draft tweets for FDA's main account on today's FDA-MDIC workshop and tying it a bit to our work on coronavirus. Please review by 4:30pm today if possible. CCing a large group for awareness. Thank you all!

1. Today, FDA cohosted a public workshop with @MDIConline on Advancing Emergency Use Diagnostic Products Toward Full Marketing Status. Planned well before the #coronavirus outbreak, it's especially timely now. http://bit.ly/36WxpC2 **[PHOTO]**

2. The workshop explored key considerations for using real world evidence to transition EUA authorized device to full marketing status. We're continuing our collaborative work across the public and private sector to prepare, mitigate and respond to this outbreak.

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell (b) (6)
Megan.McSeveney@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 3:53:22 PM
**To**: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
**CC**: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; McFarland, Scott [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=218c5dc8be76494e96a57dedad1f5509-SMF]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Hinton, Kesha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8fa467f60d1f4f12969fc6f3d1b5e10c-Kesha.Hinto]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Russ, Wanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2900752acf81445785fb0f5b23c728c8-WRuss]; Spillar, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f168f1576aff405297694b4435f2bde8-Patricia.Sp]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
**Subject**: RE: FYI - Signed copy: CDC 2019-nCoV EUA

To keep everybody in the loop:

The CDC EUA has been authorized and CDC has confirmed receipt of the authorization letter. Thanks you all for this incredible work!!

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

AMERICAN OVERSIGHT

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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uwe.scherf@fda.hhs.gov

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**From:** Finnen, April <April.Finnen@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 3:45 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
**Subject:** RE: FYI - Signed copy: CDC 2019-nCoV EUA

Would suggest not issuing press release until we are able to update the EUA web pages that are referenced. CDRH posts first, then we'll link to it from the OCET EUA page and nCoV page.

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 3:38 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
**Subject:** RE: FYI - Signed copy: CDC 2019-nCoV EUA

We will let you know as soon as we hear back from CDC.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 3:31 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
**Subject:** RE: FYI - Signed copy: CDC 2019-nCoV EUA

Hi – Kim would probably like to alert CDC first.

Thanks,

Jennifer

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 3:30 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
**Subject:** RE: FYI - Signed copy: CDC 2019-nCoV EUA

Hi Jennifer, do we need to wait on anything before issuing the press release or can that be issued ASAP from a OCET/procedural perspective? Thank you !

AMERICAN OVERSIGHT

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






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**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 3:28 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Subject:** FYI - Signed copy: CDC 2019-nCoV EUA

Hello,

Please find attached the pdf and Word documents of the EUA package for CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel

- Letter (Signed pdf and Word)
- Fact Sheet for Healthcare Providers (Word and pdf)
- Fact Sheet for Patients (Word and pdf)
- Instructions for Use (Word only)
- PIS and VR (pdf only)

A hard copy is being sent to CDC via UPS today.

Thanks,

Jennifer

**Jennifer Ross, PhD, JD**
*Senior Regulatory Counsel*

**Office of Counterterrorism and Emerging Threats**
**Office of the Chief Scientist / U.S. Food and Drug Administration**
Tel: 240-402-8155
Jennifer.Ross@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/3/2020 11:05:17 PM
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

Anna, the package just came in, see my email to FDA leadership just a moment ago. Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 9:53 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

Thanks, Uwe. Any further update since you sent your last update? Thanks so much.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 3:56 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

DMD has not received the package from CDC. The review team is in stand by. We expect we will 3-4 hours for our final review. Than it goes to OCET/OCC.
Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 3, 2020 at 3:46:56 PM EST
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

Maybe they are referring to plans for distribution. We are still awaiting the outstanding analytical validity data/EUA package. I called Uwe to confirm before I sent my reply email to you.

Adding Uwe for any additional clarity.

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**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 3, 2020 at 3:42:03 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

So this line is not accurate "our plans were submitted to them today,"?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 2:47 PM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

We haven't received any data today. We're still waiting for the EUA package.

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 3, 2020 at 2:24:25 PM EST
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

When I last asked Michael about this a few hours ago I understood that we had received more data, but not all of it. Jeff?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 2:11 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** FW: CDC wants to distribute coronavirus diagnostic test by end of week

Do we have what we need from CDC? Or are we still waiting on data? What is our turnaround time?

---

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>
**Sent:** Monday, February 3, 2020 2:09 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** CDC wants to distribute coronavirus diagnostic test by end of week

**CDC wants to distribute coronavirus diagnostic test by end of week**

By David Lim, Sarah Owermohle

02/03/2020 02:08 PM EST

The CDC wants the FDA to quickly grant an emergency authorization to use its Wuhan coronavirus diagnostic test so it can distribute it to laboratories across the country later this week.

"The process is extremely expedited and our colleagues at FDA have been working with us closely — our plans were submitted to them today, and I expect that means we should be able to start sending them out by the end of the week barring complications," Nancy Messonnier, director of the National Center for Immunization and Respiratory Diseases, said on a press call.

For the FDA to grant emergency authorization for the test, HHS Secretary Alex Azar first must declare that circumstances exist that justify its use — a step that appears imminent after Azar declared the virus a public health emergency late last week. CDC has already sent the test to the International Reagent Resource so states

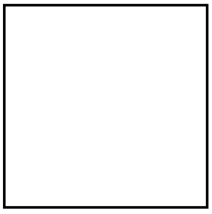
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can begin ordering it, according to Messonnier.

*To view online*:
https://subscriber.politicopro.com/health-care/whiteboard/2020/02/cdc-wants-to-distribute-coronavirus-diagnostic-test-by-end-of-week-3976275

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Arlington, VA 22209
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**Sent**: 2/2/2020 11:13:53 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
**Subject**: RE: NSC request nCoV MCM Task Force strategy

Agree,

Will need to address the molecular issue in the next round. Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 10:56 AM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: NSC request nCoV MCM Task Force strategy

Your edits look fine to me Michael, thank you

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov

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**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Sunday, February 02, 2020 9:33 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: NSC request nCoV MCM Task Force strategy

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Thx – I made some edits to the sentence where (b) (5) – but did not add anything related to the comment u made.

I also added a note (b) (5). If ok w/u?
<< File: CoV Diagnostics USG Interagency Strategy v1a_FDA.docx >>

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 5:05 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: NSC request nCoV MCM Task Force strategy

Michael,

Attached some comments from the diagnostic perspective. Kim had a good point on molecular, but we do not have time at the moment to write this up.

Thanks, Uwe << File: CoV Diagnostics USG Interagency Strategy v1a_DMD.docx >>

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 1:54 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>
**Subject:** FW: NSC request nCoV MCM Task Force strategy

Hi – and apologies for late notice on this as I am just getting to things that got buried yesterday. See note below regarding nCoV Strategy. There is a meeting on Monday from 1 – 2 PM. Let me know if you would like to join.

I addition to the doc below – there are individual documents for vaccines, therapeutics, and diagnostics that they are hoping to get comment on by noon tomorrow. Some of you may have already received directly…? Please let me know if have comments u want me to send back – and if u want invite to Monday's call. Thx

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<< File: CoV Diagnostics USG Interagency Strategy v1a.docx >> << File: CoV Therapeutics USG Interagency Strategy v1.docx >> << File: nCoV vaccine strategy v3.docx >>

---

**From:** Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>
**Sent:** Friday, January 31, 2020 8:42 AM
**To:** Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Kishimori, Jennifer M COL USARMY OSD OUSD P-R (USA) <jennifer.m.kishimori.mil@mail.mil>
**Cc:** Hassell, David (OS) <David.Hassell@hhs.gov>; anita.patel@cdc.gov; Embry, Alan C (NIH) <embrya@niaid.nih.gov>
**Subject:** NSC request nCoV MCM Task Force strategy

All,

The NSC has requested the nCoV MCM Task Force's strategy for MCM development for 2019-nCoV. We propose using the attached Strategy for Zika Vaccine Development that was used in 2016 as the template for the nCoV Strategy for MCM Development. If you are all in agreement on this approach, BARDA will initiate a draft today and send to all of you for review. In parallel, we will work with NIAID and DoD to update the figures and tables in the document. If you have information or updates to incorporate, please share them with Robert and me today (they can also be incorporated in the review stage).

We are targeting Tues 2/4 at 0900 to receive all written comments from Task Force leads and their SMEs, and Wed 2/5 at 1500 to have a finalized document. To accomplish this task as efficiently as possible, we would like to have a smaller Task Force Working Group call on Monday to discuss the draft. Ideally, the Strategy Working Group will be composed of all of the Task Force leads and the SMEs that you identify as being essential to this task. Please send me the names of the 2-4 SMEs from your team whom you would like to include in the Strategy Working Group today so that I can schedule the discussion.

We apologize for the tight timeline on this request.

Best,
Christy

<< File: HHS-DoD Vaccine Sub-Plan 2 22.docx >> --
Christy L. Ventura, Ph.D.
Tunnell Government Services
in support of CBRN/BARDA/ASPR/HHS
O'Neill 23L05
Office: (b) (6)
Cell (b) (6)

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/26/2020 1:01:20 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added
**Attachments:** EUA20000x CDC HCP FS Draft_sig_JMV.docx; EUA20000x CDC Patient FS Draft_sig_JMV.docx

Li & Tamara, this just came in from CDC

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, January 26, 2020 12:55 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

We have made some edits to the fact sheets for your consideration. Please take a look and let us know your feedback.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:18 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want signs and symptoms AND epidemiological risk factors or AND/OR epidemiological risks (i.e. would include people only with S&S but no epi risk)? Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>

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**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov
**Battelle**

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

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Happy weekend,

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

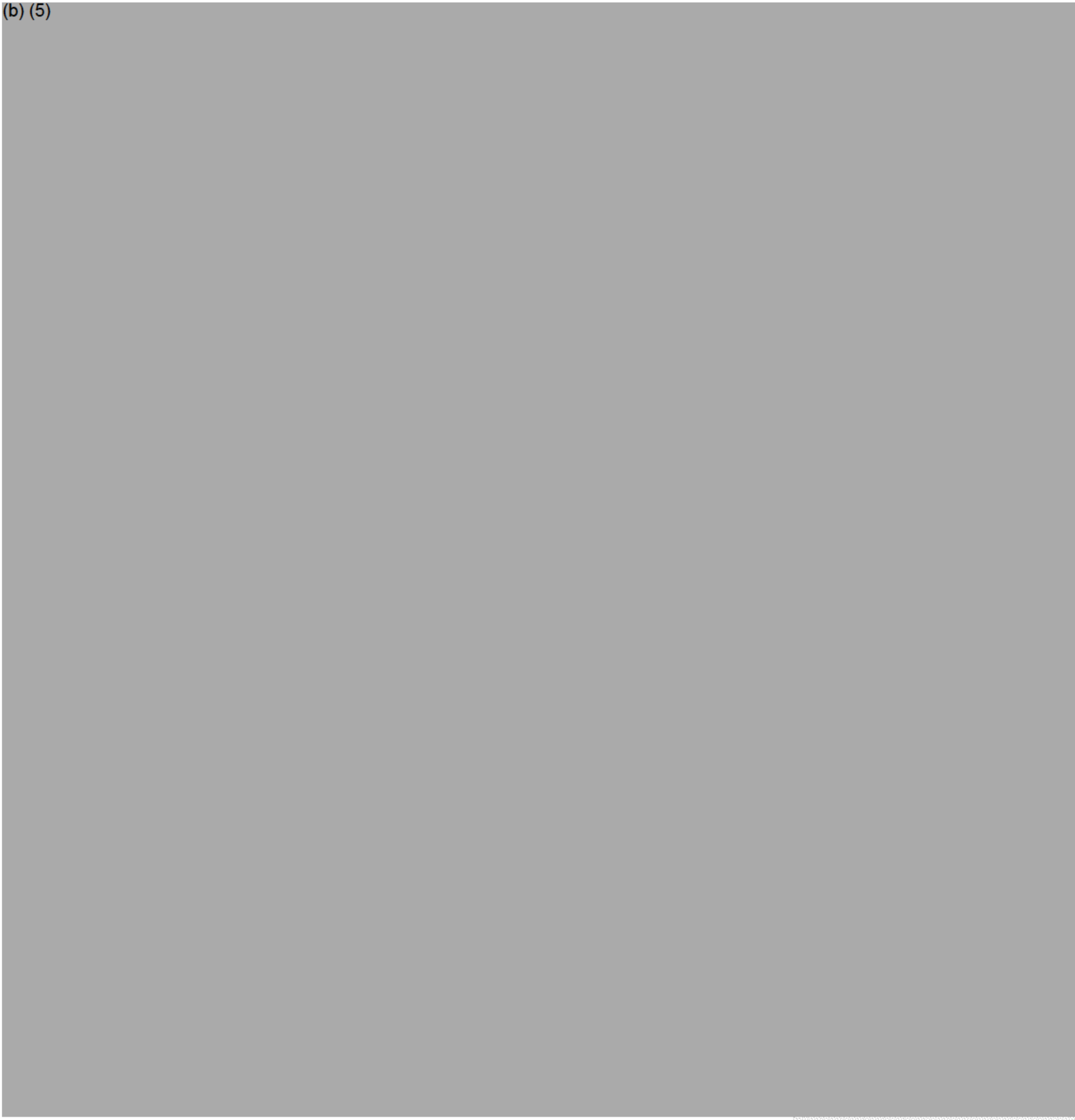
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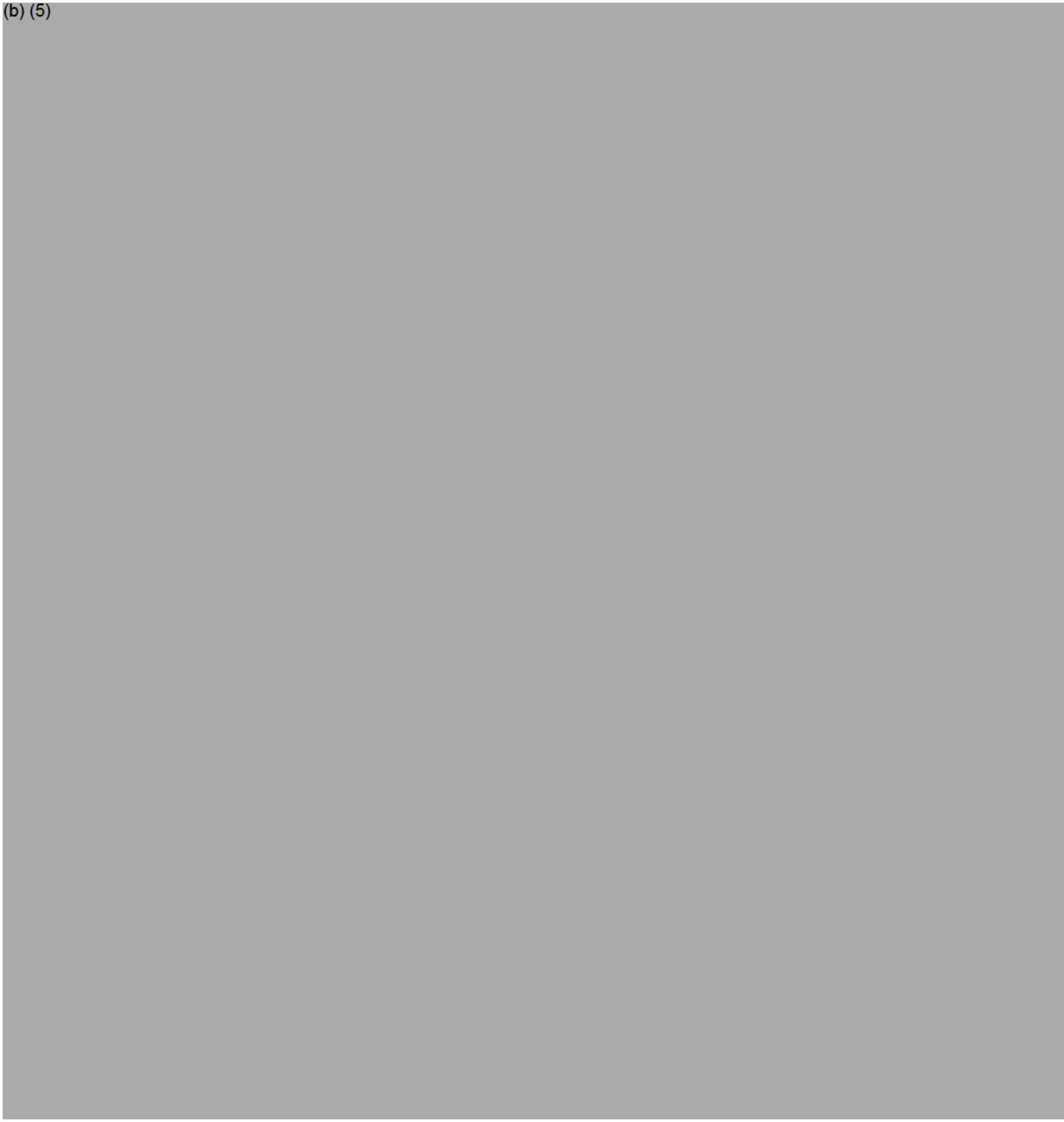
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(b) (5)



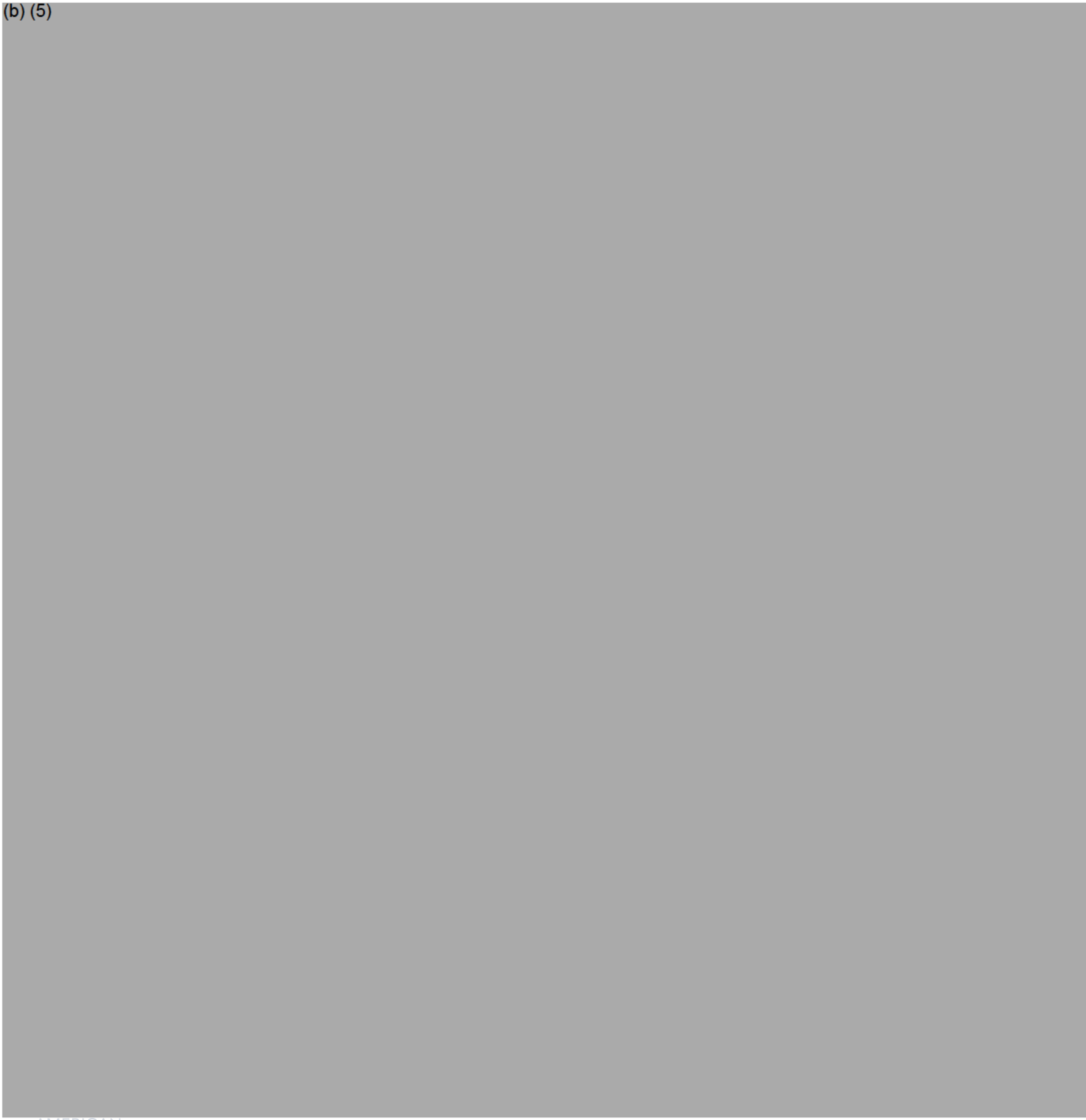
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(b) (5)



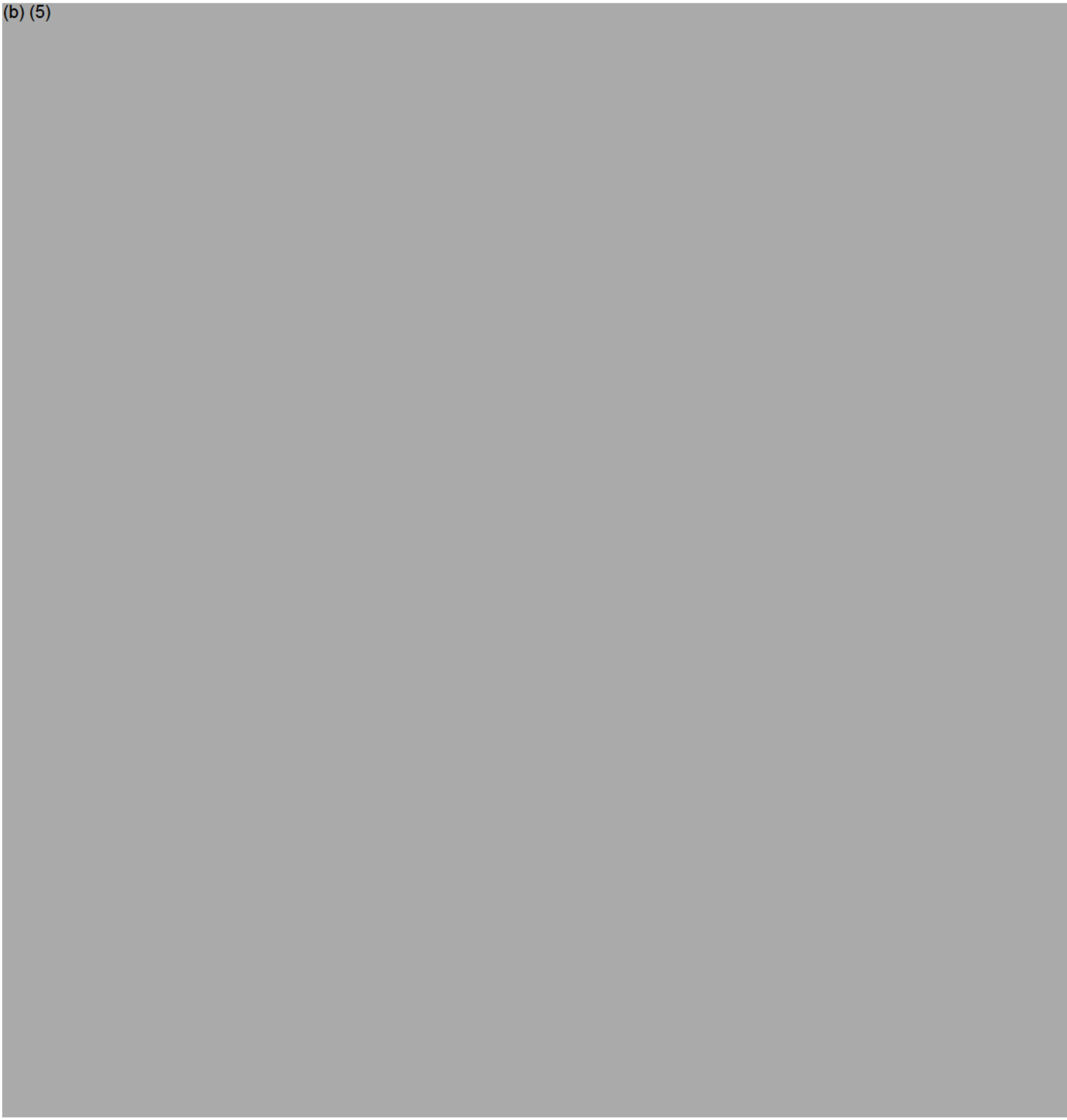
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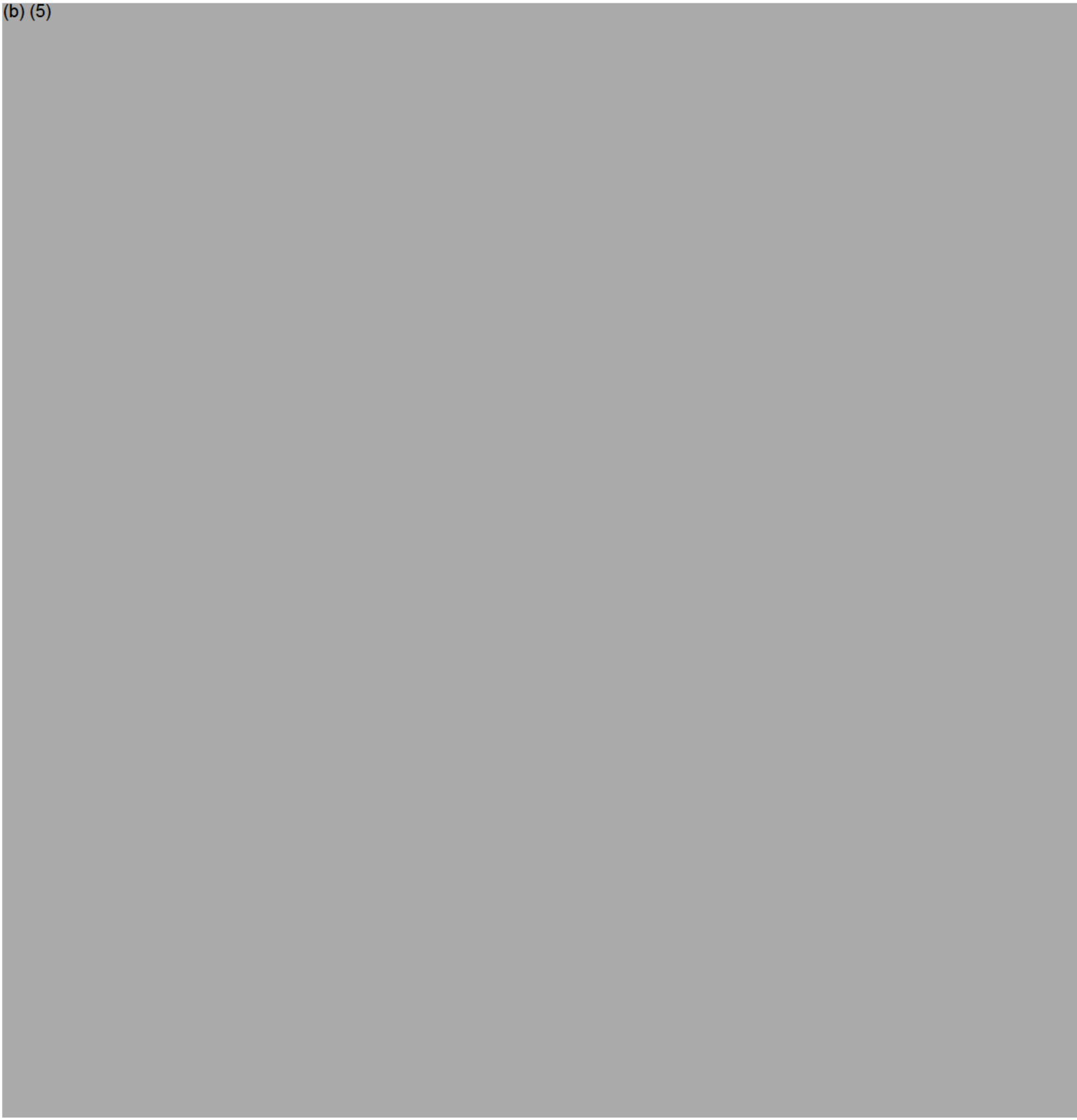
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(b) (5)



AMERICAN OVERSIGHT

(b) (5)



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/31/2020 5:47:10 PM
**To**: Patel, Anita (CDC/DDID/NCIRD/OD) [bop1@cdc.gov]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
**CC**: Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: Regulatory discretion - Need to confirm process and next steps

Dear Anita, perfect. Thanks, Uwe

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:40 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe,
We greatly appreciate FDA's rapid review of CDC's request. CDC will send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford once locations are confirmed.

We will notify our lab team of the note below and let you know if there are any additional questions.
Thanks again -
Best,
Anita

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:01 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Dear Anita,

FDA and CDC have been working interactively together on CDC's request for an Emergency Use Authorization (EUA) for its 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens. At this time, there is no *in vitro* diagnostic test approved, cleared or authorized for such use.

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On January 30th, CDC notified FDA that it would like to distribute the test to certain laboratories so that they can use the test prior to issuance of an EUA. This would help to address the significant public health concerns raised by the infectious disease at this early stage, and may help to prevent the spread of the infectious disease by addressing the high testing demands currently being faced by CDC.

We understand that CDC would like to distribute the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit, and any components, to laboratories designated by CDC as qualified and, in the United States, such laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. We also understand that CDC will ask each of the state laboratories to send positive samples and (b) (5) negative samples to CDC for further validation testing.

Based on our understanding of the facts and the public health concerns at issue here – specifically, that there is currently no other test available to respond to this emergency and that CDC is actively pursuing EUA authorization – at this time, FDA does not intend to object to the distribution and use of this test as described above. We ask that you please send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford (Kim.Sapsford@fda.hhs.gov) and the Director of the Division of Microbiology Devices, Uwe Scherf (Uwe.Scherf@fda.hhs.gov).

Kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Hi Liz,
(b) (5)

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We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
4044332667

+ Wendi who is now overseeing lab activities for the response.

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/26/2020 1:00:08 PM
**To:** Mair, Michael (Michael.Mair@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Michael.Mair]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** FW: Dx Revised Landscape slides for NSC - need your review
**Attachments:** Dx Landscape 2019 CoV 2020-01-25 v7a.pptx

Michael,

Kim and I did final review of the updated Dx Landscape and do not have additional comments we can provide.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Sunday, January 26, 2020 12:42 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Weldon, William C (CDC) <wiw4@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beanan, Maureen J (NIH) (b) (6); Marston, Hilary D (NIH) (b) (6); Munster, Vincent J (NIH) (b) (6); Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) (b) (6); Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Kayvon Modjarrad <kmodjarrad@eidresearch.org>
**Cc:** Lee, John S (OS) <John.Lee@hhs.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>
**Subject:** Dx Revised Landscape slides for NSC - need your review

Coronavirus team,
Thank you all for the responses and updates to the previous slide deck. Apologies for the second review request, information is evolving. Please review changes in slides 2,3,4.

(b) (5)

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Please send comments today if at all possible, deck for NSC is expected to be ready by tomorrow. I know there are many response demands on your time, so I really appreciate all the help everyone has provided to meet senior leadership requests for information.
Thanks,
Rosemary

---

**From:** Humes, Rosemary (OS/ASPR/BARDA)
**Sent:** Saturday, January 25, 2020 1:12 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Weldon, William C. (CDC/DDID/NCIRD/DVD) <wiw4@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Beanan, Maureen (NIH/NIAID) [E] (b) (6) >; Marston, Hilary (NIH/NIAID) [E] (b) (6) Munster, Vincent (NIH/NIAID) [E] (b) (6) ; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) (b) (6) Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>
**Cc:** Lee, John (OS/ASPR/BARDA) <John.Lee@hhs.gov>
**Subject:** Landscape slides for NSC - need your review

Coronavirus team,
BARDA and NIH have been asked to provide the interagency MCM slides for a meeting with the NSC. I have updated the Dx set, attached for your review. (b) (5)

Please reply:
Slides 3+4 - are these OK, is anything missing?
Other slides: any corrections or new info to add?

Many thanks for your continued support in meeting the expectations for information,
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
BB: (b) (6)

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# 2019-nCoV Diagnostics Landscape

## As of 1-25-2020

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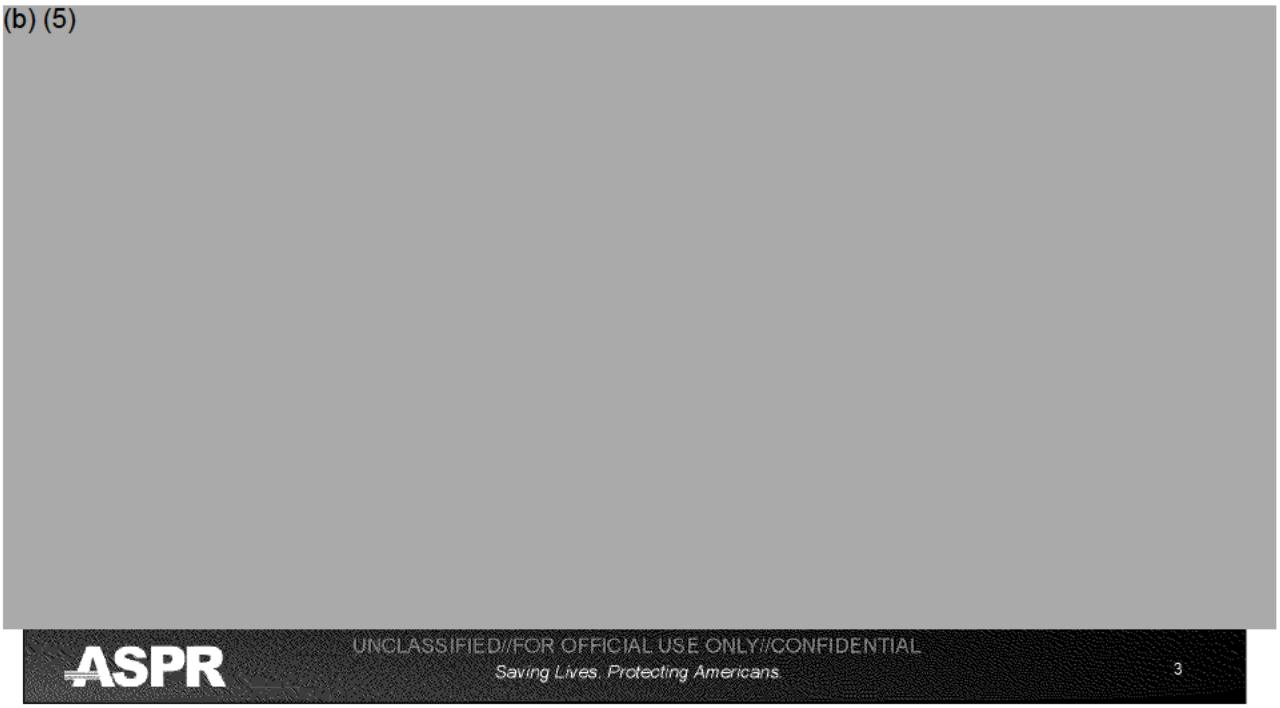
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(b) (5)





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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/25/2020 3:47:51 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft
**Attachments**: 2019-nCoV Real-Time Dx Panel Product Information Sheet_draft01252020 Li_TVF.UXS.docx

Here with one additional note. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:44 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

See attached – Uwe do you have any additional edits – I can then quickly make a DMD version Li can send back in our follow up email

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:17 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Li, you so fast, it is hard to keep up ☺

I added my comment to Li's,

Tamara

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:08 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** FW: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

See my comments in the attached.
Li

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Saturday, January 25, 2020 2:59 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

We have a draft of the product information sheet for your review. Please provide comments as soon as you can.

Thanks,
Julie

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:29 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

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Dear Steve,

FDA agree with use of "Product Information Sheet" rather than Instructions for Use and do not have any additional comments on the box/vial labels.
Please make sure to submit the developed product information sheet as part of your labeling package with the EUA submission (should include Instructions for use, product information sheet, final box/vial labels) and make sure it includes instructions to the end user for obtaining the full Instructions for Use document.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 5:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>;

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Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Sorry with attachment!!

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*
Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

(b) (5)

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
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gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
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gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

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I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of

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the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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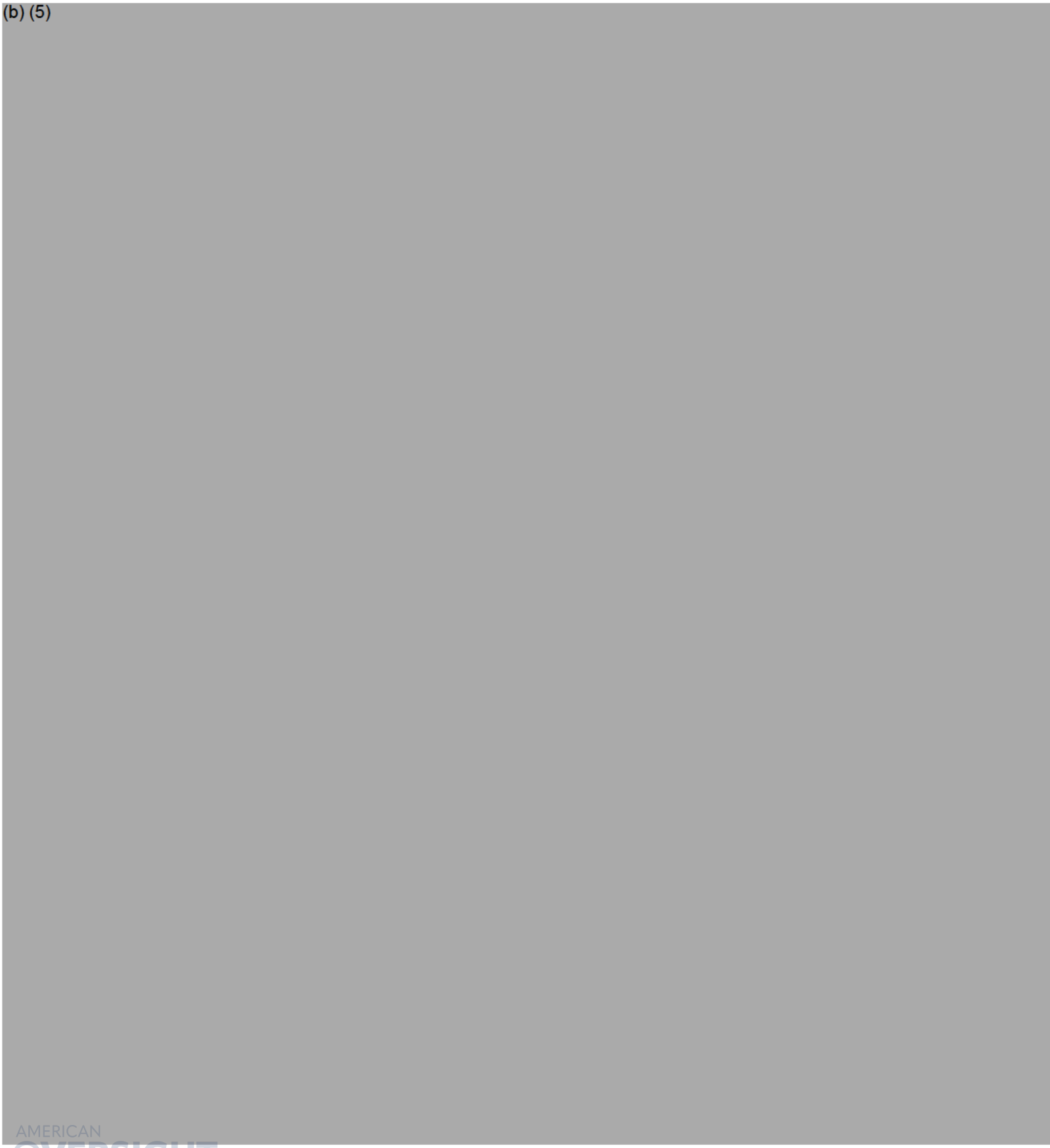





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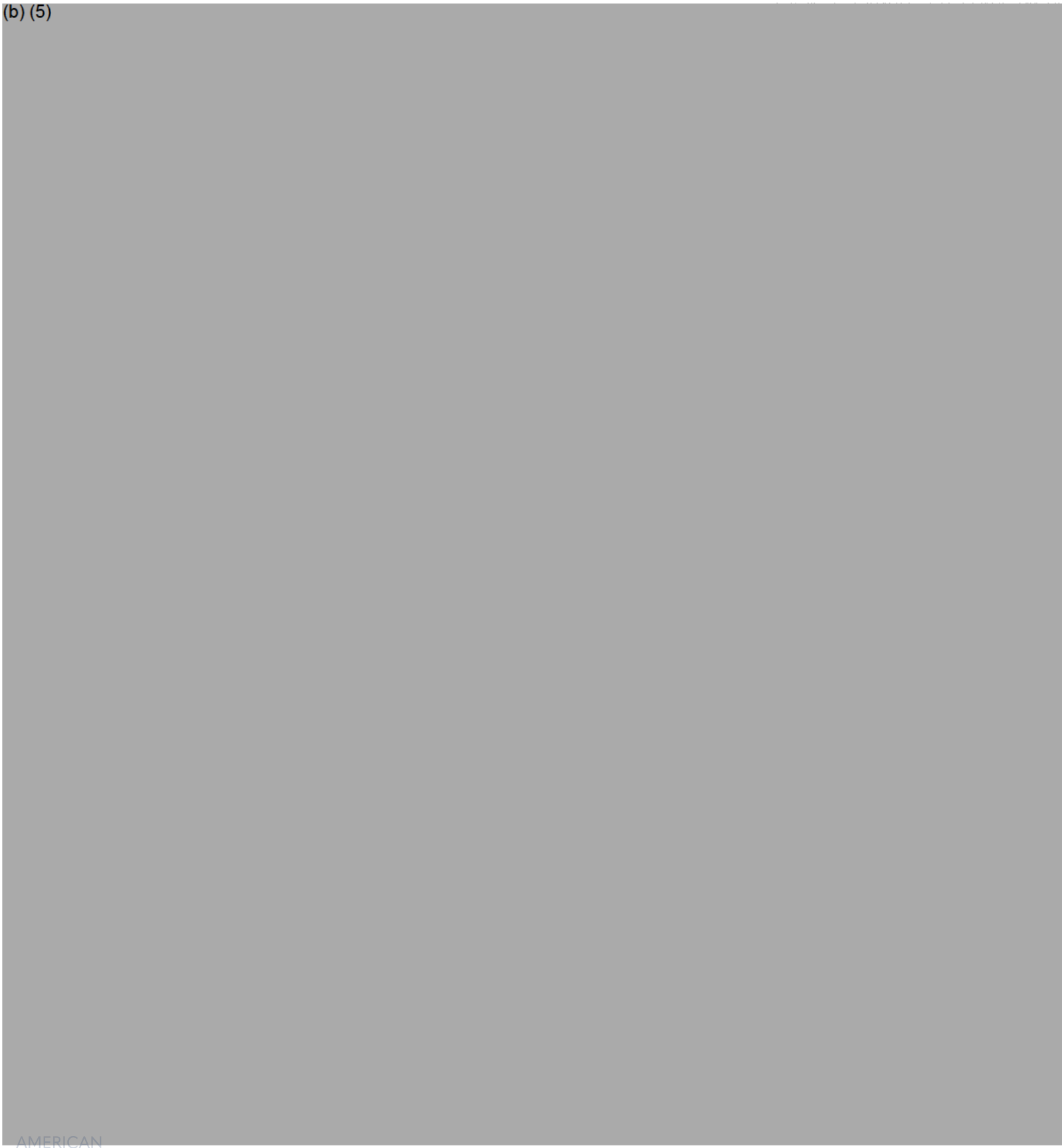
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(b) (5)



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(b) (5)



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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/26/2020 12:56:43 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: Dx Revised Landscape slides for NSC - need your review

Looking at it now, I will respond to Michael. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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uwe.scherf@fda.hhs.gov
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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 12:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Dx Revised Landscape slides for NSC - need your review

Slides look good to me

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Sunday, January 26, 2020 12:42 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Weldon, William C (CDC) <wiw4@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beanan, Maureen J (NIH) (b) (6) ; Marston, Hilary D (NIH)

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(b) (6) ; Munster, Vincent J (NIH) (b) (6) >; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) (b) (6) ; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Kayvon Modjarrad <kmodjarrad@eidresearch.org>
**Cc:** Lee, John S (OS) <John.Lee@hhs.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>
**Subject:** Dx Revised Landscape slides for NSC - need your review

Coronavirus team,
Thank you all for the responses and updates to the previous slide deck. Apologies for the second review request, information is evolving. Please review changes in slides 2,3,4.
(b) (5)

Please send comments today if at all possible, deck for NSC is expected to be ready by tomorrow. I know there are many response demands on your time, so I really appreciate all the help everyone has provided to meet senior leadership requests for information.
Thanks,
Rosemary

---

**From:** Humes, Rosemary (OS/ASPR/BARDA)
**Sent:** Saturday, January 25, 2020 1:12 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Weldon, William C. (CDC/DDID/NCIRD/DVD) <wiw4@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Beanan, Maureen (NIH/NIAID) [E] (b) (6) ; Marston, Hilary (NIH/NIAID) [E] (b) (6) ; Munster, Vincent (NIH/NIAID) [E] (b) (6) >; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) (b) (6) ; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>
**Cc:** Lee, John (OS/ASPR/BARDA) <John.Lee@hhs.gov>
**Subject:** Landscape slides for NSC - need your review

Coronavirus team,
BARDA and NIH have been asked to provide the interagency MCM slides for a meeting with the NSC. I have updated the Dx set, attached for your review. (b) (5)

Please reply:
Slides 3+4 - are these OK, is anything missing?
Other slides: any corrections or new info to add?

Many thanks for your continued support in meeting the expectations for information,
Rosemary

AMERICAN OVERSIGHT

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
BB: (b) (6)

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/21/2020 4:49:32 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** FW: Novel Coronavirus Diagnostics - request for information for landscapes (UNCLASSIFIED)

FYI

Uwe

-----Original Message-----
From: Opdyke, Jason A CIV USARMY (USA) (b) (6)
Sent: Tuesday, January 21, 2020 4:35 PM
To: Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Brown, Trevor S CTR USARMY DOD JPEOCBD (USA) (b) (6); Beanan, Maureen J (NIH) (b) (6); Erbelding, Emily J (NIH) (b) (6)
Cc: Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Lee, John S (OS) <John.Lee@hhs.gov>; Hepburn, Matthew J CIV USARMY (USA) (b) (6); Weldon, William C (CDC) <wiw4@cdc.gov>; Pallansch, Mark (CDC) <map1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
Subject: Re: Novel Coronavirus Diagnostics - request for information for landscapes (UNCLASSIFIED)

Good Afternoon, Unofficially (b) (4), (b) (5)

Respectfully,

Jason

Sent from my iPhone

> On Jan 20, 2020, at 2:02 PM, Opdyke, Jason A CIV USARMY (USA) (b) (6) > wrote:
>
> CLASSIFICATION: UNCLASSIFIED
>
> Rosemary, Repeating for the group what I communicated to you in an earlier email. Since we have a (b) (4), (b) (5)

>
> Jason
>
> Jason Opdyke PhD
> Office Phone: (b) (6)
> Cell: (b) (6)
> (b) (6)
>
> -----Original Message-----
> From: Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) [mailto:sql5@cdc.gov]
> Sent: Monday, January 20, 2020 12:55 PM
> To: Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Opdyke, Jason A CIV USARMY (USA) (b) (6); Brown, Trevor S CTR USARMY DOD JPEOCBD (USA) (b) (6); Beanan, Maureen (NIH/NIAID) [E] (b) (6); Erbelding, Emily (NIH/NIAID) [E] (b) (6)
> Cc: Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>; Lee, John (OS/ASPR/BARDA) <John.Lee@hhs.gov>; Hepburn, Matthew J CIV USARMY (USA) (b) (6); Weldon, William C. (CDC/DDID/NCIRD/DVD) <wiw4@cdc.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
> Subject: [Non-DoD Source] Re: Novel Coronavirus Diagnostics - request for information for landscapes
>
> Hi Rosemary,
> Sure. Please see my response to your question below:
>

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> CDC - can you update on status of your assay development. Is the assay intended for PHL's to use with the ABI 7500Fast?
>
> Assays have been developed and qualified under CLIA for diagnostic testing of domestic cases at CDC. Assays are intended to be qualified under EUA in partnership with FDA as soon as possible for the purpose of deployment to US PHLs. The test will be initially qualified for use on the AB 7500FastDx. Further qualification for extended capability with additional instruments/chemistries will be added as necessary/possible depending on the need/situation.
>
> I have included some other stake holders at CDC involved in these efforts. Dr. Mark Pallansch is the Division Director for the Division of Viral Diseases.
>
> thank you very much!
> Steve
>
>
>
> _____
>
> From: Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
> Sent: Monday, January 20, 2020 12:38 PM
> To: Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) (b) (6)
Brown, Trevor S (CTR)-DoD USARMY JPEOCBD (b) (6) ; Beanan, Maureen (NIH/NIAID) [E]
(b) (6) ; Erbelding, Emily (NIH/NIAID) [E] (b) (6)
> Cc: Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>; Lee, John (OS/ASPR/BARDA) <John.Lee@hhs.gov>; Hepburn, Matthew J CIV USARMY (USA) (b) (6)
> Subject: Novel Coronavirus Diagnostics - request for information for landscapes
>
> Interagency colleagues,
> Dr. Bright has asked us to prepare a landscape of diagnostics for the novel coronavirus (2019-CoV). I heard that a DX WG is being convened, but don't know by whom - still trying to get details.
> In the meantime I am reaching out to see if I can start by compiling a list of any efforts among USG partners.
>
> * CDC - (b) (5)
(b) (5)
> * FDA- (b) (5)
> * NIH - any efforts?
>
> Commercial sector: (b) (5)
>
> Any information that you can provide is much appreciated. As I get more information on a WH or coordinated planning efforts I'll keep you updated.
> Many thanks,
> Rosemary
>
> Rosemary Humes MS, MT(ASCP) SM
> HHS/ASPR/BARDA
> 202-205-8238
> BB: (b) (6)
>
>
> CLASSIFICATION: UNCLASSIFIED

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/24/2020 9:18:21 AM
**To**: Colleli, Karen M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15e75ece7b6a4fe6ab09e06fa646798b-KMC]; Dowtin, Lesa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a58cf27088244caa863aa4f57a9b11ad-LXV]; Draper, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4b05cc2fa5f4ed3b3ffc6cf62039d06-Jennifer.Dr]
**CC**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Request for overtime pay
**Attachments**: ucm030757_DMD_nCoV_DMD.pdf

Karen,

Thanks, attached the updated form, I included Anna to the names of the larger group.

Please let me know whether you need anything else.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Colleli, Karen M <Karen.Colleli@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 9:11 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Draper, Jennifer <Jennifer.Draper@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Hi Uwe,

There should not be more than 4 pay periods included on each form. Please complete block 3.e to show PP 3, 4, 5, 6 and change block 3.f to show 01/24/2020 to 03/14/2020.

*Karen Colleli*
**Management Analyst**

**Operations Staff**
**Office of Product Evaluation and Quality**

AMERICAN OVERSIGHT

**CDRH/Food and Drug Administration**
**White Oak, Bldg. 66, Rm. 1518 / 10903 New Hampshire Avenue / Silver Spring, MD 20993**
Ph: 301-796-5565 / Fax: 301-847-8120
Karen.Colleli@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1021&S=E

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 8:58 AM
**To:** Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Draper, Jennifer <Jennifer.Draper@fda.hhs.gov>; Colleli, Karen M <Karen.Colleli@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Lesa,

Thanks, attached the updated form for Anna Mielech. She is title 42 with a salary equivalent to a GS12/7 grade.

Thanks for your help.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 7:58 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Cc:** Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Colleli, Karen M <Karen.Colleli@fda.hhs.gov>; Draper, Jennifer <Jennifer.Draper@fda.hhs.gov>
**Subject:** FW: Request for overtime pay

AMERICAN OVERSIGHT

Hi Bill,

Yes, Title 42 Appointees may earn OT since they do not receive Market Pay. However, it would depend on their current salary and that would determine the # of hours they could actually work.

Uwe,

Please send your signed request to Jennifer Draper or Karen Colleli and they will verify the employee's eligibility.

Thanks

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:46 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Uwe,
I am not sure that we can authorize individuals under Title 42 for OT. I have removed Anna Mielech and authorized all others on the form attached. If we get the OK for Anna, we can complete another form or add her back.

Lesa and/or Daniel, can we authorize OT for Title 42?

Bill

**William H. Maisel, MD, MPH**
*Director, Office of Product Evaluation and Quality*
*CDRH Chief Medical Officer*

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-5550
william.maisel@fda.hhs.gov




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https://www.research.net/s/cdrhcustomerservice?ID=1000&S=E

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:42 PM
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

AMERICAN OVERSIGHT

Dear Bill,

Attached please find the updated request form with the Grade and Step information. Only one individual Anna Mielech is a staff fellow under title 42 and she does not have this information.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

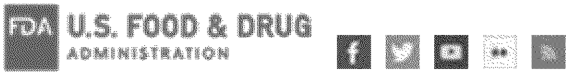
---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:18 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Uwe,
I am supportive of OT pay and would be happy to authorize. Before I can sign the form, I need the grade/step information filled in as that information determines eligibility for OT pay (i.e. certain series/grades are not eligible for OT). Therefore, I can't formally authorize it until I know the grade of the individuals for whom you are requesting OT. Looping in Lesa/Daniel. Not sure who is in the best position to quickly provide that info (OPEQ operations or OIR).
Thanks
Bill

**William H. Maisel, MD, MPH**
*Director, Office of Product Evaluation and Quality*
*CDRH Chief Medical Officer*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 301-796-5550
william.maisel@fda.hhs.gov




***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1000&S=E

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:04 PM
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** Request for overtime pay

Dear Bill,

As you have seen from the DMD updates and the information in the press, the 2019-nCoV situation has been very challenging.

Our interactive review and teleconferences indicated that CDC will send CDRH a completed EUA review template any time soon. The staff has been fabulous and supporting the program 200%. I am anticipating CDC data to be reviewed over the weekend and a complete EUA review package next week. As soon as the emergency is declared we anticipate additional documents from commercial sponsors. This work is on top of the regular review work and I feel obliged to assure appropriate compensation for my staff. Attached please find the request form for overtime for your consideration.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AMERICAN OVERSIGHT

# Overtime, Compensatory Time, and Holiday Pay Request and Authorization

*(Instructions for completing this form on reverse)*

2020-2531-CDRH

1. DATE: 01/24/2020

2. TO: *(Authorizing Official)*
a. NAME, TITLE, AND MAILING SYMBOL: William Maisel, MD, MPH, OPEQ Director, WA66-1678

3. FROM: *(Requesting Official)*
a. NAME, TITLE, AND MAILING SYMBOL: Uwe Scherf, PhD, Director Division of Microbiology Devices, OHT7/OPEQ WO66-3110
b. NO. OF PAGES FORWARDED: 2

| c. CHARGE OVERTIME TO | | d. TIME-KEEPER NO. | e. PAY PERIOD NO. *(No more than 4 PPs per form)* | f. INCLUSIVE DATES | |
|---|---|---|---|---|---|
| PAYROLL CAN | ADMIN CODE | | 3, 4, 5, 6 | FROM 01/24/2020 | TO 03/14/2020 |

4. EMPLOYEES WORKING OVERTIME

| a. NAME | b. GRADE/STEP | c. TIME-KEEPER* | d. NO. OF HOURS REQUESTED | d. NO. OF HOURS WORKED | e. TYPE PAYMENT OT | e. TYPE PAYMENT COMP TIME | e. TYPE PAYMENT HOLIDAY |
|---|---|---|---|---|---|---|---|
| Li, Li | 14/7 | | 40 | | X | | |
| Anna Mielech | 12/7 equiv. | | 40 | | X | | |
| Kim Sapsford | 14/5 | | 40 | | X | | |
| Mayra Garcia | 14/3 | | 40 | | X | | |
| Himani Bisht | 14/4 | | 40 | | X | | |
| Stephanie Akselrod | 14/5 | | 40 | | X | | |
| Silke Schlottmann | 14/3 | | 40 | | X | | |
| Tamara Feldblyum | 14/10 | | 40 | | X | | |
| | | | | | | | |
| | | | | | | | |
| *Complete for each different timekeeper. | | g. TOTAL | 320.00 | | | | |

5. SPECIFIC DESCRIPTION OF TASK *(Do not use general description, i.e., "typing," "filing")*
In timely support of the current outbreak of the 2019 novel coronavirus (nCoV) regarding pre-EUA and EUA submissions from government organizations like CDC, BARDA, and DoD to expeditiously authorize diagnostics tests for the detection of nCoV via the Emergency Use Authorization Autority.

6. REASONS FOR NOT COMPLETING TASK DURING REGULAR HOURS
The urgency of the 2019-nCoV outbreak requires constant instant responses to government stakeholders and IVD developers like CDC and commercial entities. This additional work is on top of the regular regulator review under MDUFA timelines and workload exceeds what staff can provide in 40 hours of their regular working hours.

7. COMPLETED BY REQUESTING OFFICIAL *(from box 3)*
a. DO YOU ANTICIPATE THE NEED FOR OVERTIME IN SUBSEQUENT PAY PERIODS FOR THIS TASK?
☒ Yes *(If "Yes," complete 7b.)* ☐ No
b. DESCRIBE STEPS TAKEN BY REQUESTOR TO REDUCE OR AVOID FURTHER OVERTIME
Review resources from other Branches of DMD will be used, however, specialized knowledge of the EUA process of the above listed individual might be required pending progression of the 2019-nCoV outbreak in the US.
SIGNATURE: Uwe Scherf -S Date: 2020.01.24 09:15:42 -05'00'

8. COMPLETED BY APPROVING OFFICIAL
REQUEST FOR OVERTIME
☐ Approved ☐ Disapproved
SIGNATURE
DATE

AMERICAN OVERSIGHT

## INSTRUCTIONS FOR COMPLETING FORM FDA 211

Overtime Work (within the provisions of Federal Personnel Manual Supplement 990-1) may be authorized only by officials to whom the necessary authority has been delegated (see FDA Staff Manual Guide 1430.5). Overtime or Holiday Pay will not be paid, nor compensatory time granted, without appropriate authorization. Requests should be initiated on Form FDA 211, "Overtime, Compensatory Time, and Holiday Pay Request and Authorization," and completed as follows:

| Item | Explanation |
|---|---|
| 1-3 | Self-explanatory, to be filled out by requesting official. A requesting official can be the employee, timekeeper, Administrative Officer, or supervisor. |
| 4 | If space is required for additional names of those working overtime, another Form FDA 211 should be filled out in its entirety. If more than one form is used for the same request, the forms should be clipped so that they are processed concurrently.<br><br>Only the "requested" side of the columns should be filled out by the requesting official in item 4d.<br><br>A check mark or "x" should be placed in the appropriate column of item 4e indicating the desired compensation. |
| 5-7 | Self-explanatory, to be filled out by requesting official. |
| 8 | To be filled out by authorizing official.<br><br>After evaluation (and adjustment if necessary), the authorizing official will sign to approve or disapprove the request. If disapproved, the request is returned to the requesting official. If approved, the request is returned to the requesting official who should then forward the document to the applicable timekeepers (and Budget Officer if required).<br><br>The timekeeper will enter hours worked in the appropriate column of item 4d. Hours worked are to be based on data which the employee provides on the bi-weekly time report and cannot exceed hours "requested." If hours worked exceed hours "requested," only the authorizing official may increase the "requested" amount and must initial the modification. |

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/24/2020 10:22:30 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft
**Attachments:** PI - CDC 2019-nCoV rRT-PCR Dx Panel_draft01242020 Li_UXS.docx

Here some additional comments added to Li initial edits.

Signing off now too. Thanks for the quick review.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 9:59 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

My comments to the draft PI (without the performance data) are in the attached.
I am signing off now.
Li

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 8:36 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Great thanks for your quick review.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 8:33 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

(b) (5)

I will review the draft PI without the performance data and send you all my comments.

Li

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 24, 2020 7:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

I am forwarding our draft Package Insert minus performance data sections for a first look. We will forward the one-pager product information sheet once we have that draft.

I am also forwarding a list of clinical specimens that CDC has tested with the panel so far. Since this is obviously a better representation of the clinical performance than using contrived specimens, we'd would like to ask whether we could utilize this set for our clinical data.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:29 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI)

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<jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

FDA agree with use of "Product Information Sheet" rather than Instructions for Use and do not have any additional comments on the box/vial labels.
Please make sure to submit the developed product information sheet as part of your labeling package with the EUA submission (should include Instructions for use, product information sheet, final box/vial labels) and make sure it includes instructions to the end user for obtaining the full Instructions for Use document.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 5:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Sorry with attachment!!

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

AMERICAN ONCOLOGY

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

(b) (5)

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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Kim.Sapsford@fda.hhs.gov






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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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Office of Product Evaluation and Quality (OPEQ)

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

AMERICAN OVERSIGHT

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064

AMERICAN OVERSIGHT

At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov






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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/30/2020 7:25:04 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

I am online, can be reached at (b) (6) for any questions. Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 7:18 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Regulatory discretion - Need to confirm process and next steps

I can talk now — (b) (6)

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** January 30, 2020 at 7:14:43 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Regulatory discretion - Need to confirm process and next steps

Hi Jeff,

CDC is asking (bottom of email chain) the following:

(b) (5)

OCC has stated that (b) (5)

I had a call with OCC that I would like to discuss with you, either in the morning or by phone tonight.

Thanks,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov

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---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 7:03 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

See the message below. Per our last exchange, CDRH wanted to reply. Please let me know how you plan to proceed. Thanks, Liz

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** January 30, 2020 at 7:00:06 PM EST
**To:** Patel, Anita (CDC) <bop1@cdc.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

I will consider this email a request, and we will respond accordingly. Thanks.

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Date:** January 30, 2020 at 6:58:24 PM EST
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Meant wendi not wendy ☺

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD)
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

AMERICAN OVERSIGHT

Hi Liz,

(b) (5)

[redacted]

We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
4044332667

+ Wendy who is now overseeing lab activities for the response.

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/24/2020 10:01:34 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Li, thanks, please capture you hours you worked on this. We have been granted overtime payment for this project. Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 9:59 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

My comments to the draft PI (without the performance data) are in the attached.
I am signing off now.
Li

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 8:36 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Great thanks for your quick review.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 8:33 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

(b) (5)

I will review the draft PI without the performance data and send you all my comments.

Li

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 24, 2020 7:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

I am forwarding our draft Package Insert minus performance data sections for a first look. We will forward the one-pager product information sheet once we have that draft.

I am also forwarding a list of clinical specimens that CDC has tested with the panel so far. Since this is obviously a better representation of the clinical performance than using contrived specimens, we'd would like to ask whether we could utilize this set for our clinical data.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:29 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

AMERICAN OVERSIGHT

Dear Steve,

FDA agree with use of "Product Information Sheet" rather than Instructions for Use and do not have any additional comments on the box/vial labels.
Please make sure to submit the developed product information sheet as part of your labeling package with the EUA submission (should include Instructions for use, product information sheet, final box/vial labels) and make sure it includes instructions to the end user for obtaining the full Instructions for Use document.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 5:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>;

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Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Sorry with attachment!!

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

AMERICAN OVERSIGHT

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Kim.Sapsford@fda.hhs.gov






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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

(b) (5)

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

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**Sent:** Saturday, January 18, 2020 1:15 PM
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**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

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I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of

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the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/26/2020 3:37:59 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

All,

I have no additional comments on the fact sheets for HCP or Patients, I think thy an go to OCET next. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, January 26, 2020 12:55 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

We have made some edits to the fact sheets for your consideration. Please take a look and let us know your feedback.

Thanks,
Julie

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**Sent:** Saturday, January 18, 2020 5:18 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
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**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

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Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

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*CDC Influenza Division (Battelle Contractor)*
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**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

AMERICAN OVERSIGHT

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

**Battelle**
2987 Clairmont Road
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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

AM OVERSIGHT

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
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Kim.Sapsford@fda.hhs.gov






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AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/26/2020 12:27:12 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Have you heard from Co-Diagnostics?

Yes, please send them the template

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 12:24 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Have you heard from Co-Diagnostics?

Should we reach out to co-diagnostics – see link Rosemary provided below

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Sunday, January 26, 2020 9:24 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Have you heard from Co-Diagnostics?

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http://codiagnostics.com/co-diagnostics-designs-new-coronavirus-test-using-coprimers/

We haven't heard from them.
Thanks.

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
BB: (b) (6)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/31/2020 9:04:50 PM
**To**: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Mair, Michael (Michael.Mair@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Michael.Mair]
**Subject**: FW: Regulatory discretion - Need to confirm process and next steps

Liz and Michael,

The 1st request for 2 sides, Chicago and Richmond CA came in this evening and DMD acknowledged the receipt of this information.

Uwe

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:57 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Weldon, William C (CDC) <wiw4@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe and Kim,
Please see below for the locations for the first two lab locations.
Best,
Anita

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:49 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Here is the info:

Illinois Dept of Public Health-Chicago Laboratory
Attn: Matt Charles
2121 West Taylor (2nd floor)
Chicago, IL 60612
Phone: 217-220-1739
matt.charles@illinois.gov

California Department of Public Health
Attn: Debra Wadford
850 Marina Bay Parkway
Richmond, CA 94804
Debra.wadford@cdph.ca.gov
Phone: 510-685-2965

AMERICAN OVERSIGHT
Wendi Kuhnert-Tallman
phone - 404-639-3103

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:40 PM
**To:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe,
We greatly appreciate FDA's rapid review of CDC's request. CDC will send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford once locations are confirmed.

We will notify our lab team of the note below and let you know if there are any additional questions.
Thanks again -
Best,
Anita

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:01 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Dear Anita,

FDA and CDC have been working interactively together on CDC's request for an Emergency Use Authorization (EUA) for its 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens. At this time, there is no *in vitro* diagnostic test approved, cleared or authorized for such use.

On January 30th, CDC notified FDA that it would like to distribute the test to certain laboratories so that they can use the test prior to issuance of an EUA. This would help to address the significant public health concerns raised by the infectious disease at this early stage, and may help to prevent the spread of the infectious disease by addressing the high testing demands currently being faced by CDC.

We understand that CDC would like to distribute the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit, and any components, to laboratories designated by CDC as qualified and, in the United States, such laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. We also understand that CDC will ask each of the state laboratories to send positive samples and (b) (5) negative samples to CDC for further validation testing.

Based on our understanding of the facts and the public health concerns at issue here – specifically, that there is currently no other test available to respond to this emergency and that CDC is actively pursuing EUA authorization – at this time, FDA does not intend to object to the distribution and use of this test as described above. We ask that you please send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford (Kim.Sapsford@fda.hhs.gov) and the Director of the Division of Microbiology Devices, Uwe Scherf (Uwe.Scherf@fda.hhs.gov).

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Kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Hi Liz,
(b) (5)

[redacted]

We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
4044332667

+ Wendi who is now overseeing lab activities for the response.

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/2/2020 9:34:00 AM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: draft CDC EUA template
**Attachments**: EUA CDC-2019-nCoV rRT-PCR DRAFT 27JAN2020 29JAN2020 30JAN2020 01FEB2020 CLEAN_DMD.doc; PI - CDC 2019-nCoV rRT-PCR Dx Panel_draft 31JAN20 CLEAN DMD.docx

**Importance**: High

Dear Julie,

Please find attached DMD's comments in the EUA template, looks good, we just need the LoD data. We inserted them in the clean version for ease of viewing. Once the LoD is finalized we recommend dropping the EUA template performance section into your instructions for use performance section.

We would also like to request the following limitation addition/change in the IFU:

New:

- Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has only been established in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).

And maybe strengthen the negative results one by combining two of the current limitations with the addition in green:

- Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.

Julie, also when are you planning to send the complete package for CDC clearance – in parallel with our review or after we have reviewed and say it is good.

Let us know if have any questions.

Best regards
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*
OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 2, 2020 12:10 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** draft CDC EUA template

Hi all,

Here is the latest version of the CDC EUA template. We believe that the only data set missing is the limit of detection study, which we will have for you tomorrow, likely in the afternoon. I've attached both a tracked changes version which captures all of our combined edits and a clean version from which we can work if you agree with all of our combined edits.

Please let us know if there are additional questions. We will be available all day tomorrow to discuss.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 5:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Dear Julie,

Please find attached the final redline (FYI) and clean Patient and HCP facts sheets for you to send forward for CDC clearance.
In addition, below is an outline of the main items we would expect to see in the EUA request package:

- CDC Cover Letter
- EUA Template
- Labeling:
  - Final Instructions for Use/Package Insert (let us know which you choose)
  - Final Product Information Sheet
  - Final Verification Requirements
  - Final Box and Vial Labels
- Fact Sheets:

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- HCP Fact Sheet
- Patient Fact Sheet

- Appendix – include any line data and additional information (bioinformatic analysis) used to support the summary information in the EUA template

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Saturday, February 01, 2020 3:13 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Hi Kim,

Here are some edits and comments from our epidemiologists. Please let me know if they are acceptable or if we need to discuss.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 4:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH)

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<Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Dear Julie,

Please find attached the HCP and Patient Fact Sheets, there were a number of changes resulting from the updated intended use and the additional internal review at FDA so I haven't didn't include a redline – but let me know if you need it I can send it along.

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 31, 2020 3:27 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Clean instruction for use and question regarding in silico analyses
**Importance:** High

Hi all,

Attached is the clean instructions for use without the performance data. There is one screen shot that needs to be replaced.

We have another question regarding the presentation of the in silico analyses (also attached). We have discussed the approach, and we'd like your feedback on how you would like the data summarized. The data will be sent as an appendix with the submission along with the rest of our data.

We appreciate your help!
Thanks,
Julie

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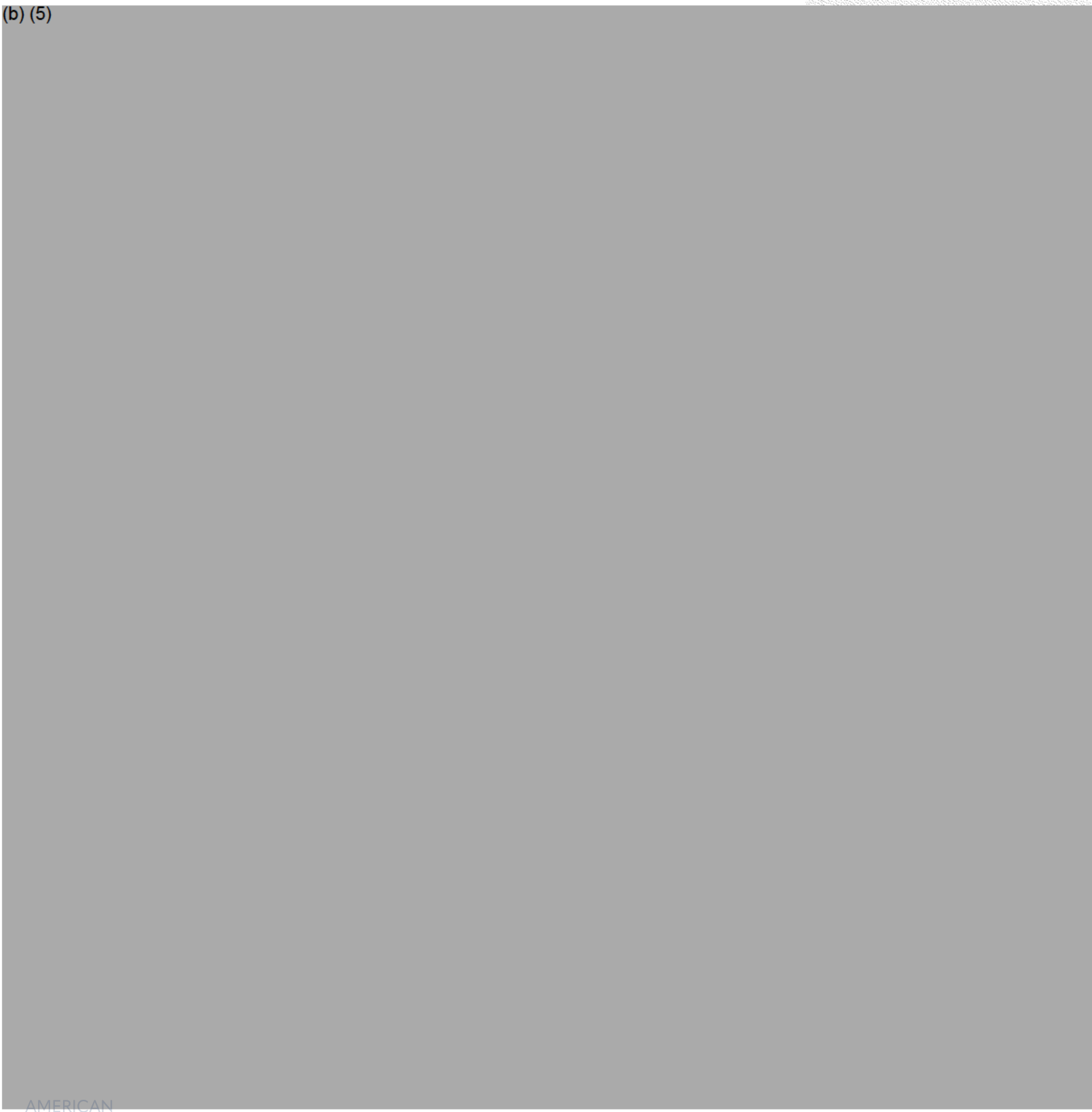
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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/26/2020 3:33:43 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Agree,

(b) (5)

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 3:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** FW: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

(b) (5)

Do you all agree?
Li

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, January 26, 2020 3:06 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Rager, Stacy (CDC) <vmk4@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi again,

AMERICAN OVERSIGHT

I am including labeling for Human Specimen Control for use with the 2019-nCoV Real-Time RT-PCR Diagnostic Panel. This will be a material not provided in the 2019-nCoV Dx Panel but will be provided as a separate product by CDC. These drafts are edits to a currently cleared IVD HSC product for the *B. anthracis* Real-time PCR Assay. HSC is a control material used in multiple IVD-cleared and EUA assays at CDC including tests for influenza and Ebola. Please let us know if you have questions or would like to discuss further.

Thanks,
Julie

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI)
**Sent:** Sunday, January 26, 2020 2:20 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Li,

We've updated the PI and have answered most of your questions – it will take us some time to update all of the screen shots. We've also updated the product information sheet for your review. Please let us know if you have questions.

Thanks,
Julie

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 4:03 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Steve and Julie,

Please find attached our feedback on the draft package insert (minus the performance sections). Let us know if you have any questions.

We have looked at the spreadsheet list of clinical specimens that CDC has tested to date with the CDC 2019-nCoV real-time RT-PCR panel and have some questions about the specimens included to help us better understand the data:

- Were they collected from patients suspected of 2019-nCoV (i.e., PUI subjects)?
- How many patients are represented in this data? Are some specimens collected from the same patient tested at different times, etc.?
- Are all the positives collected from the same patient at different times – or do they represent different patients?
- Is the "result reported" column reporting the result of only the CDC 2019-nCoV real-time RT-PCR panel or does it factor in confirmatory testing (for the positive)? Note line 8, CSID 3001920918 has 2 positive PCRs and one that would be considered negative – based on a 38 Ct cut-off – should the result for this specimen therefore be inclusive or did it factor in additional testing, such as targeted sequencing?
- Have the presumptive positives been confirmed through targeted sequencing?

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- The negative status of a specimen collected from a PUI subject is difficult to determine – were the negative individuals confirmed positive for another respiratory disease?

DMD concluded that a contrived clinical study, as discussed on our call Friday (i.e., testing of 50 individual negative and 50 contrived individual positive samples; limited pooled samples may be acceptable to address potential individual clinical sample volume limitation), is still needed to support the EUA submission. This data set may be helpful in further supporting the specificity of the test and the different respiratory specimens you intend to claim.

Also attached are our feedback on the draft "Product Information Sheet" for your consideration.

Best Regards,
Li

**Li Li**
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 762-6200 | Fax: (301) 847-8512
li.li2@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 24, 2020 7:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

I am forwarding our draft Package Insert minus performance data sections for a first look. We will forward the one-pager product information sheet once we have that draft.

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I am also forwarding a list of clinical specimens that CDC has tested with the panel so far. Since this is obviously a better representation of the clinical performance than using contrived specimens, we'd would like to ask whether we could utilize this set for our clinical data.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:29 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

FDA agree with use of "Product Information Sheet" rather than Instructions for Use and do not have any additional comments on the box/vial labels.
Please make sure to submit the developed product information sheet as part of your labeling package with the EUA submission (should include Instructions for use, product information sheet, final box/vial labels) and make sure it includes instructions to the end user for obtaining the full Instructions for Use document.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 5:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

AMERICAN OVERSIGHT

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Sorry with attachment!!

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

AMERICAN OVERSIGHT

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

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Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

(b) (5)

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

AMERICAN OVERSIGHT

Steve Burke, Ph.D., RAC
*Program Manager*

*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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FDA U.S. FOOD & DRUG ADMINISTRATION
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come

Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/

I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064

At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/24/2020 12:36:29 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) [gky2@cdc.gov]
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Thanks. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 24, 2020 12:04 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Uwe,

Thank you very much!

CDC is planning to provide oligos and control material labeled separately from our domestic EUA product for Research Use Only to international laboratories (non-U.S.).

Regards,
Steve

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:34 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Julie, Steve and Steve,

FDA also agrees with your pre-positioning proposal to distribute tests and control to the LRN labs and public health labs before the EUA authorization.

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One nuance, are you also planning to provide the device outside of the US?

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:29 AM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

FDA agree with use of "Product Information Sheet" rather than Instructions for Use and do not have any additional comments on the box/vial labels.
Please make sure to submit the developed product information sheet as part of your labeling package with the EUA submission (should include Instructions for use, product information sheet, final box/vial labels) and make sure it includes instructions to the end user for obtaining the full Instructions for Use document.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 5:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Sorry with attachment!!

**Kim Sapsford-Medintz, Ph.D.**
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**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>

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**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

(b) (5)

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(b) (5)

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
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gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/21/2020 10:41:30 AM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]
**Subject**: RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Works for me.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, January 21, 2020 10:33 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

How is 1pm?

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 10:20:09 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Just wondering if we should schedule a update call sometime today?

If so let me know times that would work best for CDC and I will send out a meeting invite

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Monday, January 20, 2020 7:45 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Excellent, thanks Kim!

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, January 20, 2020 7:41 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Steve – also I can't remember if I attached this previously but please see attached the manufacturing section CDC used for their most recent Molecular EUA (the trioplex ZIKV/DENV/CHIKV) just to give you example.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Monday, January 20, 2020 7:35 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Will do. Thanks Kim!

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, January 20, 2020 7:32 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Great thanks Steve – if that is the plan please include that in the EUA template under "materials required but not provided" and include the ordering information.

Cheers
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Monday, January 20, 2020 7:10 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Hi Kim,

Thanks for the quick response!

I believe the current thinking is that HSC will be ordered separately.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, January 20, 2020 7:06 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Steve –

The revisions look good. Do you also plan to include the HSC – Human Specimen Control - material in the kit or can that be ordered separately from CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Monday, January 20, 2020 6:44 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

AMERICAN OVERSIGHT

Just following up on the vial and package draft labels. I've incorporated the edits requested and expanded to the specific primer/probe components we anticipate for the panel.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:10 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All

Couple of minor comments on the labelling.

Also in the news:
Translated w/google translate

http://wjw.wuhan.gov.cn/front/web/showDetail/2020011909074

Wuhan Municipal Health Commission | Published: 2020-01-19 00:43:34 | Hits: 2429 | Font size: Large Middle Small

At 04:00 on January 17, 2020, 4 patients were cured and discharged, with 17 new cases and no deaths.

Analysis of the epidemiological data of the previously released cases of pneumonitis infected by the new coronavirus found that some cases had no history of contact with the South China Seafood Wholesale Market. On the basis of standardizing pre-screening triage and fever diagnosis, optimized test kits were used to sample and monitor unidentified pneumonia cases for fever diagnosis and isolation in the city, and 17 new types of coronavirus positive were detected. After comprehensive research and judgment by clinical experts, 17 cases were confirmed as confirmed cases, and all were treated in Wuhan Jinyintan Hospital and related designated hospitals. Of the 17 newly diagnosed cases, 3 were severe cases. The next step will continue to carry out the detection of suspected cases in the city.

As of 24:00 on January 17, 62 cases of pneumonitis with new coronavirus infection have been reported in our city, 19 cases have been cured and discharged, 8 cases are being treated in severe cases, and 2 cases have died. The remaining patients are in stable condition. Institution receives isolation treatment. A total of 763 close contacts have been tracked, 681 medical observations have been lifted, and 82 people are still receiving medical observations. Among the close contacts, no related cases were found. Epidemiological investigations of new cases and follow-up investigations of close contacts are ongoing.

http://wjw.wuhan.gov.cn/front/web/showDetail/2020011909075

On January 17, 2020, national and provincial experts screened some cases of unexplained pneumonia that were screened by community health service centers in the city, and found and treated in various hospitals, based on their clinical manifestations, epidemiological history, and optimization. The positive results of the novel coronavirus nucleic acid detected by the subsequent detection kit were comprehensively judged, and 17 cases of pneumonia cases with new coronavirus infection were newly identified.

Of the 17 patients, 12 were males and 5 were females; 9 were under 60 years of age, 8 were 60 years of age and older, the youngest was 30 years old and the oldest was 79 years old; the onset date was before January 13, 2020; first symptoms Fever, cough, or fever with cough; 3 cases were severe, and the rest were stable. Except for 2 cases of severe illness, which was temporarily unsuitable for transfer, the remaining 15 cases had been transferred to Wuhan Jinyintan

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Hospital for centralized treatment.

The epidemiological investigation of 17 new cases is in-depth, and close contacts are also being tracked.

In the next step, the city will continue to expand the search scope, identify suspected cases, and conduct sampling tests.

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

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Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/18/2020 2:02:43 PM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; Mielech, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bae0460265994251a830aa649b152ebc-Anna.Mielec]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject**: RE: Cut-off change - lot release testing criteria

Thanks you.

Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 18, 2020 1:41 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

We are working to find answers to your questions below and will get back to you as soon as we have the information.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 3:53 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum,

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Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thank you for this information. A couple of additional questions regarding the manufacturing of the different lots at CDC:
Is there anything different in manufacturing of the lots being used at CDC headquarters and for the EUA:

1. Where they manufactured in the same room or at different locations at CDC?
2. Were there any differences in raw material?
3. Were there any changes made between the CDC headquarters lot and the EUA lot?
4. Were there an subsequent changes made for the current production of the new lot?

Also, did CDC ever test the lot used at CDC headquarters following the newly established more stringent QC testing scheme (e.g., running 288 NTC replicates on 3 samplings of N1, N2, and N3)?

Thanks,

Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
For clarification the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel consists of two separate boxes. Box #1 contains the primers and probes as described below:

**2019-nCoVEUA-01 Box #1: Primers and Probes**

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
|---|---|---|---|---|
| 2019-nCoV_N1 | RV202001 | 2019-nCoV_N1 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N2 | RV202002 | 2019-nCoV_N2 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N3 | RV202003 | 2019-nCoV_N3 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| RP | RV202004 | Human RNase P Forward Primer/Probe Mix | 22.5 nmol | 1000 |

Primer and probes from three individual boxes that were randomly selected after kit assembly were tested as presented in the powerpoint file provided earlier.

Also as requested, please find attached the QC testing process of primer/probe reagents at bulk and post-fill analysis.

We hope this helps to clarify the data presented and addresses your request.
Thank you very much.
Steve

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**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 10:07 AM
**To:** 'Scherf, Uwe' <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
The samples tested represent 3 randomly selected kits at "final kit". I hope this addresses your question.
We will send a meeting invitation shortly for 1pm if that time is still OK for your team.
Thank you very much.
Steve

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing the sampling scheme of your heightened NTC QC testing that was used for this evaluation.

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara

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<Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| 2019-nCoV_N1 | 8/288 | 2.78% | 36.38 | 35.57-37.44 |
| 2019-nCoV_N2 | 0/288 | 0% | N/A | N/A |
| 2019-nCoV_N3 | 16/288 | 5.56% | 37.93 | 35.62-39.85 |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much
Steve

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Steve,

Thank you for the update, when will you send us the performance data for all assays to understand your rational to exclude N3?

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

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Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

Q1: Clarify how many total lots of EUA reagents are being distributed?
(b) (4)
.

Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (4)

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (4)

Please let us know if you have any additional questions.
Thank you very much!
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

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Per your email: (b) (4)
. [Q1: Clarify how many total

lots of EUA reagents are being distributed?] (b) (4) [redacted] [Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (4) [redacted] [Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately].

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5) [redacted]

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(b) (5)

[redacted]

If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts in investigating this reagent issue, please provide information regarding the reagent lot release testing criteria and results at the CDC for the original reagent lot, as well as the new replacement reagent lot for the N3 assay. We are particularly interested in learning how many replicates of NTC/HSC were tested during reagent release testing, and if any low level false positive results were ever observed during the lot release testing at the CDC. If low level false positive results were observed during reagent release testing at the CDC, at what frequency they were observed, and what were the Cts observed?

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Thanks,
Uwe

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

1. The number of national and international laboratories which have received the CDC test panel.
2. Provide an update on:
   - The number of labs that have successfully verified the CDC test panel.
   - The number of labs that observed N-3 false positive results in the negative control material and therefore could not verify the assay.
   - The number of labs that observed N-1 false positive results in the negative control material.
3. Clarify whether the false positive results for N-3 and N-1 occurred in the same laboratory or were reported from different laboratories.
4. Clarify whether CDC have received any signal of false positive results for the N-2 components from any of the laboratories.
5. In regards to manufacturing sites:
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC test panel run at CDC headquarters in Atlanta.
   - Provide the name(s) and address(es) of all manufactory site(s) of test components used for the CDC issued EUA test panel distributed nationally and internationally.
   - Provide the name(s) and address(es) of manufactory site(s) that CDC intends to use for manufacturing future EUA test panel lots.

Thanks,
Uwe

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

There are laboratories that have not had any problems and are testing. We will need to work to find more detailed information for you.

Thanks,
Julie

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding that public health and the state labs that didn't have any problems with their verification are proceeding with testing, is that correct?

Thank you for your feedback.

Uwe

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 1:58:26 PM
**To**: Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Attachments**: DRAFT CDC Surveillance EUA Request Cover letter 20FEB2020 6pm.docx; COVID_19 sentinel surveillance Feb 21 2020 FINAL CLEAN.docx; DRAFT SARS-CoV-2 surveillance risk benefit 20Feb20 6pm.docx

**Importance**: High

Brittany,

Can you please do a benefit risk assessment for the surveillance study attached. The benefit risk sheet is a separate document.

Thanks Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Friday, February 21, 2020 10:40 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** DRAFT CDC EUA Request for Sentinel Surveillance Activities

Good morning Kim and Uwe,

Please find attached a draft EUA request submission for the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in sentinel surveillance activities. We would appreciate your review of this draft submission to ensure it contains the information and wording request necessary to support FDA's planned issuance of a second letter of authorization for the diagnostic panel to support this critical epidemiologic activity.

Please do not hesitate to reach out with questions, ideas, recommendations as you review the attached. I look forward to hearing from you.

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Warm regards,

Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

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OLSS Office of Laboratory Science and Safety

*Strengthening the culture of laboratory science and safety at CDC*

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T OF HEALTH & HUMAN SERVICES
Service

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

February 20, 2020
Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
CDRH Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Request for Emergency Use Authorization:**
**CDC 2019 Novel Coronavirus (nCoV) Real-Time RT-PCR Diagnostic Panel (EUA200001)**

Dear Dr. Hahn,

Please find enclosed the Centers for Disease Control and Prevention's (CDC) formal request for Emergency Use Authorization (EUA) regarding the use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel for public health surveillance activities that do not fall within the currently authorized intended use of the assay (EUA200001). This test detects SARS-CoV-2, the virus that causes COVID-19, and is an essential tool in surveillance activities to support situational awareness, inform strategy development and guide response to COVID-19. Due to the exigent nature of this request, an electronic copy of the official submission of this EUA request is also being concurrently provided to Dr. Uwe Scherf, Director, Division of Microbiology Devices, Center for Devices and Radiological Health (CDRH) via e-mail.

CDC requests that the intended use of the assay and CDC testing guidance remain unchanged for diagnostic use of the test, as authorized in EUA. CDC asks for authorization to use the test in surveillance activities that are necessarily outside the current testing recommendations and will be used to guide future testing guidance and other response strategies.

CDC has identified an urgent need to partner with jurisdictions across the United States to perform a surveillance activity to identify possible transmission of SARS-CoV-2 among individuals without a clear epidemiologic link (contact with known cases or history of recent travel to mainland China). Thus, this testing will not be among individuals who meet the current CDC testing guidance and are therefore not included in the currently authorized populations that may be tested diagnostically with the 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Individuals tested in this sentinel surveillance to detect signals of potential community transmission of SARS-CoV-2 will include persons presenting with influenza-like illness. This sentinel surveillance activity will initially be performed in 6 health jurisdictions across the country (New York, New York; Chicago, Illinois; Seattle, Washington; San Francisco, California; Los Angeles, California; Honolulu, Hawaii), though additional jurisdictions may be added over the course of the surveillance activity.

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Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in support of the sentinel surveillance activity will be conducted according to the FDA-authorized instructions for use and will include all repeat testing and confirmatory testing recommended for diagnostic testing. Testing over the course of the sentinel surveillance activity will be performed at CDC and at public health laboratories. Samples tested by public health laboratories will be forwarded to CDC for additional testing as outlined in the authorized instructions for use.

As CDC continues to investigate this outbreak, the use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in surveillance activities within the United States is imperative. CDC anticipates that this sentinel surveillance activity will be but one of the surveillance activities needed to support our understanding of the COVID-19 threat and to guide our decision-making over the course of this response effort.

At this time, there are no adequate, approved (cleared), and available alternative tools that can detect SARS-CoV-2 during the acute phase of infection in the United States. Therefore, CDC requests this EUA to allow use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel to support critical surveillance activities within the U.S. public health system by providing a rapid diagnostic tool to qualified laboratories for the detection of RNA from 2019-nCoV in surveillance samples. Authorization of use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel for surveillance meets an unmet need of providing qualified laboratories a rapid diagnostic tool for evaluation of specimens from patients in the acute phase of infection during this public health emergency.

Please find enclosed CDC's guidance to participating jurisdictions for conduct of the sentinel surveillance activity, and an assessment of known and potential benefits and risks associated with the surveillance activity.

If you have any questions regarding this submission, please contact:

Laura E. Rose
Regulatory Affairs Activity Lead
Office of Laboratory Science
Office of Laboratory Science and Safety
Centers for Disease Control and Prevention
**[ HYPERLINK "mailto:LERose@cdc.gov" ]**
(404) 639-1084

Sincerely,

Robert R. Redfield, M.D.
Director

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Centers for Disease Control and Prevention

Enclosures: 3

- Appendix A:_Guidance for Conducting Sentinel Surveillance to Detect Signals of Potential Community Transmission of SARS-CoV-2
- Appendix B:_Assessment of Benefits and Risks

cc: Dr. Uwe Scherf, CDRH/FDA
Joseph Foster, OD/CDC

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# Guidance for Conducting Sentinel Surveillance to Detect Signals of Potential Community Trans mission of SARS-CoV-2

February 21, 2020

## Background

The Centers for Disease Control and Prevention (CDC) and state and local health departments are responding to an outbreak of respiratory disease termed coronavirus disease 2019 (COVID-19) that was first detected in Wuhan City, China in December of 2019. The virus, termed severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has since spread to many other countries, including the United States. Current strategies for preventing the spread of infection include rapid detection and isolation of cases and tracing and monitoring their close contacts for signs of illness.

If community transmission of SARS-CoV-2 were occurring in the US, the only way to detect it would be to test patients without a known exposure. Because mild disease appears to be common with COVID-19, initial cases reflecting local community transmission are likely to be mild. However, current recommendations for who to test for SARS-CoV-2 in the US rely on a case definition that includes specific clinical (fever and signs of lower respiratory tract infection) and exposure criteria (recent travel to China or close contact with a known infected person). Adherence to this definition precludes identification of persons with mild illness who do not have a travel history or exposure to a known case. Detecting community transmission by testing individuals who do not meet current testing criteria is critical for shaping future response activities including testing criteria, quarantine guidance, investigation protocols, and additional public health preparedness measures. Most critically, results of sentinel surveillance will guide decisions on whether the national public health approach should shift from an aggressive containment strategy (e.g., use of quarantine for all contacts) to one focusing on pandemic preparation and mitigation (e.g., protecting health care workers by employing universal infection control precautions in health care facilities for all cases of fever and respiratory illness, recommending that mildly ill individuals stay home to prevent wider transmission, focusing on prioritizing healthcare resources on those most critically ill and consideration of community mitigation measures such as social distancing).

## Objective

Conduct sentinel surveillance at select sites to determine if unrecognized community transmission of SARS-CoV-2 is occurring.

## Methods

### *Surveillance populations*

To identify evidence of community transmission, we propose setting up sentinel systems in some local United States jurisdictions with early COVID-19 cases or communities with large numbers of travelers from places where transmission is occurring to obtain respiratory specimens for SARS-CoV-2 testing in patients who deny recent travel history to China or direct contact with a COVID-19 case. To start, we propose establishing this "sentinel" surveillance at six sites: Los Angeles and San Francisco, California; Seattle, Washington; Chicago, Illinois; New York City, New York; and Honolulu, Hawaii. Additional sites may be added as testing capacity increases.

Under sentinel surveillance, each jurisdiction will prospectively obtain respiratory specimens collected from participants with fever and upper or lower respiratory symptoms who are presenting for clinical

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care. Some sites may choose to do this using an existing surveillance system for influenza or other respiratory viral diseases, while other sites may set up a system specifically for COVID-19 community transmission.

Each jurisdiction will determine the best source of specimens based on the predicted likelihood of detecting SARS-CoV-2. Some considerations for selection include:

1. Population served: To increase the likelihood of detecting SARS-CoV-2 if it is circulating in the US, facilities or laboratories serving populations with frequent travel from areas where transmission of SARS-CoV-2 is occurring should ideally be targeted.
2. Healthcare setting: Current clinical criteria for testing includes the presence of lower respiratory tract illness. Outpatient settings offer the opportunity to widen the scope of testing by including persons with milder respiratory infections. Other settings, including emergency department and hospital settings, are also acceptable alternatives since persons meeting the clinical criteria in those settings may not be tested because they do not meet exposure criteria (i.e. travel to China or close contact with a known case).
3. Specimens negative for other respiratory pathogens: Specimens with the highest yield may be those that are negative for influenza and other respiratory pathogens. Identification of an alternative (non-COVID-19) explanation for a person's respiratory illness may make COVID-19 detection in the specimen less likely, with the recognition that co-infections may occur.
4. Age group: While most reported COVID-19 cases have occurred in adults and there have been no cases detected in US children, it is possible that younger populations manifest more mild symptoms that would not be detected under current testing criteria. It is therefore recommended that sentinel surveillance include both children and adults.
5. Identification of persons tested: Since current recommendations include isolation of patients who have COVID-19 as well as contact tracing of close contacts, specimens will be obtained from persons who can be contacted for follow-up of a positive test (see **Follow-up of persons with SARS-CoV-2 detections** below).

Examples of how surveillance will be conducted at select sites are outlined below. Additional sites will follow similar surveillance procedures.

- Los Angeles, California: LA County DPH will conduct sentinel surveillance in the San Gabriel Valley region of LA County, which has a population of 1.35 million people and comprises 8 of the 10 cities with the highest proportion of Chinese immigrants in the U.S. We approached 10 hospitals in this region and identified 3 hospitals that conducted rapid influenza testing by using a viral transport media that is compatible with SARS-CoV-2 testing. These hospitals agreed to send to LA County DPH swab specimen that test negative for influenza. One of the hospitals (178-bed capacity) indicated that they are currently conducting an average of 40 rapid influenza tests daily, of which approximately 30% are positive for influenza. Therefore, we expect to receive approximately 25 swabs/day for testing at LA County DPH public health lab. Further, the hospital indicated that 95% of the rapid influenza tests are conducted in the Emergency Department.

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FDA-CVD-SCHERFU-00017593.0002 FDACDRH-p8-AO-001410
MULTI-HHS-20-0522-B, 20-0523-A-002339

- New York City, New York: In Phase I (CDC lab performs all testing), NYC will seek to work with up to 3 outpatient facilities operated by Charles B Wang Community Health Centers (CBWCHC). These centers are located in two communities with a high proportion of Chinese language speakers: 1 adult center and 1 pediatric center in lower Manhattan (Chinatown) and 1 combination adult and pediatric center in Flushing, Queens. Since the specimen number is capped at 50 per city per week we will aim to collect 25 specimens per borough per week. The New York City Department of Health and Mental Hygiene (DOHMH) plans to station staff at each location to facilitate data collection, specimen collection, tracking, accessioning, and transport. Any patient who denies international travel in the 2 weeks before illness onset AND tests negative for influenza, and is well enough to be sent home, will be offered coronavirus testing. Because these centers use rapid influenza test kits, new swabs will need to be collected. DOHMH will supply the center with appropriate swabs and viral transport media. Providers will be asked to inform the patients of the plans to test them for COVID-19 as part of the general consent process for their medical evaluation, as well as inform them that if positive, they will be asked to self-isolate at home until 10 days after symptoms resolve. Patients will be able to opt out. At the time of specimen collection, DOHMH will collect additional information from patients on clinical symptoms and illness onset, recent travel (in the preceding 2 weeks) and occupation. To facilitate transport to CDC, specimens will be collected Mondays, Tuesdays, and Wednesdays including evening hours as per the center's schedules and will be transported to PHL and shipped to CDC either once or twice per week. DOHMH staff will be on site at the health centers to facilitate specimen and data collection. In the likely case that we pursue identified testing, positive and negative results will be returned to the provider. Positive results will prompt a rapid case investigation by DOHMH to reconfirm absence of travel history or known epidemiological links. In this scenario, we propose to isolate patients at home who have tested positive until 10 days after their illness resolves. Close contacts (household, intimate partners) will be identified BUT not placed in quarantine or home monitoring. Close contacts of cases who are confirmed with COVID-19 will be monitored daily and medically evaluated should they develop symptoms. The project will be presented to the DOHMH Institutional Review Board for review and request for exemption as public health surveillance. Once the CDC EUA is available to the NYC Public Health Laboratory, if there is still a need to document community transmission (i.e., if this has not yet been established), we would expand to additional sites including acute care settings, such as emergency departments serving these same areas of the city.

***Collection, shipping and testing of specimens***

Acceptable specimens include nasopharyngeal (NP) (preferred) or oropharyngeal (OP) that are collected with synthetic fiber swabs with plastic shafts. To maximize the number of persons tested, only one specimen should be collected per patient. Calcium alginate swabs or swabs with wooden shafts should not be used since they contain substances that inactivate some viruses. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media. Respiratory specimens should be transported in accordance with CDC guidance: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.

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FDA-CVD-SCHERFU-00017593.0002 FDACDRH-p8-AO-001411
MULTI-HHS-20-0522-B, 20-0523-A-002340

**Guidance for Conducting Sentinel Surveillance to Detect Signals of Potential Community Trans mission of SARS-CoV-2**

February 21, 2020

Specimens will need to be labelled so they are distinguished from specimens obtained from persons under investigations (PUIs). The labeling convention for sentinel surveillance will be "SURV-state abbreviation—unique number" (e.g. SURV-WA-001).

Specimens being tested at CDC should be shipped to:

**ATTN: STAT LAB**
**c/o Steve Lindstrom, Shifaq Kamili (Unit 84)**
**Respiratory Viruses Diagnostic Laboratory / DVD**
**Centers for Disease Control and Prevention**
**1600 Clifton Road, NE**
**Atlanta, Georgia, 30333**
**Telephone: 404-639-1587**

Please email completed shipping logs to dsrstat@cdc.gov when the shipment is in route.

The respiratory specimens will be tested for SARS-CoV-2 using CDC's 2019-Novel Coronavirus Real-Time Reverse Transcriptase-PCR Diagnostic Panel that was authorized for use by the Food and Drug Administration under an Emergency Use Authorization (EUA) on February 4, 2020. It is intended for use with upper and lower respiratory specimens collected from persons who meet specified clinical and epidemiological criteria for testing. CDC will submit a new EUA request to conduct the surveillance activity outlined in this guidance. The specimens will be tested at CDC or at a public health laboratory designated by CDC as qualified and certified under the Clinical laboratory Improvement Amendments (CLIA) to perform high-complexity testing. Under current guidance, persons who test positive for SARS-CoV-2 would be identified, the positive result confirmed by CDC, and appropriate public health action would be pursued (see **Follow-up of persons with SARS-CoV-2 detections** below).

The table below shows the number of specimens that would need to be tested in order to detect one SARS-CoV-2 infection given the specified community prevalence and level of confidence. The number of specimens tested will depend in part on the availability of test kits. While CDC is doing all testing, we anticipate testing ~50 specimens a week per site (300 total specimens). Once kits are available at public health laboratories, we anticipate that each site would have enough assay reagents to test ~200 specimens a week.

| Prevalence of nCoV to detect | Confidence level | # of specimens needed to test to identify 1 nCoV positive | Approx. # of nCoV kits needed** |
|---|---|---|---|
| 0.50% | 95% | 598 | 1 kit |
| 1.00% | 95% | 299 | .5 kit |

** Assumes each kit can test 700-800 specimens using a full plate.

***Follow-up of persons with SARS-CoV-2 detections***

Current CDC guidance recommends that persons with confirmed SARS-CoV-2 infection should be isolated either in a healthcare facility or at home depending on their clinical management requirements. Isolation is also recommended if the initial test is indeterminate at CDC or if the test is positive or

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indeterminate at a public health laboratory pending results of the confirmatory test at CDC. There are infection prevention and control recommendations for healthcare settings https://www.cdc.gov/coronavirus/2019-nCoV/hcp/infection-control.html and home settings (https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html). Additionally, contact tracing and risk assessments of contacts should be initiated as soon as possible after identification of the positive result. Guidance for risk assessment and public health management of persons with potential exposure to SARS-CoV-2 can be found at: https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html. Isolation and risk assessment guidance may change based on changes to patterns of SARS-CoV-2 circulation identified by sentinel surveillance or other means.

***Considerations for when current containment strategies may change based on results of sentinel surveillance***

The purpose of this surveillance activity is to determine if SARS-CoV-2 viruses are circulating in the community among persons with no exposures known to be associated with infection. If cases are detected in this surveillance that can't be linked to a known exposure, this information will help inform local and national decisions on measures to limit spread of the virus, including shifting the public health response focus to be more aligned with mitigation of a potential pandemic. A framework for this decision process is being developed by CDC in parallel with this surveillance system, and will be discussed with collaborators before the start of surveillance.

***Data collection and analysis***

Data collected will include basic demographics of the person tested (age and sex), county and state where testing occurred, setting where test was done (outpatient clinic, emergency department, hospital), date of specimen collection and result of SARS-CoV-2 testing. Only these data will be shared with CDC through a secured data transmission pathway. Health departments will also collect the hospital/facility name and person's name and contact information so appropriate follow-up of a positive test result can occur. These data will not be shared with CDC. Data will be presented in aggregate as the proportion of patients who test positive out of those tested, stratified by location, age and sex. CDC will only receive de-identified data individual or aggregated data.

**Human subjects considerations**

The activities under this protocol are part of public health surveillance and not considered research by CDC. Individual sites may have different determinations. The specimens obtained will be collected as part of routine clinical care or as a result of enrollment in another study. However, specimens will be identifiable to site staff since finding a positive SARS-CoV-2 result does have implications for clinical management of the patient. Therefore, it is recommended that the protocols for each participating site include patient consent or notification (and documentation in the medical record) that SARS-CoV-2 testing is being done prior to specimen collection. An example of the notification sheet is included in Appendix A.

**Communication plan**

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**Guidance for Conducting Sentinel Surveillance to Detect Signals of Potential Community Trans mission of SARS-CoV-2**

February 21, 2020

In preparation for the possibility that community cases not linked to travel will be identified through this sentinel surveillance, CDC and sites are developing a communication plan. It will outline for the public how surveillance is being conducted, how numbers of positives may translate into unrecognized cases in the communities where surveillance is being conducted and how containment or mitigation strategies may change as a result of the findings.

**Appendix A**

The *[State Department of Health]* and the Centers for Disease Control and Prevention (CDC) are closely monitoring an outbreak of respiratory disease caused by a novel (new) coronavirus. Some person-to-person spread of this virus outside China has been detected. In the United States, no ongoing community spread of the virus has been found. Because of your symptoms today, we would like to test to see if you (or your child) have an infection caused by this new coronavirus. Results from this test could help identify spread of the virus in the community.

A healthcare worker will use a sterile cotton-tipped swab to reach gently through your nostril (your child's nostril) to swab the inside of the back of your (your child's) nose. The swab will be sent to a public health laboratory. You (your child) may experience some temporary discomfort from the swab. If the test is positive, you might be asked to restrict your (your child's) movement. This may mean that you ( your child) would need to stay away from other people until the infection has cleared. Only the persons conducting this investigation and the state or local health department will know about your personal (and your child's) information or the results of testing. Beyond this, your name (and your child's name) will be kept private and will not be shared.

There are currently no plans for future use of your laboratory specimens but it is possible the information will be used in future public health investigations. However, these will NOT include genetic analysis.

If you have any questions you can contact *[DPH contact info?]*

Please sign here to indicate that you have read and understand this information:

_____

Print Name

_____

Signature/Parent's/guardian's signature

_____

Date

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Assessment of Benefits and Risks:

CDC has considered both the risks and benefits of conducting sentinel surveillance for detection of local transmission of SARS-CoV-2. The positive and negative impact to study participants, to the communities selected for testing, and to national emergency response activities are summarized below. CDC has determined the benefits of this surveillance activity outweigh the known and potential risks.

| Benefits | |
|---|---|
| Surveillance Participants | • If positive for the presence of SARS-CoV-2 RNA, the participant will know a potential cause of their symptoms/illness<br>• Individuals who test positive will have access to appropriate medical care<br>• Knowledge of infection could allow action to be taken to limit transmission to others, aid in identification of contacts who may have been exposed, and allow for early intervention in illness among contacts |
| Communities | • Health care providers would know their risk of exposure and could be actively monitored for signs of illness<br>• Identification of the presence of new chains of transmission could help limit spread<br>• Local public health authorities could assess the risk of spread and provide appropriate guidance to the public |
| National Emergency Response | Knowledge of local transmission allows for:<br>• more accurate situational awareness<br>• better prioritization of health care resources to the most critically ill<br>• better-informed decisions on national public health approach and the most appropriate strategies for detection and mitigation of further transmission |
| Risks | |
| Surveillance Participants | • Positive or indeterminate test results would require isolation of individuals and negatively impact work and home life<br>• Individuals isolated following indeterminate or positive results could encounter stigmatization |

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| | |
|---|---|
| Communities | • Health care professionals providing care to identified cases could face immediate furlough, resulting in potential loss of pay<br>• Communities in which local transmission has been identified could face stigmatization<br>• Sampling may fail to identify transmission occurring |
| National Emergency Response | • Media coverage of positive individuals in a community could result in panic and decreased participation in ongoing surveillance studies<br>• Sampling may not reveal an accurate picture of actual transmission of SARS-CoV-2 in the US |
| Conclusions:<br>Do the probable benefits outweigh the probable risks? | |
| CDC believes that the benefit of these surveillance activities outweighs the risk, and awareness of these risks will help CDC mitigate their effect through communication and coordination with jurisdictions performing surveillance. | |

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/21/2020 2:53:06 PM
**To**: Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Brittany,

Thanks this was the CDC's benefit risk assessment. I think we should keep our comments to their statements to a minimal.

What would FDA's benefit risk assessment look and conclude?

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:44 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

I had a number of edits and questions regarding the BR assessment provided by CDC, but I think they can be easily and quickly resolved. I wrote some proposed language as answers to many of my questions to try and speed this along.

I quickly read the other documents, but did not comment. Would you like me to comment on those as well? I didn't see anything egregious, but my read-through was admittedly very quick.

Brittany

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 1:58 PM
**To:** Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

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**Subject:** FW: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Importance:** High

Brittany,

Can you please do a benefit risk assessment for the surveillance study attached. The benefit risk sheet is a separate document.

Thanks Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Friday, February 21, 2020 10:40 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** DRAFT CDC EUA Request for Sentinel Surveillance Activities

Good morning Kim and Uwe,

Please find attached a draft EUA request submission for the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in sentinel surveillance activities. We would appreciate your review of this draft submission to ensure it contains the information and wording request necessary to support FDA's planned issuance of a second letter of authorization for the diagnostic panel to support this critical epidemiologic activity.

Please do not hesitate to reach out with questions, ideas, recommendations as you review the attached. I look forward to hearing from you.

Warm regards,
Laura

==
Laura E. Rose, RAC
*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*
*Office of Laboratory Science and Safety (OLSS)*
**Centers for Disease Control & Prevention**

AMENDED
OFFICIAL

P: 404-639-1084 | E: LERose@cdc.gov

---

OLSS Office of Laboratory Science and Safety

*Strengthening the culture of laboratory science and safety at CDC*

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/23/2020 11:08:33 AM
**To:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) [zey9@cdc.gov]
**CC:** Spies, Stacey (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e485767534a483f864f0222cf10a505-HHS-khq7-cd]; Langley, Gayle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09640f099c74468d9480b73a6d194d5d-HHS-fez7-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Attachments:** COVID_19 sentinel surveillance Feb 21 2020 FINAL CLEAN_FDA 2.23.2020.docx; DRAFT SARS-CoV-2 surveillance risk benefit 20Feb20_FDA_2.23.2020.docx; DRAFT CDC Surveillance EUA Request Cover letter 20FEB2020 6pm FDA 2.23.2020.docx

Dear Laura,

Attached please find the following documents you submitted on February 21, 2020 to support the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in surveillance activities. These documents have been reviewed and edited by FDA's OCET and OCC.

1. Draft COVID-19 sentinel surveillance
2. Draft SARS-CoV-2 surveillance risk benefit
3. Draft CDC Surveillance EUA Request Cover letter

Please do not hesitate to reach out to me with questions.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:54 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

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Dear Uwe,

Please find attached the final documents to share back with Laura Rose at CDC.

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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Kim.Sapsford@fda.hhs.gov






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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:45 AM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Awesome. I am at the CDC in the Emergency Operations Center and have connected with Wendi and working in the Lab Office. I am going to an 11 am briefing shortly.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 10:42 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Confirming they have OCC's okay! Thanks, all.

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 23, 2020 at 10:35:28 AM EST
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

If OCC is fine with these, then OIR can send them to CDC. Thanks!

---

**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Date:** February 23, 2020 at 8:54:28 AM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Nothing further from me, thanks.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 8:12 AM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

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Thanks Claire

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch

Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

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Kim.Sapsford@fda.hhs.gov






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---

**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 8:11 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

I had a couple minor editorial comments in the attached.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 8:03 AM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hello,

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I have two minor comments in the letter, highlighted in yellow and as a comment at the end of the letter and

One minor edits in one of the comments in the procedure (yellow) and a recommendation for clarification in the second to last sentence under the Consideration for Individuals Tested.

Thanks,

Uwe

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 7:27 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hello,

I had one minor comment on the letter, highlighted in yellow.

Thanks,

Jennifer

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 12:19 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

Please find attached the final documents with edits/comments back to CDC for your final review. I would like to send them back to CDC tomorrow morning. I will be unavailable 9-10:30am and 11:30 am – 1:00pm. If I could get any comments before 10:30 am hopefully I can send final docs back to CDC in the 10:30-11:30 window.

Thanks

Best regards

Kim

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch

Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

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Kim.Sapsford@fda.hhs.gov






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**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 6:22 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Importance:** High

Hi Team,

I just heard from Jeff. We have to get these documents cleaned up and back to CDC ASAP, per direction of the FDA Commissioner and the CDC Director.

(b) (5)

So that CDC can get moving right away, FDA/CDRH will be granting enforcement discretion to CDC to begin prior to approval of the EUA but note that an EUA must be submitted and approved. I will draft that language.

Thanks,
Ellen

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 3:19 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Thanks Ellen,

Some comments/suggestions based on your feedback

Best regards

Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch

Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-0311

Kim.Sapsford@fda.hhs.gov






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**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 2:08 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

AMERICAN OVERSIGHT

Hi all,

I attached two of the documents with my comments and suggestions.

In the Risk/Benefit document: it says (b) (5)

Thanks,
Ellen

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 12:35 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

Revised documents attached for your review. (b) (5)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 10:57 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear All,

My comments are in the attached. (b) (5)

Anyway let me know what you think

Thanks

Best regards

Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 9:19 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Hi all,

Comments from me and Marcy on the protocol are attached (b) (5) . Please let us know if you have any questions – my calendar is up to date on when I am available this weekend.

Thanks!

Claire

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 5:22 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: DRAFT CDC EUA Request for Sentinel Surveillance Activities

All,

Here the draft EUA request we just discussed. Thanks for getting this addressed so quickly.

Uwe

**From:** Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Sent:** Friday, February 21, 2020 10:40 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** DRAFT CDC EUA Request for Sentinel Surveillance Activities

Good morning Kim and Uwe,

Please find attached a draft EUA request submission for the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in sentinel surveillance activities. We would appreciate your review of this draft submission to ensure it contains the information and wording request necessary to support FDA's planned issuance of a second letter of authorization for the diagnostic panel to support this critical epidemiologic activity.

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Please do not hesitate to reach out with questions, ideas, recommendations as you review the attached. I look forward to hearing from you.

Warm regards,

Laura

==

Laura E. Rose, RAC

*Regulatory Affairs Activity Lead, Office of Laboratory Science (OLSci)*

*Office of Laboratory Science and Safety (OLSS)*

**Centers for Disease Control & Prevention**

**P: 404-639-1084 | E: LERose@cdc.gov**

---

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*Strengthening the culture of laboratory science and safety at CDC*

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**From**: Uwe.Scherf@fda.hhs.gov [Uwe.Scherf@fda.hhs.gov]
**Sent**: 2/4/2020 8:28:16 PM
**To**: Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject**: Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Steve,
We are arranging to assure that when the package comes will be accepted. I heard the name of the CDC individual is Bryan Tayler. Do you have his phone number so I can call him.
Thanks, Uwe

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Date:** February 4, 2020 at 6:54:47 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/27/2020 4:33:36 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: Market Pathways - interview request

Yes

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 4:02 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Market Pathways - interview request

Should we ask the press office to handle this one

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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---

**From:** Tracy Schaaf (b) (6) @medtechstrategist.com>
**Sent:** Monday, January 27, 2020 3:53 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Market Pathways - interview request

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Hi Dr. Sapsford-Medintz, I'm a medical device market analyst working with MedTech Strategist's publication for the global device regulatory, reimbursement and market access space, called *Market Pathways*. I saw this great presentation online that you gave in October 2018 re: the Zika virus - https://www.medicalcountermeasures.gov/BARDA/Documents/BID2018_Presentations/Sapsford%20FDA%20EUA%20%20Zika%20BID18.pdf.

I was hoping I could schedule a few minutes of your time this week for a call to discuss FDA's emergency use authorization, and how this might apply to diagnostics that address the coronavirus outbreak?

Thank you so much in advance for your time and assistance!

Best,
Tracy

**Tracy A. Schaaf**
*Director, Industry Partnerships & Senior Market Analyst*
MedTech Strategist
Ph: (b) (6)
(b) (6) @medtechstrategist.com
www.medtechstrategist.com

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MARKET PATHWAYS

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/30/2020 6:50:01 AM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** 2019-nCoV 1/30/20 6 AM update

Jeff, Elizabeth Ellen, Bill and Tim,

1/30/20 6 AM update

**Status of activities on diagnostics**:

- Update on use of (b)(5) provision under section (b)(5)
  - (b)(5) (b)(5)
  - CDRH/OCET/OCC are drafting email to communicate use of enforcement discretion to allow distribution and limited testing
- Interactive review with CDC continues
  - Intended use and Contact Fact Sheet were discussed
  - Outstanding clinical data received late yesterday
  - Indication for Use updated and finalized
- Bioinformatic analysis to predict cross-reactivity of cleared respiratory panels to 2019-nCoV:
  - BireFire/BioMérieux and GenMark DX: analysis completed, technical note posted - no cross-reactivity predicted
  - FDA landing webpage's link to sponsor's technical note in preparation
- Additional IVD Developers, Thermo Fisher Scientific, (b) (4), (b) (5), Roche Molecular Systems Inc., Primer Design, have requested and received EUA review template. Now 14 total.
- Provided technical accuracies feedback on coronavirus briefing points for Denise Hinton ahead of E&C subcommittee briefing 1/30/20

**New roadblocks/challenges/delays:**

- Need clarification on negative clinical samples tested by CDC - data received late yesterday.

**Summary of sponsors requested and received review template:**

- Altona Diagnostics (1/17/20)
- Inbios International (1/23/20)

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- Quest Diagnostics (1/24/20)
- Quidel (1/25/20)
- Luminex (1/28/20)
- Qiagen (1/28/20)
- Abbott Diagnostics (1/28/20)
- Roche Molecular Diagnostics (1/28/20)
- BioMérieux (1/28/20)
- Thermo Fisher Scientific (1/29/20)
- (b) (4), (b) (5)
- (b) (4), (b) (5)
- Roche Molecular Systems Inc. (apparently independent of Roche Molecular Dx) 1/29/29)
- (b) (4), (b) (5)

Please let me know if you have any questions.
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**Sent**: 1/30/2020 8:35:35 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: Follow-up for EUA for nCoV

All,

See below, it look like Quidel has a TR-PCR in late stage development that does not cross-react with SARS nor with MERS, does not react with influenza A and B isolates, RSV, hMPV, Adenoviruses, parainfluenza, and other respiratory viruses and bacteria, BUT from the bioinformatics analysis seems to detect SARS and 2019-nCoV, both being SARS like viruses.

Will discuss tomorrow whether such an approach is good enough for an EUA, or whether we need a 2019-nCoV specific primer and probe signal.

Uwe

---

**From:** John Tamerius <jtamerius@quidel.com>
**Sent:** Thursday, January 30, 2020 8:22 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Follow-up for EUA for nCoV

Hi again Uwe. Thank you so much for calling me last night and on such short notice. Here is information that I hope is helpful to you:

(b) (4)



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(b) (4)

Uwe, if I get more information tonight or tomorrow, I will send it to you. Please let me thank you again for your call to me earlier this evening.

Best regards, John

Quidel Confidentiality Notice: This electronic mail message, including any attachments, may contain information that is privileged, confidential, proprietary in nature, or otherwise private information that is protected by law from disclosure or subject to copyright and is intended only for the designated recipient. If you are not the designated recipient, you are hereby notified that any use, disclosure, distribution, reproduction, review, or copying is unauthorized and may be unlawful. If you have received this electronic message in error, please notify the sender immediately and delete the message completely from your computer system. Thank you.

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**Sent**: 1/31/2020 5:46:13 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Rosemary's request

Kim,

I drafted some point for Rosemary which we can send tomorrow. Any additional points that come to your mind? I am fine with the goals.

Thanks, Uwe

**Subject:** USG Strategy needed for Diagnostics 2019-nCoV

CoV Dx Team,
I have been asked to coordinate the drafting of a USG strategy for CoV diagnostics, this will be used to brief up, including possibly to the NSC. Some of you will remember we had to do this for Zika in 2016. As expected , turn around is short, expectation is to have this ready early next week. Vaccine and Therapeutics groups are doing same, it is my understanding that everything will be vetted and approved through the official 2019-nCoV MCM Task Force that includes senior representative from every agency.

Using what we did for Zika as a template, I have started drafting, and will share draft later today, but wanted to give you a heads up so you can start working.
To speed things along, I ask:
1. Review the proposed goals below – are these acceptable – please suggest edits/revisions. Send your input back today - just at the WG level now, vetting with leadership will come later.
2. Please provide by ~~Monday morning~~ COB today a draft brief summary of what you are currently doing, and what you plan to do if funding is made available.
Current activities
- Developed pre-EUA Review template for nucleic acids available by request under CDRH-EUA-Templates@fda.hhs.gov
- Provided template to 19 IVD sponsors
- Interactive review of pre-EUA submitted by sponsors
- Proactive drafting of documents requires for EUA authorization (e.g., Letter of Authorization, Fact sheet for HCP & Patients)
- Requested cross-reactivity prediction assessment of sponsors with cleared devices with respiratory devices
- Establishing LOINC codes for 2019-nCoV molecular tests to advance outbreak surveillance through advanced data interoperability

Plan if funding is available
- Development of reference material for traceability purposes
-

3. Please provide ~~Monday morning~~ COB today by a list of any key challenges (other than access to samples/viruses) that you think need to be highlighted.
- Development of reference material for traceability purposes
- Develop material for verification purposes

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**Proposed goals:**

Leveraging individual federal agency roles and expertise, USG interagency collaborative efforts are underway to achieve the following 2019-nCov diagnostic strategic goals:

- Expand 2019-nCoV testing capacity by providing the CDC Real-Time RT-PCR Assay for Detection 2019-Novel Coronavirus under EUA to public health and DoD laboratories.
- Rapidly advance the development of specific and sensitive commercial molecular assays to detect 2019-nCoV in clinical samples for use in the U.S. under EUA, and outside the U.S.
- Advance the development of pan-coronavirus assays that can also differentiate known human coronaviruses (2019-nCoV, MERS-CoV, SARS-CoV, CoV 229E, CoV OC43, CoV NL63, and CoV HKU1) in clinical specimens.
- Identify, collect, produce, and distribute necessary development reagents and materials including viruses, antigens, clinical samples and reference panels for test validation.
- Define and communicate to developers the FDA regulatory pathways for development, approval or clearance, and emergency use of coronavirus assays.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/24/2020 1:00:06 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: (b) (4)

Yes, please set up the call and invite Michael Mair as optional. Can add to sitrep later. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 12:58 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: (b) (4) ?

Uwe – you want me to set up a meeting for 3 pm?

Also – include Michael Mair as optional?

Also – Include in the SITREP to OCET

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 12:38 PM
(b) (4) Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Conenello, Gina <Gina.Conenello@fda.hhs.gov>; (b) (4)
(b) (4)
**Subject:** RE: (b) (4) ?

(b) (4)

Would you and your team available for a quick call today at 3 PM EST?

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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**From:** (b) (4)
**Sent:** Friday, January 24, 2020 10:24 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Conenello, Gina <Gina.Conenello@fda.hhs.gov>; (b) (4)
(b) (4)
**Subject:** (b) (4) (b) (4)

Dear Uwe and Kim,

We know you all are likely busy with the emerging coronavirus and other business. We are looking to understand whether there is a (b) (4)

Regards,
(b) (4)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/28/2020 7:44:06 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject**: RE: nCoV 1/28/20 8 AM update:

Absolutely, Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 7:27 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: nCoV 1/28/20 8 AM update:

Uwe,

Thank you. I have a leadership call today at 4 PM which will be a standing call every Tuesday for the present time. Therefore, if anything of relevance comes up before then, please let me know.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 7:07 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** nCoV 1/28/20 8 AM update:

Jeff, Elizabeth, Bill, Don,

Enclosed 1/28/20 8 AM update:

**Status of activities on diagnostics**:

(b) (5)

- HCP and Patient Fact Sheets in final review by CDC and FDA
- CDC's 2019-nCoV PCR Diagnostic Panel package Verification Requirement insert received, under DMD review
- LOINC codes for 2019-nCoV molecular tests requested to advance outbreak surveillance through advanced data interoperability
- Letter of authorization drafted and in review with OCET and OCC
- Kept CDC and BARDA apprised of commercial entities that requested EUA Review Template to assist sister agencies in prioritizing potential funding/specimen sharing activities.

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**New roadblocks/challenges/delays:**

- Need clarification on negative clinical samples tested by CDC - Telecom scheduled to address issue 1/28/20 3 PM

Summary of sponsors requested and received review template:

- Altona Diagnostics (1/17/20)
- Inbios International (1/23/20)
- Quest Diagnostics (1/24/20)
- Quidel (1/25/20)

Please let me know if you have any questions

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/23/2020 10:25:37 AM
**To**: Lovell, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a4cfa4fc4094bbf8fac0e16bf710049-SXL]
**Subject**: 2019-nCoV update

Steve,

Here the update
**Division of Microbiology**:

- **has been proactively coordinating with CDC on diagnostic activities** and held Teleconferences with **CDC on Jan 8, 15, and 17, 21**, 2020.

- **CDRH/DMD finalized** an **EUA Interactive Review Template** specific for Molecular-based technologies detecting the 2019-nCoV. The objective is to share this document with IVD developers to proactively communicate the required data and expedite the regulatory process. The template was shared with CDC on 1/20/20.

- **DMD** is **currently working interactively** with **CDC to complete the data information needed to support an EUA request to FDA**.

- CDC will submit an EUA package to **facilitate distribution of the test** within the **Laboratory Response Network**.

- **As of 1/23/2020 one** other **IVD developers, Altona Diagnostics** has **requested** and **received** the Interactive Review Template from DMD.

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/30/2020 3:10:20 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: 2019-nCoV 1/30/20 6 AM update

Thanks, Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 2:14 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: 2019-nCoV 1/30/20 6 AM update

**Summary of sponsors requested and received review template:**

- Altona Diagnostics (1/17/20)
- Inbios International (1/23/20)
- Quest Diagnostics (1/24/20)
- Quidel (1/25/20)
- Luminex (1/28/20)
- Qiagen (1/28/20)
- Abbott Diagnostics (1/28/20)
- Roche Molecular Diagnostics (1/28/20)
- BioMérieux (1/28/20)
- Thermo Fisher Scientific (1/29/20)
- (b) (4)
- (b) (4)
- Roche Molecular Systems Inc. (apparently independent of Roche Molecular Dx) 1/29/29)
- Primer Design (1/29/20)
- (b) (4)
- (b) (4)
- Rheonix Inc. (1/30/20)

New today in red
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 6:50 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** 2019-nCoV 1/30/20 6 AM update

Jeff, Elizabeth Ellen, Bill and Tim,

1/30/20 6 AM update

**Status of activities on diagnostics**:

(b) (5)

- Interactive review with CDC continues
  - Intended use and Contact Fact Sheet were discussed
  - Outstanding clinical data received late yesterday
  - Indication for Use updated and finalized
- Bioinformatic analysis to predict cross-reactivity of cleared respiratory panels to 2019-nCoV:
  - BireFire/BioMérieux and GenMark DX: analysis completed, technical note posted - no cross-reactivity predicted
  - FDA landing webpage's link to sponsor's technical note in preparation
- Additional IVD Developers, Thermo Fisher Scientific, (b) (4), (b) (4), Roche Molecular Systems Inc., Primer Design, have requested and received EUA review template. Now 14 total.
- Provided technical accuracies feedback on coronavirus briefing points for Denise Hinton ahead of E&C subcommittee briefing 1/30/20

**New roadblocks/challenges/delays:**

- Need clarification on negative clinical samples tested by CDC - data received late yesterday.

**Summary of sponsors requested and received review template:**

- Altona Diagnostics (1/17/20)
- Inbios International (1/23/20)
- Quest Diagnostics (1/24/20)
- Quidel (1/25/20)
- Luminex (1/28/20)

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- Qiagen (1/28/20)
- Abbott Diagnostics (1/28/20)
- Roche Molecular Diagnostics (1/28/20)
- (b) (4)
- Thermo Fisher Scientific (1/29/20)
- (b) (4)
- (b) (4)
- Roche Molecular Systems Inc. (apparently independent of Roche Molecular Dx) 1/29/29)
- Primer Design (1/29/20)

Please let me know if you have any questions.
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**Sent**: 1/26/2020 12:51:30 PM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Potential composite comparator for the real clinical specimens collected from PUI subjects

Li,

Very thoughtful points. Getting information on the characterization of the negative samples will be essential. Like your idea of the composite comparator, question would be, since specimens are from PUI, which are likely still closely monitored and received instructed to come back for evaluation if their disease e.g. common cold progresses into serious cases, whether some PUI negative patient actually developed 2019-nCoV by now (after the initial negative results). (b) (5)

Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 10:51 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** Potential composite comparator for the real clinical specimens collected from PUI subjects

Looking back at the MERS-CoV CDC EUA, they also had data testing real clinical specimens. (b) (5)

However, if they provide all test results, including results of targeted sequencing and other CoV assays (at least two other), we may be able to develop a composite comparator, e.g., negative results from at least two other CoV assays can be considered as true negative, provided that the LoDs for the other CoV assays are equivalent or better than the CDC panel. All positives from the other CoV assays were further sequenced. Positive results by targeted sequencing (meeting sequencing quality criteria) can be considered as true positive.

(b) (5)

Li

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 5:14 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: This evening

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We might need to see what their LoD studies show. Uwe

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 5:12 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: This evening

(b)(5)

[redacted]

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 5:04 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: This evening

Thanks Li – sounds like they are (b) (5) [redacted]

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 4:58 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** This evening

Hi all,
I am signing off now, but will be back on line after 8:00 pm. Looks like we may get CDC's responses to our edits/comments tonight.
Thanks,
Li

AMERICAN OVERSIGHT

Li Li

Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 762-6200 | Fax: (301) 847-8512
li.li2@fda.hhs.gov






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**Sent**: 1/28/2020 4:13:51 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: 2019 Novel Coronavirus Cross Reactivity

Kim,

I do not think we need more details on the bioinformatics. The most important message it that their commercial tests do NOT cross-react.

Yes, they should post this on their website, so we can link from our FDA landing page to their official notice.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov
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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 4:08 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: 2019 Novel Coronavirus Cross Reactivity

Do we want to see more detailed information about the bioinformatics? Assume I should request they post in the documents section of their website?

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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Ph: (301) 796-0311
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**From:** Kristen J Kanack, PhD <Kristen.Kanack@biofiredx.com>
**Sent:** Tuesday, January 28, 2020 1:01 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** RE: 2019 Novel Coronavirus Cross Reactivity

Dear Kim,

I have attached our very brief tech note regarding non-crossreactivity of the Wuhan nCoV with any Coronavirus assays on BioFire Panels. Please let me know if you would like any detailed information about the bioinformatics assessment.

The tech note is available through our support and field teams. We can certainly post it in the documents section of our website as well if that is desired.

Best regards,
Kristen

**Kristen Kanack**
*SVP Regulatory & Clinical Affairs*
**BioFire Diagnostics, LLC**
Office: (b) (6)

**From:** Sapsford, Kim E [mailto:Kim.Sapsford@fda.hhs.gov]
**Sent:** Tuesday, January 28, 2020 10:46 AM
**To:** Kristen J Kanack, PhD <Kristen.Kanack@biofiredx.com>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** 2019 Novel Coronavirus Cross Reactivity

ATTENTION: Third party email, use caution with links and attachments.

Dear Kristen,

Due to the recent emergence in December 2019 of the novel coronavirus (2019-nCoV) in Wuhan City, Hubei Province, China, and in light of the increasing number of US cases, we are requesting all companies with cleared respiratory panels that detect human coronaviruses to perform a bioinformatic analysis against the released 2019-nCoV genome

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sequences, available through the GISAID Initiative (https://www.gisaid.org/), to predict if the test is likely to cross-react with the 2019-nCoV. We have heard that BioFire have already released a technical note on this topic but have not seen it posted online. FDA would like to include on our 2019-CoV webpage (https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-2019-ncov) a statement regarding any potential or lack of potential cross-reactivity with cleared respiratory panel devices that detect the common human coronaviruses and/or MERS-CoV. Please provided us (via email) with the conclusion from your bioinformatics analysis as soon as possible.

We appreciate your timely assistance in this matter
Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**Sent**: 1/21/2020 4:47:49 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Lias, Courtney H [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98a0fa6159ce418898b4b97381a76112-CDL]
**CC**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: DMD - 2019-nCoV update

Dear Jeff, Bill, Tim, and Courtney,

I just wanted to provide you an update on the 2019-nCoV outbreak - in light of the rapidly increasing number of cases reported in China over the weekend, the confirmed human-to-human transmission and based on our discussion with CDC today who indicated that the US detected their first case (which already made the news!).
DMD and CDC are working interactively to complete the data information needed to support an EUA request to FDA, and currently CDC anticipates a data package for review towards the end of this week, early next week. In addition WHO is holding an emergency meeting tomorrow to determine if the current situation should be declared a global health emergency.

Let me know if you have any questions

Best regards
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/27/2020 1:46:51 PM
**To:** St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]
**Subject:** FW: Daily 2 PM update

Email from last Friday

Uwe

---

**From:** Scherf, Uwe
**Sent:** Friday, January 24, 2020 1:37 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Daily 2 PM update

Jeff,

**Status of activities on diagnostics**:

- OCET and OCC support Center recommendation to exercise enforcement discretion to allow CDC to preposition their test
- Additional IVD Developer has requested and received EUA review template [Inbios International]
- Updating FDA 2019-nCoV landing webpage to provide information on cleared respiratory devices on predicting cross-reactivity to 2019-nCoV. BioFire/Biomerieux provided technical note to customer, FDA plans to link to this information and encourage other manufactures of cleared respiratory tests to perform similar analysis and provide this information. [e.g., GenMark Diagnostics, Qiagen, Luminex, Applied BioCode Inc]

**New roadblocks/challenges/delays:**

- Considerations for support of (b) (5) and OCET at 3 PM today

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**Sent**: 1/23/2020 4:05:13 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Notes from today

Excellent, thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:04 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Notes from today

Dear Uwe,

Draft email below (apologize for the delay):

Dear Jeff, Bill, Tim and Courtney,

(b)(5) [redacted]

DARPA and CDC are involved in diagnostic platforms, all specimens currently go to CDC for testing. There is consideration of (b) (5) [redacted] Number of vaccines in development based on MERS-CoV and SARS but there is a need for wild-type virus for the development of animal models. Funding is under discussion.

In addition, we had a call CDC today to discuss data requirements to support their EUA request. They anticipate a more complete data package for review very early next week. In other updates WHO have determined at this point that the Wuhan coronavirus is not yet a public health emergency of international concern.

In past emergencies we have worked directly with OCET on EUA package requests and cc CDRH as the final package moves up to OCET and the Commissioner. We would like to know if under the new OPEQ structure in CDRH if this is still the approach we should take or do OPEQ/CDRH want to be involved in the EUA request package review. We would like

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to know so we can factor this into the review timelines and if so please identify individuals we should bring up to speed – given the time sensitive nature of these EUA requests.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/20/2020 3:02:10 PM
**To:** STRÖHER, Ute [stroheru@who.int]
**CC:** Proctor, Tremyl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35056b97ee224343b77af6a0973d5d61-Tremyl.Proc]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: FDA visit

Dear Ute,

For the upcoming visit of my division on 2/4/20, please provide the following information by COB Wednesday. This information is needed for obtaining clearance for you to visit the CDRH buildings.

Here the info we need:

VISITOR'S FULL NAME (First, Middle, **LAST**)

GENDER

COUNTRY OF ORIGIN / CITIZENSHIP

DATE OF BIRTH (MM/DD/YYYY)

PLACE OF BIRTH (city and country)

PASSPORT NUMBER

COUNTRY THAT ISSUED THE PASSPORT

PASSPORT ISSUANCE DATE:

PASSPORT EXPIRATION DATE:

VISITOR'S ORGANIZATION / EMPLOYER

Thanks, Uwe
**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** STRÖHER, Ute <stroheru@who.int>
**Sent:** Wednesday, January 15, 2020 9:24 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: FDA visit

AMERICAN OVERSIGHT

Hallo Uwe,

Much easier than CDC ☺

Thank you,
Ute

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** 15 January 2020 15:17
**To:** STRÖHER, Ute <stroheru@who.int>
**Subject:** RE: FDA visit

Hallo Ute,

There is no VIAS required to enter FDA for the meeting or the second day (Feb 4), we just to obtain some information from you to request your visit to us in the internal FDA clearing system.

I will send you the require information later in the week (e.g., passport #, date birth etc.)

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** STRÖHER, Ute <stroheru@who.int>
**Sent:** Wednesday, January 15, 2020 9:02 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: FDA visit

Dear Uwe,

Sorry to bother you with a logistic question. But I am wondering what kind of visa is required to enter FDA.
Carolyn said for the meeting in the Great Room it doesn't matter as FDA security doesn't seemed to be involved, but which visa is preferred for the second day (Feb 4).
I have the option of(b) (6) or(b) (6)

Thanks a lot,
Ute

**From:** STRÖHER, Ute
**Sent:** 10 January 2020 18:59
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: FDA visit

AMERICAN OVERSIGHT

Thanks a lot Uwe. I'm looking forward to my visit and to get to know your team.

Wishing you a great weekend too.
Ute

Sent from my iPhone

On 10 Jan 2020, at 18:44, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov> wrote:

Ute,

Thanks, 11 AM sounds great. We will start your visit with your suggested topic, followed by interaction with the team and lunch.

Look forward to hosting you on the 1/4/20.

Have a great weekend.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** STRÖHER, Ute <stroheru@who.int>
**Sent:** Friday, January 10, 2020 12:35 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: FDA visit

Dear Uwe,

Excellent. Should we say 11am?
If of interest I can certainly give a talk about the scope of the PQ-IVD team and my role within.

Best,
Ute

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** 10 January 2020 18:21
**To:** STRÖHER, Ute <stroheru@who.int>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: FDA visit

AMERICAN OVERSIGHT

Dear Ute,

Happy New Year! Good to hear from you and thanks for sharing in advance that you are coming to the Feb 3rd MDIC workshop.

So far Feb 4th looks good for me to get together, I can meet any time between 9-10 AM and 11 AM and 3 PM, please let us know what can work for you.

Would you be interested to give a talk to my division about your work at WHO? My staff would be very interested to get to know you closer and understand your role at WHO.

Best, Uwe

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---

**From:** STRÖHER, Ute <stroheru@who.int>
**Sent:** Friday, January 10, 2020 12:06 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FDA visit

Dear Kim and Uwe,

Happy New Year to both of you!

I just want to check with you if you have any availability on Feb 4th to meet with me.
I am attending the MDIC workshop (Advancing EUA IVD Products) on Feb 3 and thought it might be a good opportunity.

Best wishes,
Ute

Dr. Ute Ströher
Prequalification Team – Diagnostics
Access to Medicines and Health Products
World Health Organization
Geneva, Switzerland

Office: +(b) (6)
Mobile:
Web: www.who.int/medicines/en/

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/21/2020 7:44:53 AM
**To:** STRÖHER, Ute [stroheru@who.int]
**CC:** Proctor, Tremyl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35056b97ee224343b77af6a0973d5d61-Tremyl.Proc]
**Subject:** RE: FDA visit

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** STRÖHER, Ute <stroheru@who.int>
**Sent:** Tuesday, January 21, 2020 2:13 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Proctor, Tremyl <Tremyl.Proctor@fda.hhs.gov>
**Subject:** RE: FDA visit

Dear Uwe,

Please find the information below.

Best,
Ute

Dr. Ute Ströher
In Vitro Diagnostics assessment
WHO Prequalification
World Health Organization
Geneva, Switzerland

Office: (b) (6)
Mobile:
Web: www.who.int/medicines/en/

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** 20 January 2020 21:02
**To:** STRÖHER, Ute <stroheru@who.int>
**Cc:** Proctor, Tremyl <Tremyl.Proctor@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: FDA visit

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VISITOR'S FULL NAME (First, Middle,**LAST**)
(b) (6)

GENDER
Female

COUNTRY OF ORIGIN / CITIZENSHIP
Germany/German

DATE OF BIRTH (MM/DD/YYYY)
(b) (6)

PLACE OF BIRTH (city and country)
(b) (6)

PASSPORT NUMBER
(b) (6)

COUNTRY THAT ISSUED THE PASSPORT
Germany

PASSPORT ISSUANCE DATE:
(b) (6)

PASSPORT EXPIRATION DATE:
(b) (6)

VISITOR'S ORGANIZATION / EMPLOYER
World Health Organization

Thanks, Uwe
**Uwe Scherf, M.Sc., Ph.D.**
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**Sent:** Friday, January 10, 2020 12:06 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FDA visit

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Prequalification Team – Diagnostics
Access to Medicines and Health Products
World Health Organization
Geneva, Switzerland

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Mobile:
Web: www.who.int/medicines/en/

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 3/1/2020 11:25:26 AM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]; Pagan Motta, Monica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39552e3b45c741f19b0bebbf796d96c2-Monica.Paga]
**Subject**: RE: EUA COVID-19 Lab Tests - Webinar deck.pptx
**Attachments**: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Elizabeth,

I had to make one additional edit on slide 9 for clarity. See attached

Uwe

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 11:06 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Uwe and Tim, Thank you very much. I have cleaned up the redlines and made some edits on slides 8, 13-15. (slide 15 just moved, no edits to the screenshot from CDC's website) Marcy is planning to review early afternoon. Is it possible for you to take a quick look before then? I especially want to make sure Tim is comfortable since he is presenting.
Elizabeth

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 9:16 AM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Here my comments on the slides.

Uwe

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 9:03 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

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Thank you Tim!

I have some questions about one of your additions: (b) (5) [redacted]?

Also standing by for any edits Uwe may have.

Elizabeth

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** March 1, 2020 at 8:40:06 AM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>, Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Good morning,

I made some minor edits and added an update slide near the end, see attached. Uwe is working on making sure viral and disease names are all correct and double checking the content at well. Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:40 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Happy to delete that slide, but note that Dan asked us to include it (attached). Do we know if CDC is planning their own slides? I thought they would just be on to answer questions.

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I will send to Marcy and Claire in parallel while we sort this out.

Elizabeth

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:34 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Elizabeth,

They look good. I wouldn't include the CDC criteria in Tim's presentation. Dan is welcome to use slides if he wants to discuss the CDC criteria after Tim finishes his presentation.

I agree they need to go to OCC and then shared with OC. I can share them with OC once OCC finishes their review.

Jeff

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:16 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** EUA COVID-19 Lab Tests - Webinar deck.pptx

Jeff and Tim,
Attached are draft slides for the webinar Monday for your review. I think they will may to go through OCC as well.
Elizabeth

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FDA U.S. FOOD & DRUG ADMINISTRATION

# *Welcome to today's FDA/CDRH Webinar*

*Thank you for your patience while additional time is provided for participants to join the call.*

**Please connect to the audio portion of the webinar now:**
**U.S. Callers: 1-888-946-7601**

**International Callers: 1-312-470-7136**

**Conference Number: PWXW9976446**
**Passcode: 6470708**

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# Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency: Immediately in Effect Guidance

Timothy Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health

March 2, 2020

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# Agenda

- Background
- Summary of Immediately In Effect Guidance
- Questions and Answers



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# Objective

- Explain policy for molecular diagnostics testing in high-complexity Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories prior to emergency use authorization for coronavirus disease-2019 (COVID-19) during the public health emergency.

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# Background

- Guidance issued February 29, 2020 describes a policy enabling laboratories to immediately use tests they developed and validated in order to achieve more rapid testing capacity in the U.S.
- To address the COVID-19 public health emergency, the FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment.
- This guidance document is immediately in effect, but it remains subject to comment in accordance with the FDA's good guidance practices.

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# Scope

- The new policy is limited to:
  - Laboratories certified to perform high complexity testing, consistent with the requirements under the Clinical Laboratory Improvement Amendments (CLIA)
  - Molecular diagnostics for SARS-CoV-2
  - (b) (5)
- The new policy does NOT impact:
  - Requirements under the Clinical Laboratory Improvement Amendments (CLIA)
  - CDC recommendations for who should be tested

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# Policy

- Labs should complete validation of newly developed SARS-CoV-2 tests prior to clinical use
- Labs should notify FDA when clinical use of a validated test begins
- Labs should confirm the first 5 positive and negative samples with an EUA authorized test
- Test reports should indicate the test has been validated but independent review by FDA is not yet complete
- Labs should submit an EUA within 15 days of initiating testing
- If any specimens fail confirmatory testing or if FDA is unable to authorize the EUA, labs should stop testing and issue corrected test reports indicating prior results may not be valid

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(b) (5)

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# Test Validation

- Validation should meet minimal recommendations outlined in the guidance for:
  - Limit of Detection (LoD)
  - Clinical Evaluation
  - Inclusivity
  - Cross-Reactivity
- Limited viral materials are available
  - FDA, BARDA, and CDC prioritize and coordinate shipments to labs when ready to validate

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# Limit of Detection

- Defined as the lowest concentration at which 19/20 replicates are positive
- Methods:
  - test dilution series with 3 replicates per concentration (range finding)
  - confirm final concentration with 20 replicates (around initially identified LoD only)
- Samples:
  - ~~may~~ use pooled negative clinicals samples or artificial matrix ~~contrived samples (i.e., spiking RNA or inactivated virus into artificial or real clinical matrix)~~
  - if multiple specimen types are intended, evaluate most challenging (e.g., sputum)

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# Clinical Evaluation

- Test at least 30 contrived reactive specimens and 30 non-reactive specimens
  - Contrived reactive specimens can be created by spiking viral RNA or inactivated virus into leftover clinical specimens
  - Twenty (20) of the contrived specimens should be spiked at a concentration of 1x-2x LoD, with the remainder of specimens spanning the assay testing range.

- Acceptable performance:
  - 95% agreement at 1x-2x LoD and
  - 100% agreement at all other concentrations and for negative specimens

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# Inclusivity

- Conduct an *in silico* analysis of the percent identity matches against publicly available SARS-CoV-2 sequences that can be detected by the proposed molecular assay.
- 100% of published SARS-CoV-2 sequences should be detectable with the selected primers and probes



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# Cross-Reactivity

- Conduct an *in silico* analysis of the assay primer and probes compared to common respiratory flora and other viral pathogens is sufficient
- There should be >80% homology between one of the primers/probes and any sequence present in the targeted microorganism
- Follow recognized laboratory procedures for any additional cross-reactivity testing in the context of the sample types intended for testing

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# Status of EUA Tests

- CDC EUA authorization Feb 4, 2020
  - Covers CDC-qualified IDT 2019-nCoV Kit Lot#0000500383
  - Additional IDT lots undergoing qualification by CDC
- NYS Wadsworth Center EUA Authorization Feb 29, 2020
- CDC, FDA and BARDA are working with multiple IVD manufacturers and laboratories to enable additional EUA authorizations as soon as possible; monitor at:
  https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019

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(b) (5)



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# CDC's Clinical Criteria for Testing

| Clinical Features | & | Epidemiologic Risk |
|---|---|---|
| Fever[1] **or** signs/symptoms of lower respiratory illness (e.g. cough or shortness of breath) | **AND** | Any person, including healthcare workers[2], who has had close contact[3] with a laboratory-confirmed[4] COVID-19 patient within 14 days of symptom onset |
| Fever[1] **and** signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath) requiring hospitalization | **AND** | A history of travel from affected geographic areas[5] (see below) within 14 days of symptom onset |
| Fever[1] with severe acute lower respiratory illness (e.g., pneumonia, ARDS) requiring hospitalization and without alternative explanatory diagnosis (e.g., influenza)[6] | **AND** | No source of exposure has been identified |

https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html

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# Submissions to FDA

- **Notification** of clinical use of a validated test should be directed to CDRH-EUA-Templates@fda.hhs.gov and should include:
  - name of the laboratory
  - name of the lab director
  - address
  - contact person

- **EUA** should be submitted within 15 days of initiating clinical testing to OIR-Operations@fda.hhs.gov and should include:
  - Form 3514 available at: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf
  - Completed EUA template available at: https://www.fda.gov/media/135658/download

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(b) (5)

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# Resources

- COVID-19 Guidance Document: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia-prior
- General EUA Guidance Document: https://www.fda.gov/media/97321/download
- Novel Coronavirus (COVID – 19) webpage: https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-covid-19

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# Questions?

For questions on the guidance and accelerated EUA template, or if you wish to consider use an alternative specimen type, contact the Division of Microbiology devices at (301) 348-1778 or: CDRH-EUA-Templates@fda.hhs.gov.

Slide Presentation, Transcript and Webinar Recording will be available at:
http://www.fda.gov/training/cdrhlearn
Under Heading [Insert respective webpage heading]

18

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/28/2020 9:21:47 PM
**To**: Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Instructions for use

Joe,

I am trying to help with the PI which is (b)(5)

Here some point I see need to be added to the Wadsworth PI

## For Emergency Use Only

## For *In-vitro* Diagnostic (IVD) Use

## Rx Only

## Intended Use

From their Review Memo

## Warnings and Precautions

The yellow section are already in their PI

- For *in vitro* diagnostic use (IVD).
- For emergency use only.
- Follow standard precautions. All patient specimens and positive controls should be considered potentially infectious and handled accordingly.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCoV https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html.
- Specimen processing should be performed in accordance with national biological safety regulations.
- If infection with 2019-nCoV is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions.
- (b)(5)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/27/2020 7:23:25 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: 2/27/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/27/20 6 AM update:

**Status of activities on diagnostics:**

- CDC announced to today during an APHL conference call with its members that it will go forward with the exclusion of it N3 target and move its test into a N1-N2 test only.
A new lot of N1/N2 primers and probes was made and is being QCed with an enhanced QC protocol. If material pass it will be ready to shipment shortly after. Additional commercially manufactures N1/N2 primer and probes are also QC tested for possible distribution. CDC intend to submit an amendment request to their EUA for the change to utilize N1/N2 primer/probes
(b)(5) [redacted]

- A total of 76 IVD Developers have requested and received EUA review template.

- 18 developers have submitted pre-EUA documents for FDA feedback

- CDRH sent respond letter to APHL and held follow-up telecom with AHPL leadership and 12 other PHLs. (b)(5) [redacted]

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(b)(5)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 10:58:59 AM
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Due by NOON - Review of EUA Text in Response to Sen. Markey re COVID-19

Jennifer,

sorry cannot confirm the appropriate wording with CMS. Please strike the blue text. Added red text for clarification.

Uwe

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 10:48 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Due by NOON - Review of EUA Text in Response to Sen. Markey re COVID-19
**Importance:** High

Kim and Uwe,

HHS has asked us to review a response to Senator Markey re COVID, and most of it looks fine but they have a section on EUAs with some wording that I was not sure of. Below is the text; in particular, (b)(5) [redacted]. Most of the rest of it is the same as the testimony you reviewed last week. Can you let me know if you have edits/feedback on this? Sorry for the short turnaround (once again). I might suggest just striking the text in blue if that is easiest.

I already made the changes Kim had suggested to the testimony (in yellow highlight).

Best,

Jennifer

(b)(5) [redacted]

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(b)(5)
[redacted]

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On Monday, February 3, 2020, CDC submitted an EUA package to the FDA in order to expedite FDA permitted use of the CDC-developed laboratory test kit, called the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. FDA approved the EUA on February 4, 2020, and the test kit began shipping on February 5, 2020 to select qualified U.S. and international laboratories. Distribution of the tests will help improve the global capacity to detect and respond to the 2019 novel coronavirus.

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/27/2020 11:01:27 AM
**To:** (b) (6)@jantdx.com
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** FW: RAPID COVID-19 SCREEN

Dear Dr. Elkins,

The current route for submitting your request to the FDA is via a pre-EUA process.

Before we start this process, please provide a summary of your device and any studies you have done so far for validation the test. Especially the validation of your this test vs RT-PCR for COVID-19.

After we receive this information we will consider to set up a conference call to discuss next steps.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Samuel Elkin
**Sent:** Wednesday, February 26, 2020 10:24:34 PM (UTC+00:00) Monrovia, Reykjavik
**To:** Breakthrough Devices Program
**Cc:** Jack Tawfik
**Subject:** RAPID COVID-19 SCREEN

To whom it may concern,

We are interested in exploring your Breakthrough Devices Program. Our company is currently working with a (b) (4)

We would appreciate guidance regarding the Breakthrough Devices Program.

Thanks and best regards,

Sam

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Samuel Elkin, PharmD
President

JANT PHARMACAL CORPORATION
LABORATORY & POINT OF CARE DIAGNOSTICS
Tel: (b) (6)
Fax: (818) 986-0235

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/24/2020 3:46:24 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; uxs; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]
**Subject:** RE: draft language

All,

In case you need to talk to Steve Lindstrom after he sends the data for clarification: This is his cell phone number 404-639 1587 (b)(6)

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 2:49 PM
**To:** uxs; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** draft language

(b)(5)

AMERICAN OVERSIGHT

Li Li
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6200 | Fax: (301) 847-8512
li.li2@fda.hhs.gov






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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/17/2020 11:09:35 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]

**Subject:** FW: Discussion on Cut-off change - lot release testing criteria
**Location:** bldg 18, 7th floor conference room (for CDC paticipants

**Start:** 2/17/2020 1:00:00 PM
**End:** 2/17/2020 2:00:00 PM
**Show Time As:** Tentative

Tim,

It would be great if you could make it to this call. I will be in the office to take this call at 1 PM. Uwe

-----Original Appointment-----
**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 10:14 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD); Scherf, Uwe; Villanueva, Julie M (CDC)
**Cc:** Sapsford, Kim E; Li, Li (CDRH); Bisht, Himani; Mielech, Anna; Feldblyum, Tamara; Rose, Laura E (CDC); Kuhnert-Tallman, Wendi L (CDC); Jernigan, Daniel B (CDC)
**Subject:** Discussion on Cut-off change - lot release testing criteria
**When:** Monday, February 17, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** bldg 18, 7th floor conference room (for CDC paticipants

---

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AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/25/2020 3:51:54 PM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: CDC 2019-nCoV DMD Feedback

Good, one small update in green. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:46 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: CDC 2019-nCoV DMD Feedback

What do you think the following:

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** CDC 2019-nCoV DMD Feedback

DRAFT Email to CDC for review – I will look at the product information sheet now – maybe we can send that along also:

Dear Steve,

Please find attached our feedback on the draft package insert (minus the performance sections). Let us know if you have any questions.

We have looked at the spreadsheet list of clinical specimens that CDC has tested to date with the CDC 2019-nCoV real-time RT-PCR panel and have some questions about the specimens included to help us better understand the data:

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- (b)(5) [redacted]

[redacted]

Please let us know if you have any questions
Best regards

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/25/2020 3:36:43 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: CDC 2019-nCoV DMD Feedback

Thanks, this looks good, I suggest that we briefly summarize the (b)(5) to provide clear expectations. Please add to the email.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** CDC 2019-nCoV DMD Feedback

DRAFT Email to CDC for review – I will look at the product information sheet now – maybe we can send that along also:

Dear Steve,

Please find attached our feedback on the draft package insert (minus the performance sections). Let us know if you have any questions.

We have looked at spreadsheet list of clinical specimens that CDC has tested to date with the panel and have some questions about the specimens included to help us better understand the data:

- (b)(5)

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- (b)(5)

(b)(5)

Please let us know if you have any questions
Best regards

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/25/2020 7:12:53 AM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** 2/54/206 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/25/206 AM update:

**Status of activities on diagnostics:**

- 2/24/20 CDC proposed to change wording the intended use of their EUA from:
  - The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals **who meet CDC criteria for 2019-nCoV testing**

  - To:

(b)(5)

[redacted]

**Also, CDC communicate that they will move forward with changing their assay to a N1+N2 only assay. CDC's intention is to have both changes done with one submission.**

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- CDC will provide additional confirmation testing had been conducted by CDC on presumptive positive samples. FDA will rely this additional information for the statistical justification included in the benefit-risk assessment for CDC to exclude using the N3 primer/probeset as part of their assay moving forward.

- A total of 75 IVD Developers have requested and received EUA review template

(b) (4), (b) (5)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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CDRH | Food and Drug Administration
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**From:** Uwe.Scherf@fda.hhs.gov [Uwe.Scherf@fda.hhs.gov]
**Sent:** 2/8/2020 3:06:45 PM
**To:** Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** Fwd: (b) (4) screening for Coronavirus

Kris, who from the (b) (4), (b) (5)
(b) (5)

Uwe

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Date:** February 8, 2020 at 2:10:54 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Krueger, Angela C <Angela.Krueger@fda.hhs.gov>
**Subject:** Re: (b) (4) screening for Coronavirus

AMERICAN OVERSIGHT

**From**: Uwe.Scherf@fda.hhs.gov [Uwe.Scherf@fda.hhs.gov]
**Sent**: 2/8/2020 2:59:55 PM
**To**: Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Patel, Bakul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ce7d58d8b9c473c8ba4d6fcb8b02b5a-BYP]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Krueger, Angela C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96c8f1f9d6a8481195be2aa3147e0b4f-ACS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Re: (b) (4) screening for Coronavirus

Bill, Jeff,
I confirm this belongs to DMD. We had similar apps for the Zika outbreak and will find out how those request were handled (b) (5) . DMD will follow up with a phone call to the sponsor.
Uwe

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Date:** February 8, 2020 at 2:10:54 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Krueger, Angela C <Angela.Krueger@fda.hhs.gov>
**Subject:** Re: (b) (4) screening for Coronavirus

AMERICAN OVERSIGHT

**From**: Uwe.Scherf@fda.hhs.gov [Uwe.Scherf@fda.hhs.gov]
**Sent**: 2/4/2020 9:30:50 PM
**To**: Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject**: Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

Steve, issue resolved. Got in contact with Dr. Odle, she will hand over the package to me tomorrow morning at 8:30 AM.
Uwe

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 4, 2020 at 8:28:08 PM EST
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Re: Urgent - CONGRATULATIONS! CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization submission

AMERICAN OVERSIGHT

**From**: Uwe.Scherf@fda.hhs.gov [Uwe.Scherf@fda.hhs.gov]
**Sent**: 2/4/2020 8:18:35 PM
**To**: Sally A Hojvat [sally.hojvat@gmail.com]
**CC**: Sally A. Hojvat [sally.hojvat@gmail.com]
**Subject**: Re: FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic

Thanks, took some heavy lifting. Uwe

---

**From:** Sally A Hojvat <sally.hojvat@gmail.com>
**Date:** February 4, 2020 at 7:50:45 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sally A. Hojvat <sally.hojvat@gmail.com>
**Subject:** Fwd: FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic

AMERICAN OVERSIGHT

**From**: Uwe.Scherf@fda.hhs.gov [Uwe.Scherf@fda.hhs.gov]
**Sent**: 2/4/2020 8:13:08 PM
**To**: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: CDC Documents related to Corona Virus

Suzanne,
We do not need the documents tonight, but need to make sure the carrier can deliver the documents to CDRH tomorrow. They are the hard copies of the EUA request we already received electronically earlier today and approved with the issuance of CDC's EUA.

Please give me a call at (b) (6)
so we can assure to be prepare with the Emergency OP's coordinator to be ready to accept the documents tomorrow.

Uwe

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 4, 2020 at 7:04:41 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: CDC Documents related to Corona Virus

AMERICAN OVERSIGHT

**From**: Uwe.Scherf@fda.hhs.gov [Uwe.Scherf@fda.hhs.gov]
**Sent**: 1/25/2020 8:37:38 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject**: RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Got the invite, thanks

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** January 25, 2020 at 8:24:48 AM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

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**From**: Uwe.Scherf@fda.hhs.gov [Uwe.Scherf@fda.hhs.gov]
**Sent**: 1/25/2020 8:36:12 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject**: RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Kim,
Thanks , 2PM works for me.
Have not seen the invite yet.
Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** January 25, 2020 at 8:24:48 AM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/28/2020 10:32:31 AM
**To**: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
**Subject**: RE: Slides- MDIC EUA Workshop 2/3/20

Jennifer, I know and this is fine, but I do not want to have this changed. Thanks, Uwe

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 10:30 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Waters, Michael <Michael.Waters@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>
**Subject:** RE: Slides- MDIC EUA Workshop 2/3/20

I may not have been clear, but Uwe you are only listed once on the agenda, and panel at the end.

Thanks,

Jennifer

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 10:27 AM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Waters, Michael <Michael.Waters@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>
**Subject:** RE: Slides- MDIC EUA Workshop 2/3/20

Tim, Jennifer,

Unfortunately, with the ongoing crisis on the 2019-nCov, I will not have time to prepare for another talk in another section of the meeting. I appreciate your consideration.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 10:24 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

AMERICA'S OVERSIGHT

**Cc:** Waters, Michael <Michael.Waters@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Slides- MDIC EUA Workshop 2/3/20

Tim,

Attached are some slides for your consideration.

MDIC is also finalizing the workshop agenda today. I think you have it from Carolyn Hiller for review, and Uwe will speak after you.

If you have any questions or need anything from me before Monday, then let me know.

Thanks!

Jennifer

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, December 09, 2019 10:32 AM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Cc:** Waters, Michael <Michael.Waters@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>
**Subject:** RE: Speaker Request: MDIC EUA Workshop 2/3/20

Hi Jennifer,

Yes, I can speak at this meeting and am of course going to attend. I do wonder if Uwe Scherf wouldn't be a better speaker or at least to consider him for another place on the agenda, since he leads the Division of DMD in our Office that handles and reviews all EUAs.

Thanks! It will be a pleasure to see this program happen.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Tuesday, December 3, 2019 2:19 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Waters, Michael <Michael.Waters@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>
**Subject:** Speaker Request: MDIC EUA Workshop 2/3/20

Tim,

Your calendar should already have a hold on February 3rd for the MDIC RWE IVD EUA workshop (from Carolyn Hiller) to be held at FDA White Oak. The full steering committee met to draft the agenda and identify session organizers. We have started planning the FDA session and would like to invite you to make a presentation. Please confirm that you will be available.

The full draft agenda is attached. If you have comments, then please let us know. Copied below for reference is the draft FDA session, the session will most likely start around 9 or 10am, but we will be able to confirm the exact time after MDIC determines when the workshop will start and identifies keynote speaker(s).

(b) (5)



Thanks,

Jennifer

-----Original Appointment-----
**From:** Carolyn Hiller, MDIC <chiller@mdic.org>
**Sent:** Tuesday, May 28, 2019 1:21 PM
**To:** Carolyn Hiller, MDIC; Stenzel, Timothy; Ross, Jennifer; Salerno, Reynolds M (CDC); Scherf, Uwe; Lowe, Toby A; Saha, Anindita; Alberto Gutierrez (alberto.gutierrez.phd@gmail.com); Rose, Laura E (CDC); Chaitram, Jasmine M (CDC); Henderson, Deborah L (CDC); Chowdhury, Katharine; Sapsford, Kim E; Kondratovich, Marina V; Tezak, Zivana; Jithesh Veetil; Miller, Danelle; 'Jeff Zinza'; Lathrop, Julia
**Cc:** Pamela Goldberg; Waters, Michael; Jon Hunt
**Subject:** HOLD - MDIC EUA Workshop
**When:** Monday, February 03, 2020 8:30 AM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** FDA Great Room

AMERICAN OVERSIGHT

New date to accommodate Schedule

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/21/2020 4:40:34 PM
**To:** Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
**Subject:** RE: URGENT IHR REVIEW REQUIRED: Potential PHEIC - Confirmation of novel coronavirus (nCoV) in the United States

Michael,

As I just mentioned on the phone, we have not received any data from the CDC on their test.

Uwe

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: URGENT IHR REVIEW REQUIRED: Potential PHEIC - Confirmation of novel coronavirus (nCoV) in the United States

FYI – curious what u know about testing CDC performed to determine positive for 2019 nCoV…

---

**From:** Simms, Joshua <Joshua.Simms@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 2:41 PM
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; CVM ECRS <CVMECRS@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Yee, James C <JC.Yee@fda.hhs.gov>; Livsey, Kimberly <Kimberly.Livsey@fda.hhs.gov>; Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>; Russo, Mark <Mark.Russo@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Morrison, Ellen F <Ellen.Morrison@fda.hhs.gov>; Howard King, Vinetta <Vinetta.HowardKing@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>
**Subject:** URGENT IHR REVIEW REQUIRED: Potential PHEIC - Confirmation of novel coronavirus (nCoV) in the United States

Good afternoon,

FDA OEO received notification from the HHS International Health Regulations (IHR) Program regarding a potential PHEIC involving the first confirmed novel coronavirus (nCoV). The IHR event notification form is attached.

The HHS/ASPR International Health Regulations (IHR) Program requests FDA's review of the attached pending notification of a potential public health emergency of international concern (PHEIC). Subsequent to this review period, HHS/ASPR will request the approval of the Assistant Secretary for Preparedness and Response, who serves as the IHR Message Authorizing Official, to send this notification to the World Health Organization.

If you have any comments, please advise OEO by **5:00PM EDT today (1/21/2020).**

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**Event information**

The IHR Program has been notified of a potential PHEIC involving a Chinese citizen in the United States who tested positive for nCoV.

**Title:** Confirmation of novel coronavirus (nCoV)

**Location**: United States

**PHEIC notification criteria met:**

Criteria 1- Public health impact of the event is serious
Criteria 2- Event is unusual/unexpected
Criteria 3 –Significant Risk of International Spread
Criteria 4- Significant Risk of Travel or Trade Restrictions

The Centers for Disease Control and Prevention (CDC) is closely monitoring an outbreak caused by a novel (new) coronavirus (nCoV) in Wuhan City, Hubei Province, China. Chinese authorities first identified the new coronavirus, which has resulted in about 200 confirmed human infections and three reported deaths in China. A number of countries, including the United States, are actively screening incoming travelers from Wuhan, and exported cases have been confirmed in Thailand, Japan, and South Korea. The first case confirmed case in the United States was announced on January 21, 2020.

United States Patient Case Summary:
35 year old otherwise healthy male, Chinese citizen, traveled from the United States to Wuhan, China on November 26, 2019. He returned to the United States on January 15, 2020 and began to experience symptoms on January 16, 2020. He had normal chest x-ray and a negative test for influenza virus. He did not report exposure to ill persons, livestock or seafood/animal markets while in China. Due to travel to Wuhan, he was tested for nCoV (and was discharged home with instructions for home isolation). The patient specimen, acquired on January 19, 2020, was sent overnight to CDC and on January 20, 2020 tested positive for nCoV. CDC is actively coordinating with state and local health departments on the response.

Thank you,

Josh

**Joshua Simms**
*CAPT, U.S. Public Health Service*
*Director*
**Office of Emergency Operations**
**U.S. Food and Drug Administration**
Desk: 301-796-5599
Cell: 240-705-2946
Email: joshua.simms@fda.hhs.gov
24 hour Emergency Number: 1-866-300-4374






AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/22/2020 1:49:39 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
**CC**: Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
**Subject**: RE: Please review ASAP - Media Inquiry on FDA preparedness for coronavirus spread to US

Agree, looks good, thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:24 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Please review ASAP - Media Inquiry on FDA preparedness for coronavirus spread to US

Looks good to me
Thanks for the opportunity to review

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
**Subject:** RE: Please review ASAP - Media Inquiry on FDA preparedness for coronavirus spread to US

Kim – are you and Uwe good with the edits form Liz? Liz, thanks so much I think the edits look great! Appreciate it.

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:13 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
**Subject:** RE: Please review ASAP - Media Inquiry on FDA preparedness for coronavirus spread to US

The attached includes some edits for your consideration. Thanks, Liz

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 11:30 AM
**To:** Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Rabin, Tara G.

AMERICAN OVERSIGHT

<Tara.Rabin@fda.hhs.gov>
**Subject:** Please review ASAP - Media Inquiry on FDA preparedness for coronavirus spread to US

Hi all, we have a media inquiry on US diagnostics preparedness from Pharmaintelligence. They are asking about US preparedness to deal with people coming into the US who might be carrying coronavirus? Could you please review and edit the proposed response below as soon as possible. Reporter's deadline is 2:30 pm. Thank you! Megan

My questions would be:

1) Has FDA recently received any applications from US or international firms to develop and approve a diagnostics test for the coronavirus 2019-nCOV from China?
2) Would there be an expedited process to approve such a diagnostic test?
3) How does the process work, and are any additional legal or regulatory authorities triggered when FDA is quickly trying to approve use of a test for an infectious disease in the US?

(b) (5)



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/24/2020 9:02:42 PM
**To**: Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Request for Input for 21 Feb Update on FDA 2019-nCoV SITREP

Here the update from today. 75

Uwe

---

**From:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 2:56 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Request for Input for 21 Feb Update on FDA 2019-nCoV SITREP

Elizabeth, per our conversation, see below for the numbers as of Friday. (70 developers requested/received EUA template and/or are working interactively with DMD through pre-EUA. I believe some of these are academic medical centers/ LDTs.)

Kim, Uwe – any updates on these numbers for today?

Thanks,
Toby

**Toby Lowe**
*CDRH/OIR*
Tel: 301-796-6512

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:21 PM
**To:** Measer, Gregory <Gregory.Measer@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Subject:** RE: Request for Input for 21 Feb Update on FDA 2019-nCoV SITREP

Dear Greg:

AMERICAN OVERSIGHT

**CDRH Diagnostics SITREP Friday Feb 21, 2020**

| Diagnostic Pipeline | | | |
|---|---|---|---|
| **Sponsor** | **Product** | **Regulatory Status** | **Notes** |
| CDC | CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel | EUA | Molecular DX |
| Inbios | Molecular DX | Pre-EUA | |
| Roche Molecular Systems | Molecular DX | Pre-EUA | |
| BioFire Defense | Molecular DX | Pre-EUA | |
| Cepheid | Molecular DX | Pre-EUA | |
| Vela Diagnostics | Molecular DX | Pre-EUA | |
| Novacyt S.A | Molecular DX | Pre-EUA | |
| ScienCell Research Laboratories | Molecular DX | Pre-EUA | |
| (b) (4) | Molecular DX | Pre-EUA | |
| | Molecular DX | Pre-EUA | |
| | | | |
| | | | |

-Additional IVD Developers have requested and received the appropriate EUA review template [(b) (4) , University of Nebraska Medical Center] for a total of 70 to date or are working interactively with DMD in order to get comments in their preliminary EUA Study design [Pre-EUA]. Note University of Nebraska Medical Center (UNMC) campus also houses the Nebraska Public Health Laboratory – which was able to verify the CDC EUA test. There are currently have confirmed 11 COVID-19 positive patients quarantined at UNMC after being evacuated from the Dimond Princess cruise ship.
-Interactions with CDC are still ongoing to discuss the proposed outline of a community transmission surveillance activity under a new EUA – study protocol has been provided.
-Interactions with CDC are still ongoing regarding the verification issues with their EUA test – CDC are currently re-manufacturing the test kits and are hoping to have kits ready next week.
- TTFED call held around EUA test implementation.

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Measer, Gregory <Gregory.Measer@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 12:37 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hall, Valerie <Valerie.Hall@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Lucas, Tanisha <Tanisha.Lucas@fda.hhs.gov>; Gutierrez, Sacha <Sacha.Gutierrez@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Harrison, Tina <Tina.Harrison@fda.hhs.gov>; Arsenault, Sam <Samuel.Arsenault@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>
**Cc:** FDA Emergency Operations <emergency.operations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>
**Subject:** Request for Input for 21 Feb Update on FDA 2019-nCoV SITREP

Hi All,

Attached is the draft 21 Feb SITREP on the FDA response to the 2019-nCoV outbreak.

Please **provide any additional updates by 3:30 PM if possible.**

Please highlight any info that should not be shared outside of FDA in **red**.

Thank you for your continued assistance with this effort. Let me know if you have any questions or concerns.

Best,
Greg

**Gregory Measer, JD**
*Regulatory Counsel*

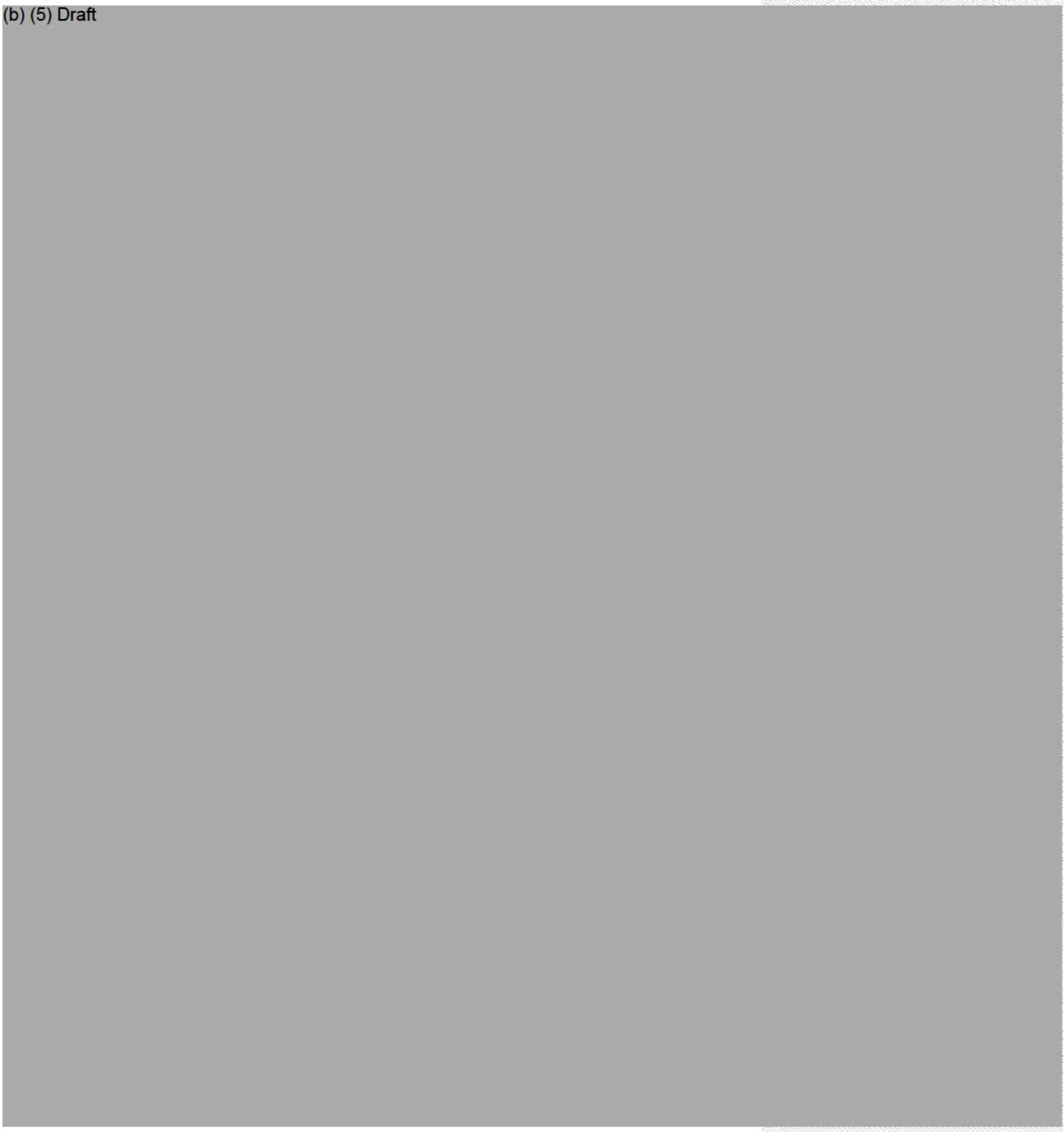
Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist, Office of the Commissioner
U.S. Food and Drug Administration
202-774-4146 / Gregory.Measer@fda.hhs.gov






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(b) (5) Draft



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Assessment of Benefits and Risks:

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T OF HEALTH & HUMAN SERVICES
Service

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

February 20, 2020
Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
CDRH Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Request for Emergency Use Authorization:**
**CDC 2019 Novel Coronavirus (nCoV) Real-Time RT-PCR Diagnostic Panel (EUA200001)**
(b) (5) Draft

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(b) (5) Draft

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(b) (5) Draft

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**From**: Uwe.Scherf@fda.hhs.gov [Uwe.Scherf@fda.hhs.gov]
**Sent**: 2/3/2020 4:26:39 PM
**To**: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
**Subject**: Re: Pinging OCC: Review requested - Tweets- coronavirus - FDA- MDIC meeting today - Advancing Emergency Use Diagnostic Products Toward Full Marketing Status

Do you need anything from me

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Date:** February 3, 2020 at 4:25:24 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>, Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, OC OCC Device Team Requests <OCOCCDeviceTeamRequests@fda.hhs.gov>
**Subject:** Pinging OCC: Review requested - Tweets- coronavirus - FDA- MDIC meeting today - Advancing Emergency Use Diagnostic Products Toward Full Marketing Status

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**From**: Uwe.Scherf@fda.hhs.gov [Uwe.Scherf@fda.hhs.gov]
**Sent**: 1/31/2020 7:07:48 PM
**To**: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
**Subject**: RE: Potential diagnostic EUA for coronavirus PR

Yes, sorry for the confusion.
Uwe

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Date:** January 31, 2020 at 1:54:40 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

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U.S. FOOD & DRUG ADMINISTRATION

# *Welcome to today's FDA/CDRH Webinar*

*Thank you for your patience while additional time is provided for participants to join the call.*

**Please connect to the audio portion of the webinar now:**
**U.S. Callers: 1-888-946-7601**

**International Callers: 1-312-470-7136**

**Conference Number: PWXW9976446**
**Passcode: 6470708**

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# Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency: Immediately in Effect Guidance

Timothy Stenzel
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health

March 2, 2020

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# Agenda

- Background
- Summary of Immediately In Effect Guidance
- Questions and Answers



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# Objective

- Explain policy for molecular diagnostics testing in high-complexity Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories prior to emergency use authorization for coronavirus disease-2019 (COVID-19) during the public health emergency.

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# Background

- Guidance issued February 29, 2020 describes a policy enabling laboratories to immediately use tests they developed and validated in order to achieve more rapid testing capacity in the U.S.
- To address the COVID-19 public health emergency, the FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment.
- This guidance document is immediately in effect, but it remains subject to comment in accordance with the FDA's good guidance practices.

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# Scope

- The new policy is limited to:
  - Laboratories certified to perform high complexity testing, consistent with the requirements under the Clinical Laboratory Improvement Amendments (CLIA)
  - Molecular diagnostics for COVID-19

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- The new policy does NOT impact:
  - Requirements under the Clinical Laboratory Improvement Amendments (CLIA)
  - CDC recommendations for who should be tested

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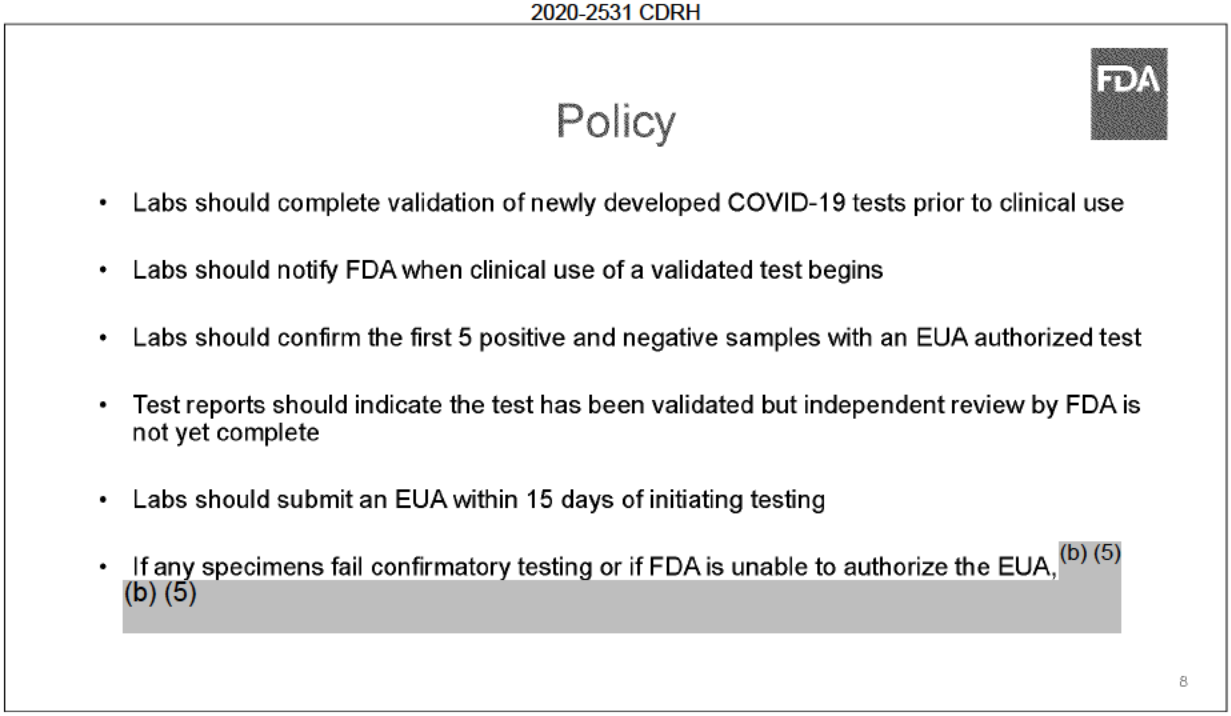
# CDC's Clinical Criteria for Testing

| Clinical Features | & | Epidemiologic Risk |
|---|---|---|
| Fever[1] **or** signs/symptoms of lower respiratory illness (e.g. cough or shortness of breath) | **AND** | Any person, including healthcare workers[2], who has had close contact[3] with a laboratory-confirmed[4] COVID-19 patient within 14 days of symptom onset |
| Fever[1] **and** signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath) requiring hospitalization | **AND** | A history of travel from affected geographic areas[5] (see below) within 14 days of symptom onset |
| Fever[1] with severe acute lower respiratory illness (e.g., pneumonia, ARDS) requiring hospitalization and without alternative explanatory diagnosis (e.g., influenza)[6] | **AND** | No source of exposure has been identified |

https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html

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FDA does not intend to object to the clinical use of diagnostics for COVID-19 that have been developed and validated in a lab certified to perform high complexity testing during this emergency if the following are criteria are met:
Labs should validate tests per guidance

Labs should notify FDA when clinical use of a validated test begins

Labs should confirm the first 5 positive and negative samples with an EUA authorized test

Test reports should indicate the test has been validated but that independent review by FDA is not yet complete

Labs should submit an EUA within 15 days of initiating testing

If any specimens fail confirmatory testing or if FDA is unable to authorize the EUA, (b) (5)
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# Policy

Validation should meet minimal recommendations outlined in the guidance for:

- Limit of Detection
- Clinical Evaluation
- Inclusivity
- Cross-Reactivity



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# Limit of Detection

- Defined as the lowest concentration at which 19/20 replicates are positive
- Methods:
  - test dilution series with 3 replicates per concentration
  - confirm final concentration with 20 replicates
- Samples:
  - may use contrived samples (i.e., spiking RNA or inactivated virus into artificial or real clinical matrix)
  - if multiple specimen types are intended, evaluate most challenging (e.g., sputum)

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# Clinical Evaluation

- Test at least 30 contrived reactive specimens and 30 non-reactive specimens
  - Contrived reactive specimens can be created by spiking RNA or inactivated virus into leftover clinical specimens
  - Twenty of the contrived specimens should be spiked at a concentration of 1x-2x LoD, with the remainder of specimens spanning the assay testing range.

- Acceptable performance:
  - 95% agreement at 1x-2x LoD and
  - 100% agreement at all other concentrations and for negative specimens



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# Inclusivity

- Conduct an *in silico* analysis of the percent identity matches against publicly available SARS-CoV-2 sequences that can be detected by the proposed molecular assay.
- 100% of published SARS-CoV-2 sequences should be detectable with the selected primers and probes



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# Cross-Reactivity

- Conduct an *in silico* analysis of the assay primer and probes compared to common respiratory flora and other viral pathogens is sufficient
- There should be >80% homology between one of the primers/probes and any sequence present in the targeted microorganism
- Follow recognized laboratory procedures for any additional cross-reactivity testing in the context of the sample types intended for testing



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## Submissions to FDA

- **Notification** of clinical use of a validated test should be directed to CDRH-EUA-Templates@fda.hhs.gov and should include:
  - name of the laboratory
  - name of the lab director
  - address
  - contact person

- **EUA** should be submitted within 15 days of initiating clinical testing to OIR-Operations@fda.hhs.gov and should include:
  - Form 3514 available at: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf
  - Completed EUA template available at: https://www.fda.gov/media/135658/download

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Mention: Under normal circumstances, an EUA should be mailed to our document control center. Due to the extenuating circumstances, we will waive this requirement and accept submissions via email.

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# Resources

- COVID-19 Guidance Document: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostics-testing-laboratories-certified-perform-high-complexity-testing-under-clia-prior

- General EUA Guidance Document: https://www.fda.gov/media/97321/download

- Novel Coronavirus (COVID – 19) webpage: https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-covid-19

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# Questions?

For questions on the guidance and accelerated EUA template, or if you wish to consider use an alternative specimen type, contact the Division of Microbiology devices at (301) 348-1778 or: CDRH-EUA-Templates@fda.hhs.gov.

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Slide Presentation, Transcript and Webinar Recording will be available at:
http://www.fda.gov/training/cdrhlearn
Under Heading [Insert respective webpage heading]

16

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 10:23:50 PM
**To**: Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Elizabeth J Hillebrenner (Elizabeth.Hillebrenner@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: EUA COVID-19 Lab Tests - Webinar deck.pptx
**Attachments**: EUA COVID-19 Lab Tests - Webinar deck.pptx

Hi Uwe,

I wanted you to see this sooner than later. I'm a little tired and so will look at it again in the morning. I see the virus name will require updating and will check the rest for accuracy, content and delivery as well.

Again, thank you to you and your team for the NYS authorization!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:16 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** EUA COVID-19 Lab Tests - Webinar deck.pptx

Jeff and Tim,
Attached are draft slides for the webinar Monday for your review. I think they will may to go through OCC as well.
Elizabeth

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/29/2020 1:08:06 PM
**To:** Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]

**Subject:** FW: Seattle Flu Study - FDA discussion
**Location:** https://washington.zoom.us/j/(b) (6)

**Start:** 2/29/2020 2:00:00 PM
**End:** 2/29/2020 3:00:00 PM
**Show Time As:** Tentative

**Recurrence:** (none)

---

**From:** Robin A Prentice <robins4@uw.edu>
**Date:** February 29, 2020 at 2:00:00 PM EST
**To:** Mark Rieder <mrieder@uw.edu>, Cowgill, Karen <n-kcowgill@kingcounty.gov>, Helen Y Chu <helenchu@uw.edu>, Langley, Gayle E (CDC) <fez7@cdc.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Duchin, Jeff <Jeff.Duchin@kingcounty.gov>, Kay, Meagan <Meagan.Kay@kingcounty.gov>, Janet Englund (janet.englund@seattlechildrens.org) <janet.englund@seattlechildrens.org>, Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>, Jay A. Shendure <shendure@uw.edu>, Trevor Bedford <trevor@bedford.io>, lstarita <lstarita@uw.edu>
**Subject:** Seattle Flu Study - FDA discussion

---

**From:** Robin A Prentice
**Sent:** Saturday, 29 February 2020 17:48:39 UTC
**To:** Robin A Prentice; Mark Rieder; Stenzel, Timothy; Cowgill, Karen; Helen Y Chu; Langley, Gayle E (CDC); Kuhnert-Tallman, Wendi L (CDC); Duchin, Jeff; Kay, Meagan; Janet Englund (janet.englund@seattlechildrens.org); Lindquist, Scott SL (CDC doh.wa.gov); Jay A. Shendure; Trevor Bedford; lstarita
**Subject:** Seattle Flu Study - FDA discussion
**When:** Saturday, February 29, 2020 7:00 PM-8:00 PM.
**Where:** https://washington.zoom.us/j/(b) (6)

Robin A Prentice is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://washington.zoom.us/j/(b) (6)

Meeting ID:(b) (6)

One tap mobile
(b) (6) # US (San Jose)
# US (New York)

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Dial by your location
+(b) (6) US (San Jose)
+ US (New York)
Meeting ID: (b) (6)
Find your local number: https://washington.zoom.us/u/aBKpLE0ae

Join by SIP
8830137437@zoomcrc.com

Join by H.323
(b) (6) S West)
S East)
China)
dia Mumbai)
dia Hyderabad)
EMEA)
Australia)
ong Kong)
Brazil)
anada)
(Japan)
Meeting ID: (b) (6)

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/27/2020 7:06:32 AM
**To:** Werner Kroll [(b) (6) @quidel.com]
**CC:** Doug Bryant [dbryant@quidel.com]; Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: COVID-19

Thanks for the update Werner. I am copying Uwe who may have the UTMB contact info and can give feedback on your plans. Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Werner Kroll <(b) (6) @quidel.com>
**Sent:** Wednesday, February 26, 2020 10:51 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Doug Bryant <dbryant@quidel.com>
**Subject:** COVID-19

Hello Tim,

As promised yesterday, following please find a short summary of the current status of our COVID-19 Lyra project:

Yesterday you mentioned the availability of inactivated virus through (b) (4) Despite trying to contact someone at (b) (4) to evaluate availability of the inactivated virus we were not able to get any further there. Could you please provide some more information on whom specifically to contact?
Similarly the evaluation of availability of extracted RNA through (b) (4) showed that material could only be shipped by end of March. Do you have any further or different information you could provide?

The internal project status is as follows:

(b) (4)

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(b) (4)



Thank you so much.

Best regards

Werner

Werner Kroll, PhD
SVP Research & Development
9975 Summers Ridge Road, San Diego, CA, 92121 USA
Office: +(b) (6) /Cell: +(b) (6)
(b) (6) @quidel.com
**quidel.com**

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/28/2020 2:08:29 PM
**To:** Shearstone, Peter E. [(b) (6) @thermofisher.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: EUA Submission

That's a large number. Thanks Peter.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Shearstone, Peter E. <(b) (6) @thermofisher.com>
**Sent:** Friday, February 28, 2020 2:06 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: EUA Submission

We can get to (b) (4) tests (b) (4) after authorization.
We've got the raw materials and are getting the facility production plans in place.

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) Mobile: (b) (6)
Internal extension (b) (6)
(b) (6) @thermofisher.com

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:02 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Shearstone, Peter E. <(b) (6) @thermofisher.com>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>

AMERICAN OVERSIGHT

**Cc:** Fenton, Tim <tim.fenton@thermofisher.com>; Kerr, Liz <(b) (6) @thermofisher.com>
**Subject:** RE: EUA Submission

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Thanks Peter, this is great news.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 12:51 PM
**To:** Shearstone, Peter E. <(b) (6) @thermofisher.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Fenton, Tim <tim.fenton@thermofisher.com>; Kerr, Liz <(b) (6) @thermofisher.com>
**Subject:** RE: EUA Submission

Adding Uwe who can better opine on timing of response.

---

**From:** Shearstone, Peter E. <(b) (6) @thermofisher.com>
**Sent:** Friday, February 28, 2020 12:37 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Fenton, Tim <tim.fenton@thermofisher.com>; Kerr, Liz <(b) (6) @thermofisher.com>
**Subject:** EUA Submission

Dear Jeff, Tim and Wendi,

A quick update from Thermo Fisher's efforts on COVID-19.

We plan to submit the EUA pre-sub to Uwe between 7-8pm EST tonight.
Let me know when we could expect a response in order to keep moving.

AMERICAN OVERSIGHT

Also :
(b) (4)

(b) (4)

Let me know what else you may need.

Best,
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) | Mobile: (b) (6)
Internal extension (b) (6)
(b) (6) @thermofisher.com

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 1:01:21 PM
**To**: Robin A Prentice [robins4@uw.edu]

**Subject**: Accepted: Seattle Flu Study - FDA discussion
**Location**: https://washington.zoom.us/j/(b) (6)

**Start**: 2/29/2020 2:00:00 PM
**End**: 2/29/2020 3:00:00 PM
**Show Time As**: Busy

**Recurrence**: (none)

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/29/2020 1:01:01 PM
**To:** Robin A Prentice [robins4@uw.edu]; Cowgill, Karen [n-kcowgill@kingcounty.gov]; Mark Rieder [mrieder@uw.edu]; Helen Y Chu [helenchu@uw.edu]; Langley, Gayle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09640f099c74468d9480b73a6d194d5d-HHS-fez7-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Duchin, Jeff [Jeff.Duchin@kingcounty.gov]; Kay, Meagan [Meagan.Kay@kingcounty.gov]
**CC:** Janet Englund (janet.englund@seattlechildrens.org) [janet.englund@seattlechildrens.org]; Lindquist, Scott SL (CDC doh.wa.gov) [scott.lindquist@doh.wa.gov]; Jay A. Shendure [shendure@uw.edu]; Trevor Bedford [trevor@bedford.io]; lstarita [lstarita@uw.edu]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: SEATTLE Flu Study Lab Result

Sounds good.

---

**From:** Robin A Prentice <robins4@uw.edu>
**Date:** February 29, 2020 at 12:44:15 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Cowgill, Karen <n-kcowgill@kingcounty.gov>, Mark Rieder <mrieder@uw.edu>, Helen Y Chu <helenchu@uw.edu>, Langley, Gayle E (CDC) <fez7@cdc.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Duchin, Jeff <Jeff.Duchin@kingcounty.gov>, Kay, Meagan <Meagan.Kay@kingcounty.gov>
**Cc:** Janet Englund (janet.englund@seattlechildrens.org) <janet.englund@seattlechildrens.org>, Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>, Jay A. Shendure <shendure@uw.edu>, Trevor Bedford <trevor@bedford.io>, lstarita <lstarita@uw.edu>
**Subject:** RE: SEATTLE Flu Study Lab Result

Hello Tim,

Would it work for us to talk at 11am Pacific time, 2pm Eastern? I will send a zoom invite in a moment.

Robin

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:11 AM
**To:** Cowgill, Karen <n-kcowgill@kingcounty.gov>; Mark Rieder <mrieder@uw.edu>; Helen Y Chu <helenchu@uw.edu>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Kay, Meagan <Meagan.Kay@kingcounty.gov>
**Cc:** Robin A Prentice <robins4@uw.edu>; Janet Englund (janet.englund@seattlechildrens.org) <janet.englund@seattlechildrens.org>; Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>; Jay A. Shendure <shendure@uw.edu>; Trevor Bedford <trevor@bedford.io>; lstarita <lstarita@uw.edu>
**Subject:** RE: SEATTLE Flu Study Lab Result

Hi,

Can one or more folks from the Seattle Flu Study lab give me a call on my cell (b) (6) ? Leave a VM with number to get back to you right away if it goes to VM.

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Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:53 AM
**To:** Cowgill, Karen <n-kcowgill@kingcounty.gov>; Mark J Rieder <mrieder@uw.edu>; Helen Y Chu <helenchu@uw.edu>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Kay, Meagan <Meagan.Kay@kingcounty.gov>
**Cc:** Robin A Prentice <robins4@uw.edu>; Janet Englund (janet.englund@seattlechildrens.org) <janet.englund@seattlechildrens.org>; Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>; Jay A. Shendure <shendure@uw.edu>; Trevor Bedford <trevor@bedford.io>; Istarita <lstarita@uw.edu>
**Subject:** RE: SEATTLE Flu Study Lab Result

Hi Karen,

I did connect with Mark a little after an hour yesterday by phone.

Wanted to let you know of this PR and linked new guidance that just was released.

We are still working on your particular situation.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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**Jennifer Campbell**
*Administrative Assistant*

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Cowgill, Karen <n-kcowgill@kingcounty.gov>
**Sent:** Friday, February 28, 2020 4:46 PM
**To:** Mark J Rieder <mrieder@uw.edu>; Helen Y Chu <helenchu@uw.edu>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Kay, Meagan <Meagan.Kay@kingcounty.gov>
**Cc:** Robin A Prentice <robins4@uw.edu>; Janet Englund (janet.englund@seattlechildrens.org) <janet.englund@seattlechildrens.org>; Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>; Jay A. Shendure <shendure@uw.edu>; Trevor Bedford <trevor@bedford.io>; Istarita <Istarita@uw.edu>
**Subject:** RE: SEATTLE Flu Study Lab Result
**Importance:** High

Hi Tim, et al. at CDC and Mark, et al. at SFS – Jeff Duchin (Chief Health Officer at Public Health Seattle-King County) asked me to follow up with you about the outcome of our discussion earlier today (9 PT/12 ET) about Seattle Flu Study testing for SARS-CoV-2.

At the end of the call, Tim said he would get back to Mark within the hour, but we haven't heard anything on our end.

Could someone please send a summary of where things stand and specifically
- what the current guidance is about SFS continued testing of samples for nCoV (retrospective and prospective)
- if testing continues, what is the flow of information to public health / re-contacting patients with results
- any other relevant info (e.g., was the lot of the kit SFS used to confirm their initial positive the same lot that CDC had QC'd?)

Thank you,

Karen Cowgill, PhD, MSc *(she/her)*
COVID-19 Response Epidemiologist
Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Affiliate Assistant Professor in Global Health, University of Washington
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (b) (6) Fax: (206) 296-4803
E-mail: n-kcowgill@kingcounty.gov

---

**From:** Mark J Rieder <mrieder@uw.edu>
**Sent:** Thursday, February 27, 2020 10:57 PM
**To:** Helen Y Chu <helenchu@uw.edu>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Robin A Prentice <robins4@uw.edu>; Janet Englund (janet.englund@seattlechildrens.org)

AMERICAN OVERSIGHT

<janet.englund@seattlechildrens.org>; Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>; Jay A. Shendure <shendure@uw.edu>; Trevor Bedford <trevor@bedford.io>; Istarita <lstarita@uw.edu>
**Subject:** Re: SEATTLE Flu Study Lab Result

[EXTERNAL Email Notice! ] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

Here is the Zoom link for the call in tomorrow (Friday, 2/28 @ 9 am PT)
Mark Rieder is inviting you to a scheduled Zoom meeting.

Topic: CDC Call
Time: Feb 28, 2020 09:00 AM Pacific Time (US and Canada)

Join Zoom Meeting
https://washington.zoom.us/j/(b) (6)

Meeting ID:(b) (6)

One tap mobile
+(b) (6) # US (San Jose)
+ # US (New York)

Dial by your location
+(b) (6) US (San Jose)
+ US (New York)
Meeting ID: (b) (6)

On Thu, Feb 27, 2020 at 10:50 PM Helen Y Chu <helenchu@uw.edu> wrote:

> Let's all plan to be on a 9:00 am call tomorrow to discuss this. Robin, can you set up a zoom call and include whoever else should join from the SFS team.
> Thank you.
>
> Get Outlook for iOS
>
> ---
>
> **From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
> **Sent:** Thursday, February 27, 2020 8:19 PM
> **To:** Duchin, Jeff (CDC kingcounty.gov)
> **Cc:** Helen Y Chu; Janet Englund (janet.englund@seattlechildrens.org); Lindquist, Scott SL (CDC doh.wa.gov); Cowgill, Karen
> **Subject:** Re: SEATTLE Flu Study Lab Result
>
> Thanks much Jeff for connecting us. Happy to make the time any time - 7:30 your time is fine but I will wait to see the calendar invite to confirm.
>
> Thanks!
>
> Get Outlook for iOS

AMERICAN OVERSIGHT

**From:** Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
**Sent:** Thursday, February 27, 2020 11:17:20 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Cc:** Helen Y Chu <helenchu@uw.edu>; Janet Englund (janet.englund@seattlechildrens.org) <janet.englund@seattlechildrens.org>; Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>
**Subject:** SEATTLE Flu Study Lab Result

Wendy,

Thanks for helping us navigate with FDA colleagues what we can say/do in response to a potential positive test result from the SFS research assay. Helen Chu and Jan Englund are the SFS researchers that can provide the details of the test method and other relevant information. I'm also copying Scott Lindquist, the WA State DOH communicable disease epidemiologist and Karen Cowgill who works on surveillance with us. It probably would be good to have a call early tomorrow Pacific time (7:30) but Helen and Jan should schedule the time with you.

Very much appreciate your help.

Jeff

Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (b) (6) ; Fax: (206) 296-4803
E-mail: jeff.duchin@kingcounty.gov

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/29/2020 10:45:17 AM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: IDT

Got it reviewing second draft

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:44 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: IDT

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 10:28 AM
**To:** Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** IDT

Tim,

Below is a draft email not yet ready to be share but I wanted to get your feedback on whether it captures what would be covered under the no object. We will address (b) (5), (b) (4) when we know their test is validated. Please note that this draft does not currently include (b) (5)

Dear Wendi,

AMERICAN OVERSIGHT

(b) (5)



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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/28/2020 3:05:55 PM
**To**: Becker, Scott | APHL [Scott.Becker@aphl.org]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]
**CC**: Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Wroblewski, Kelly | APHL [kelly.wroblewski@aphl.org]; Emergency Center | APHL [eoc@aphl.org]; Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Elizabeth J Hillebrenner (Elizabeth.Hillebrenner@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Language consideration for expedited EUA process

APHL suggestions

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Becker, Scott | APHL <Scott.Becker@aphl.org>
**Sent:** Friday, February 28, 2020 2:18 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Wroblewski, Kelly | APHL <kelly.wroblewski@aphl.org>; Emergency Center | APHL <eoc@aphl.org>
**Subject:** Language consideration for expedited EUA process
**Importance:** High

Dear Drs. Stenzel and Jernigan,

AMERICAN OVERSIGHT

We appreciate your work on rolling out an expedited approach for laboratories interested in pursuing Emergency Use Authorization of tests developed in their laboratories. We think this is an important step in expanding testing capacity in the United States. We would like to put forward two points for you to consider as you are developing guidance on this process in case they have not already been considered.

1. Please consider including language on requiring rapid notification of positive results to public health agencies to assure appropriate public health steps are taken to mitigate spread of disease.
2. Consider limiting use of EUA assays made available through the expedited EUA process to individuals who meet CDC criteria for testing, as has been required in other public health emergencies.

We applaud your efforts to identify pathways to expand testing capacity more quickly and look forward to working with you on how to move forward.

Scott Becker

**Scott J. Becker** (he/him)
Chief Executive Officer
**P** +1 240.485.2747 | **M** +1 301.526.5704
scott.becker@aphl.org | @scottjbecker

Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
www.aphl.org | APHL Blog
Facebook | Twitter | LinkedIn | Instagram

ID Lab Con 2020 | APHL 2020 Why Attend? (video)

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 7:48:40 AM
**To**: Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Research lab is asking to do clinical testing for coronavirus and report results to patients

Hi Uwe,

A seemingly expert research lab (b) (4) is asking for permission to do clinical patient testing with IDT RUO kits. They do not have CLIA certification. They have capability and want to help.

Question for you, (b) (5)
(b) (5)

Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/28/2020 5:33:56 PM
**To**: Carroll, Darin S (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1e41f0ca9984d0ea6d434fd7dc0908d-HHS-zuz4-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**CC**: Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Guidance on Minimum Criteria for LDTs

The minimal criteria acceptable to validate the test to be developed by the target laboratories are listed below. We foresee that it will take 3-4 days for a CLIA-certified, high-complexity laboratory to complete these evaluations.

(b) (5)

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Office of Product Evaluation and Quality

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 10:17:04 PM
**To**: St. George, Kirsten (HEALTH) [kirsten.st.george@health.ny.gov]; Taylor, Jill (HEALTH) [jill.taylor@health.ny.gov]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Thank you Kirsten! This is great!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-7692
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**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Saturday, February 29, 2020 10:15 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph

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<Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Subject:** RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Dear Dr. Stenzel,

Current capacity at the Wadsworth Center for SARS-CoV-2 real-time RT-PCR testing is (b) (4) specimens per week.

We will be working in the coming weeks to enhance that with some additional automation, with the goal to increase capacity to (b) (4) per week. That is our capacity for (b) (4).

Kind regards, Kirsten

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george

NEW YORK STATE | Department of Health | Wadsworth Center

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:54 PM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

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Drs. Taylor and St. George,

You are most welcome! We are curious, what is your lab's weekly capacity for Coronavirus test volume? We are trying to keep track of this number nationwide.

Thanks in advance!

Best,
Tim

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**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Saturday, February 29, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Thank you so much Uwe. Being able to work with you and your FDA colleagues has been a privilege. We are grateful that the FDA is with us as we work to protect our citizens.
Very best wishes,
Jill

Sent from my iPhone

On Feb 29, 2020, at 9:35 PM, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov> wrote:

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Drs. Taylor and St. George,

It is a pleasure to inform you that your submission for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issued an Emergency Use Authorization.

Attached please find the electronic version of the signed letter. Please confirm the receipt of the letter.

Congratulations, it has been a pleasure to work with you and your team.

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Kind regards,

Uwe Scherf

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Saturday, February 29, 2020 6:02 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** RE: Material to discuss for 1 PM
**Importance:** High

Here is the new letter

Please let me know if it OK or if you need adjustments

Best, Kirsten

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george

<image001.png.secure>

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:09 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** RE: Material to discuss for 1 PM

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Dear Kirsten

Please find attached Draft EUA request cover letter you can use.

You can delete the hard copy part as you EUA submission is already logged in

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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<image004.jpg.secure>

<image005.jpg.secure>

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<image007.jpg.secure>

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:56 PM
**To:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Material to discuss for 1 PM

Kristen,

We would like to go over the following documents with you during our 1 PM call:

Intended Use

Instructions for Use

And discuss the Fact Sheets

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**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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<NYS DOH EUA Letter of Authorization 02292020 FINAL.pdf.secure>

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/26/2020 4:30:03 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Thank you Ellen, I just forwarded it to Dr. Redfield copying Jeff and Dan.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 4:21 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Dear Wendi,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

On February 24, 2020, CDRH/FDA was informed that enforcement discretion from FDA was needed for the following:

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1. CDC qualified laboratories to perform testing using only the already distributed N1 and N2 (and not N3) primers of CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel, upon verification of those primers by the laboratory, until such time as they receive and verify new primers that will be supplied by CDC and/or Integrated DNA Technologies (IDT) and begin performing testing with them. CDC would also distribute and these laboratories would use new result interpretation instructions that FDA has reviewed but has not yet authorized as part of an EUA, for performing testing with only the N1 and N2 primers. CDC requests this enforcement discretion to address the manufacturing issues that have been identified with certain N3 primers and to avoid significant delays in testing given increased testing demands. CDC and IDT, a CDC-identified third-party manufacturer, are preparing new lots and kits for the new primers, but it will take some time to complete quality control testing and to send these primers to the CDC qualified laboratories.

2. CDC qualified laboratories to test individuals who meet COVID-19 clinical and/or epidemiological criteria using the authorized test and the two primer test (as set forth above). This enforcement discretion is being requested to address growing concerns of community transmission of COVID-19, and would be until authorization of a new or amended EUA for this use.

CDC has generated data indicating that testing using the N1 and N2 primers of the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel may be effective in the detection of SARS-CoV-2, and CDC and FDA have worked interactively in connection with FDA's review of the data. At this time, there are no adequate, approved, and available alternative tools that can detect SARS-CoV-2.

Our understanding of the facts and the public health concerns at issue here are: that there is currently no other test available to detect SARS-CoV-2 to respond to this emergency; significant public health concerns are presented by the infectious disease; and the proposed testing may help to prevent the spread of the infectious disease COVID-19. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the conditions that presumptive positives and inconclusive results will be confirmed by testing at the CDC headquarters in Atlanta, GA, and that CDC will act promptly to submit a new or amended EUA to authorize the testing described above.

Sincerely,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov






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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/26/2020 4:29:28 PM
**To**: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
**CC**: Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Hi Dr. Redfield,

Enforcement Discretion for N1 and N2 only testing was just delivered to the CDC. See below.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-7692
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**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 4:21 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Dear Wendi,

AMERICAN OVERSIGHT

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase

(RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

On February 24, 2020, CDRH/FDA was informed that enforcement discretion from FDA was needed for the following:

1. CDC qualified laboratories to perform testing using only the already distributed N1 and N2 (and not N3) primers of CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel, upon verification of those primers by the laboratory, until such time as they receive and verify new primers that will be supplied by CDC and/or Integrated DNA Technologies (IDT) and begin performing testing with them. CDC would also distribute and these laboratories would use new result interpretation instructions that FDA has reviewed but has not yet authorized as part of an EUA, for performing testing with only the N1 and N2 primers. CDC requests this enforcement discretion to address the manufacturing issues that have been identified with certain N3 primers and to avoid significant delays in testing given increased testing demands. CDC and IDT, a CDC-identified third-party manufacturer, are preparing new lots and kits for the new primers, but it will take some time to complete quality control testing and to send these primers to the CDC qualified laboratories.

2. CDC qualified laboratories to test individuals who meet COVID-19 clinical and/or epidemiological criteria using the authorized test and the two primer test (as set forth above). This enforcement discretion is being requested to address growing concerns of community transmission of COVID-19, and would be until authorization of a new or amended EUA for this use.

CDC has generated data indicating that testing using the N1 and N2 primers of the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel may be effective in the detection of SARS-CoV-2, and CDC and FDA have worked interactively in connection with FDA's review of the data. At this time, there are no adequate, approved, and available alternative tools that can detect SARS-CoV-2.

Our understanding of the facts and the public health concerns at issue here are: that there is currently no other test available to detect SARS-CoV-2 to respond to this emergency; significant public health concerns are presented by the infectious disease; and the proposed testing may help to prevent the spread of the infectious disease COVID-19. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the conditions that presumptive positives and inconclusive results will be confirmed by testing at the CDC headquarters in Atlanta, GA, and that CDC will act promptly to submit a new or amended EUA to authorize the testing described above.

Sincerely,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov






AM OVERSIGHT

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/27/2020 6:39:48 PM
**To**: Melina Cimler [bmcimler@pandiadx.com]
**CC**: Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: EUA - Corona

Hi Melina,

Uwe or someone in his group can help. I have copied him.

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant
OHT7: Office of In Vitro Diagnostics and Radiological Health
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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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-----Original Message-----
From: Melina Cimler <bmcimler@pandiadx.com>
Sent: Thursday, February 27, 2020 6:20 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: EUA - Corona

Hi Tim,

Long time no chat. I just had Jeff Trent reach out as I boarded a flight to head back to Dallas. Who can I chat with as to an EUA for their assay? State of AZ public health lab has reached out to them. I asked them to send me a summary of where they are with their assay and will be glad to share when I get it.

Can you chat tomorrow morning?

Best regards,

Melina

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 7:41:49 AM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: NYS Wadsworth Center COVID-19 Test

Hi Dan, We want to prospectively ask this for (b) (4), (b) (5)
(b) (4), (b) (5)

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Jennifer.Campbell@fda.hhs.gov

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:37 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Busch,

AMERICAN OVERSIGHT

Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Hi Dan, Thanks for the quick call this morning. A simple email to the FDA/me stating "Yes, The New York State Wadsworth Center can reference the data in the CDC's 2019 nCoV EUA application" is sufficient for the FDA's review purposes that should lead to a quick EUA authorization for Wadworth's EUA, as early as this afternoon. Therefore, this is obviously an urgent matter.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Hi Dan and Wendi,

This right of reference is important to get this and additional assays based on the CDC through the EUA process quickly. The other two companies we discussed today will be similar.

I believe a simple email stating "Yes, The New York State Wadsworth Center can reference the data in the CDC 2019 nCoV EUA application".

Hope this helps.

Thanks in advance!

Best,
Tim

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 7:55:22 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Adding additional people.

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:50 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** NYS Wadsworth Center COVID-19 Test
**Importance:** High

Wendi, Dan, Laura,

NYS Wadsworth Center submitted an EUA request to us this afternoon for a test that uses the CDC protocol but only for N1/N2 (consistent with the CDC test currently subject to enforcement discretion). To support their EUA, Wadsworth conducted a bridging study that demonstrates performance similar to CDC's N1/N2 test. We know their performance is comparable because we have seen CDC's data but Wadsworth has not. **Would CDC allow Wadsworth to have a right of reference to its data, under which does not get access to the data but can reference it in support of their EUA?** Wadsworth has one more test to perform, which if it looks good, we would otherwise grant the EUA.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov
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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/28/2020 11:31:01 AM
**To:** Elizabeth J Hillebrenner (Elizabeth.Hillebrenner@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**CC:** Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: Minimal Criteria for test validation

Hi Elizabeth, I concur with these criteria.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Jennifer.Campbell@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:42 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Minimal Criteria for test validation

Jeff and Tim,

The minimal criteria acceptable to validate the test to be developed by the target laboratories are listed below. We foresee that it will take 3-4 days for a CLIA-certified, high-complexity laboratory to complete these evaluations.

(b) (5)



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(b) (5)



Let me know if you have any questions.

Uwe

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/28/2020 11:30:21 AM
**To**: Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]
**CC**: Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: Minimal Criteria for test validation

**Importance**: High

Hi,

We are hearing the Secretary will announce the new pathway at 2 pm today in a press conference. The FDA has been tasked with getting guidance up on the FDA website by 2 pm. Below are the draft criteria for validation. Please give feedback if any as soon as possible.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Jennifer.Campbell@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:42 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Minimal Criteria for test validation

Jeff and Tim,

AMERICAN OVERSIGHT

The minimal criteria acceptable to validate the test to be developed by the target laboratories are listed below. We foresee that it will take 3-4 days for a CLIA-certified, high-complexity laboratory to complete these evaluations.

(b)(5) DRAFT

[redacted]

specimens.

Let me know if you have any questions.

Uwe

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/29/2020 10:42:30 AM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: IDT

Reviewing it

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:28 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** IDT

Tim,

Below is a draft email not yet ready to be share but I wanted to get your feedback on whether it captures what would be covered under the no object. We will address (b) (4), (b) (5) when we know their test is validated. Please note that this draft does not currently include (b) (5)

Dear Wendi,

(b) (5)

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/26/2020 1:31:49 PM
**To**: Zale, Amy (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=259a8ac6fdee4f1baf12a36a0fe5078f-HHS-Amy.Zal]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Coronavirus EUA kit update

**Importance**: High

Hi Amy,

The CDC has asked that I give you an update on a change to the CDC EUA kit. Can you give me a call at your earliest convenience? This is an urgent, fast moving issue.

I can be reached on my FDA cell at 202-308-9464.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Office of Product Evaluation and Quality

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 7:03:49 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Fwd: NYS Wadsworth Center COVID-19 Test

Morning Jeff, I will make calls to Wendi and/or Dan early this morning to get CDC's permission. If we don't get a clear yes immediately in writing from Dan or Wendi, I recommend we run this up the chain going next to either Redfield's COS or Redfield. Thanks! Tim

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 9:08:37 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

We still need to get all the documents fixed and get final versions back to NY. It cannot happen before the afternoon.

Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:57 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Fwd: NYS Wadsworth Center COVID-19 Test

Hi Uwe, How soon can you finish this if you get the right of reference? I will work on the CDC again in the morning. Best, Tim

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 28, 2020 at 8:30:18 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Hi Dan and Wendi,

This right of reference is important to get this and additional assays based on the CDC through the EUA process quickly. The other two companies we discussed today will be similar.

I believe a simple email stating "Yes, The New York State Wadsworth Center can reference the data in the CDC 2019 nCoV EUA application".

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Hope this helps.

Thanks in advance!

Best,
Tim

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 7:55:22 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

Adding additional people.

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:50 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** NYS Wadsworth Center COVID-19 Test
**Importance:** High

Wendi, Dan, Laura,

NYS Wadsworth Center submitted an EUA request to us this afternoon for a test that uses the CDC protocol but only for N1/N2 (consistent with the CDC test currently subject to enforcement discretion). To support their EUA, Wadsworth conducted a bridging study that demonstrates performance similar to CDC's N1/N2 test. We know their performance is comparable because we have seen CDC's data but Wadsworth has not. **Would CDC allow Wadsworth to have a right of reference to its data, under which does not get access to the data but can reference it in support of their EUA?** Wadsworth has one more test to perform, which if it looks good, we would otherwise grant the EUA.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AM OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/28/2020 2:47:18 PM
**To**: Mark J Rieder [mrieder@uw.edu]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: IDT lot numbers

Thanks Mark. That is not the same lot number. Stay tuned.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Mark J Rieder <mrieder@uw.edu>
**Sent:** Friday, February 28, 2020 2:42 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Fwd: IDT lot numbers

See lot # pics attached.
Mark
(b) (6)

---------- Forwarded message ---------
From: **Jay Shendure** <shendure@uw.edu>
Date: Fri, Feb 28, 2020 at 10:26 AM
Subject: IDT lot numbers
To: Mark Rieder <mrieder@uw.edu>, Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>, Helen Y Chu <helenchu@uw.edu>

Hi Wendi, Mark, Helen --

I did not see on the invite the contact info for the person who was asking for the IDT lot numbers, but they are below/attached.

AMERICAN OVERSIGHT

Wendi, do you have their contact information and can you forward on (or Helen, if you happen to have it?)

Jay

---

Jay Shendure, MD, PhD
Investigator, Howard Hughes Medical Institute
Director, Allen Discovery Center for Lineage Tracing
Director, Brotman Baty Institute for Precision Medicine
Professor, Genome Sciences, University of Washington
shendure@uw.edu | (b) (6)

---

---------- Forwarded message ---------
From: **petedhan** (b) (6) @uw.edu>
Date: Fri, Feb 28, 2020 at 10:17 AM
Subject: Re: Lot numbers
To: Jay A. Shendure <shendure@uw.edu>, lstarita <lstarita@uw.edu>

---

**From:** petedhan
**Sent:** Friday, February 28, 2020 10:16 AM
**To:** Jay A. Shendure <shendure@uw.edu>; lstarita <lstarita@uw.edu>
**Subject:** Lot numbers

Taq Path lots # (b) (4)
2019 nCoV Kit (b) (4)
2019-nCoV_N positive control (b) (4)

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/28/2020 11:22:06 AM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Minimal Criteria for test validation

Giving further thought it looks good. Jeff, Can I share with the CDC?

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-7692
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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:48 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Minimal Criteria for test validation

Hi Uwe,

This is wonderful. Can we change the (b) (5) [redacted]

Thanks in advance Uwe! :)

Best,
Tim

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 10:41:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Minimal Criteria for test validation

Jeff and Tim,

The minimal criteria acceptable to validate the test to be developed by the target laboratories are listed below. We foresee that it will take 3-4 days for a CLIA-certified, high-complexity laboratory to complete these evaluations.

(b) (5)



AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/29/2020 10:08:07 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Hi Elizabeth,

The slide deck looks generally good to me. Let's run it by Uwe for his review. Do we ask him tonight or in the morning? Feel free to send it to him, copying me or I can send. COVID-19 is the disease not the virus so we will want to make sure we refer to the virus correctly and the disease correctly, depending on the context. The virus is called SARS-CoV-2.

Thanks!

Best,
***Tim***

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:55 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck.pptx

Elizabeth,

Sorry. If CDC sent the slide then okay to include it and Tim can have Dan cover it before turning back to Tim.

Jeff

---

AMERICAN OVERSIGHT

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:43 PM

**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** FW: EUA COVID-19 Lab Tests - Webinar deck.pptx

Marcy and Claire,

Attached are draft slides for our webinar Monday. We are still sorting out the slide on CDC criteria for testing. CDC will join us for the webinar and asked us to include this, but its not clear if they will have their own slide(s) or not. I wanted to get the rest of the deck to you for review right away, so I am sending in parallel while we sort that piece out.

Elizabeth

---

**From:** Hillebrenner, Elizabeth J
**Sent:** Saturday, February 29, 2020 9:16 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** EUA COVID-19 Lab Tests - Webinar deck.pptx

Jeff and Tim,
Attached are draft slides for the webinar Monday for your review. I think they will may to go through OCC as well.
Elizabeth

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/28/2020 11:21:07 AM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Minimal Criteria for test validation

Correct, (b) (5) [redacted]

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 11:17 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: Minimal Criteria for test validation

Tim,

(b) (5) [redacted]

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:48 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Minimal Criteria for test validation

Hi Uwe,

This is wonderful. Can we change the (b) (5) [redacted]

AMERICAN OVERSIGHT

Thanks in advance Uwe! :)

Best,
Tim

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 10:41:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Minimal Criteria for test validation

Jeff and Tim,

The minimal criteria acceptable to validate the test to be developed by the target laboratories are listed below. We foresee that it will take 3-4 days for a CLIA-certified, high-complexity laboratory to complete these evaluations.

(b) (5)



Let me know if you have any questions.

Uwe

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/29/2020 8:26:37 PM
**To:** Bennett, Shannon A., M.S. [(b) (6) @mayo.edu]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC:** Humes, Rosemary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6de8a41cc8d54da69787255ca964affa-HHS-Rosemar]; Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Pre-EUA Request: Mayo Clinic SARS-CoV-2 Molecular Detection Assay

Hi Shannon,

Once you get the RNA, how soon can you finish your validation and begin clinical testing under the FDA's new accelerated EUA pathway? And when you begin, what will your weekly testing capacity be?

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
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---

**From:** Bennett, Shannon A., M.S. <(b) (6) @mayo.edu>
**Sent:** Saturday, February 29, 2020 3:56 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: Pre-EUA Request: Mayo Clinic SARS-CoV-2 Molecular Detection Assay
**Importance:** High

Thank you Dr. Scherf,
We're very interested in extracted RNA, but are unfortunately not staffed to receive delivery on Sunday - is receiving material on Monday a possibility?

AMERICAN OVERSIGHT

Shannon

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 1:53 PM
**To:** Bennett, Shannon A., M.S. (b) (6) @mayo.edu>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** [EXTERNAL] RE: Pre-EUA Request: Mayo Clinic SARS-CoV-2 Molecular Detection Assay

Dear Mr. Brennet,

Please let me know whether you would be interested to receive extracted RRNA form SARS-CoV-2 for testing and can receive a shipment on Sunday

**Shannon Bennett, MS, MBA, CMQ/OE (ASQ)**
Quality Manager
Department of Laboratory Medicine & Pathology
Phone: (b) (6)
Pager: (b) (6)

**Mayo Clinic**
200 First Street SW
Rochester, MN 55905

I have copied Ms. Humes from BARDA who will help with the facilitation.

Best,

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/28/2020 12:11:55 PM
**To:** Morreale, Eric [EMorreale@seracare.com]; Russell Herbert [(b) (6) @LGCGroup.com]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Darren Cook [(b) (6) .@LGCGroup.com]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: LGC - Seracare - COVID-19 Reference Material - IVD Communications

Thanks Eric! We will discuss. Best, Tim

---

**From:** Morreale, Eric <EMorreale@seracare.com>
**Date:** February 28, 2020 at 11:55:36 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Russell Herbert <(b) (6) @LGCGroup.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Darren Cook <(b) (6) @LGCGroup.com>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** RE: LGC - Seracare - COVID-19 Reference Material - IVD Communications

Hi All,

Just to provide some additional detail that was not provided in the attachments, SeraCare's COVID-19 reference materials will cover the following genomic regions:

| Regions included | Location |
|---|---|
| ORF1a region | 417..1899 |
| | 3094..3360 |
| RdRp region | 13291..13560 |
| | 14700..15950 |
| | 18577..19051 |
| E (Envelop) region | 25801..28200 |
| N (Nucleocapsid) region | 27952..29873 |

Please don't hesitate to reach out if I can be of any further assistance.

Sincerely,

Eric

**Eric Morreale, Ph.D.**
*Director, Marketing and Product Management*
Clinical Diagnostics Business Unit
Phone: +1 508-244-6455
Mobile: +(b) (6)
Fax: +1 508-244-6541
SeraCare Life Sciences is now part of LGC Group.

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 6:12 PM
**To:** Russell Herbert (b) (6) :@LGCGroup.com>
**Cc:** Eric Morreale (b) (6) :@LGCGroup.com>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Darren Cook (b) (6) .@LGCGroup.com>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** RE: LGC - Seracare - COVID-19 Reference Material - IVD Communications

Hi Uwe,

I wanted to let you know that the (b) (4) kit utilized a control that is different from the CDC design. See attached.

Hi Russell, Let me know if you sent the quote, I may have missed it.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

**From:** Russell Herbert <(b) (6) :@LGCGroup.com>
**Sent:** Thursday, February 27, 2020 5:53 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Eric Morreale <Eric.Morreale@LGCGroup.com>
**Subject:** LGC - Seracare - COVID-19 Reference Material - IVD Communications

Tim

Timely information from my colleague at Seracare – I have forwarded this to you with a customer communication and also the product sheet with all information you were asking.

His contact details are below and I made him aware I was sending this over.

Hope it is useful

AMERICAN OVERSIGHT

Regards

Russell Herbert | Director Global Sales | Biosearch Technologies
Strategic Accounts | Healthcare & Diagnostic Market
Cell: (b) (6) (b) (6) @LGCGroup.com

Attached are the 2 pieces I'd like to speak to. The word document is the standard email communication we're sending directly to relevant IVD customer contacts; the second is a product sheet overview of AccuPlex technology.

We're also in the process of making a COVID-19 specific product sheet. We anticipate to have that ready in a week or so and will send it to you once we have it.

Please let me know if you need any more information on my end.

Thanks,

Eric

**Eric Morreale, Ph.D.**
*Director, Marketing and Product Management*
Clinical Diagnostics Business Unit
Phone: +1 508-244-6455
Mobile: (b) (6)
Fax: +1 508-244-6541
SeraCare Life Sciences is now part of LGC Group.
***Science for a Safer World***

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 10:42:25 AM
**To**: Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**CC**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: QC Testing of CDC 2019- nCoV rRT-PCR Primers Probes DRAFT.pdf

Hi,

(b) (5)

[redacted]

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:53 AM
**To:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Kuhnert-Tallman, Wendi L

AMERICAN OVERSIGHT

(CDC) <wdk1@cdc.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** QC Testing of CDC 2019- nCoV rRT-PCR Primers Probes DRAFT.pdf

Hi Steve, Dan and Wendi,

I want to suggest that (b) (5) [redacted]

This may only be temporary until manufacturers can do this on their own.

I am copying Uwe for his concurrence as well.

Thanks!

Best,
Tim

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/27/2020 8:13:58 PM
**To:** Russell Herbert (b) (6) @LGCGroup.com]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**CC:** Darren Cook (b) (6) .@LGCGroup.com]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: LGC Biosearch - RUO coronavirus Kit PO

Thanks Russell, The FDA and CDC will discuss and get back tomorrow morning. Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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**From:** Russell Herbert <(b) (6) :@LGCGroup.com>
**Sent:** Thursday, February 27, 2020 6:20 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Darren Cook (b) (6) :@LGCGroup.com>
**Subject:** LGC Biosearch - RUO coronavirus Kit PO

Tim

As discussed earlier I have attached quote for the (b) (4) kits, apologies for short delay but needed to get the key information correct, particularly the highlighted which seems minor but needs clarifications.

Manufactured under ISO 9001 in our RUO factory
Mixed and Aliquot in our ISO 13485 factory
Same specifications as already ordered.

Lead time – With internal process QC – (b) (4)
Without internal process QC – (b) (4)
These will be highest priority and we can update as they progress for you.
We have started manufacture already on (b) (4) – so the lead times are from this date.

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(b) (4)

I will send a separate note on the Licensing and Darren will be reaching out to you.
I will send a separate note from SeraCare group.

thanks

Russell Herbert | Director Global Sales
Strategic Accounts | Healthcare & Diagnostic Market
Head Office | 2199 S McDowell Blvd | Petaluma | CA | 94954 | US
GMP Manufacturing Facility: 51 Digital Dr | Novato | CA 94949-5728 | US
Cell: +(b) (6) | Toll-free: +1 800 GENOME 1
(b) (6) @LGCGroup.com | www.lgcgroup.com/genomics

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**AccuPlex Coronavirus Reference Material Available**

SeraCare, part of LGC Clinical Diagnostics, has initiated development of a reference material targeted to the COVID-19 (Coronavirus), consensus sequences, published by the CDC and WHO.

Utilizing proprietary AccuPlex technology, we are packaging target sequences of interest into a stable, non-infectious, replication-deficient, alphavirus particle. The resulting material represents a true, full-process control – from sample preparation to detection – in a safe and non-infectious format. This technology supports both IVD development efforts, as well as diagnostic quality control, for routine clinical QC use.

We anticipate that we'll have RNA transcripts available for evaluation by the first week in March, and the final packaged AccuPlex material available by the middle of March. We're offering the final product in 2 formats:

- high titer stock material that can be used for assay development and regulatory submission efforts
- low-copy-number, low-positive, reference material for clinical laboratory assay verification activities

Attached is a product sheet providing more details of the technology.

Please let me know if this may be of interest, and if you have any questions.

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# AccuPlex™ Recombinant Viral Technology

A SAFE, FULL-PROCESS CONTROL SOLUTION FOR YOUR INFECTIOUS DISEASE MOLECULAR ASSAYS

## HIGHLIGHTS

REAL MAMMALIAN VIRUS ENABLES FULL-PROCESS QC FOR RT-PCR BASED VIRAL DISEASE ASSAYS.

NON-INFECTIOUS AND REPLICATION DEFICIENT; ENSURES SAFETY DURING ASSAY DEVELOPMENT AND END-USER UTILITY.

ACCEPTS MULTIPLE SEQUENCES FROM SAME OR DIFFERENT RNA VIRUSES; OFFERS FULL GENOME COVERAGE.

## INTRODUCTION

**Emerging infectious diseases pose a severe threat to public health due to their pathogenic, contagious nature. Quick development, validation, and implementation of precision diagnostic tests are necessary to ensure accurate detection of these infectious agents in order to ensure public safety and rapid treatment. Positive controls are a crucial component for these diagnostic assays to ensure accurate performance, but can potentially harm assay developers and laboratory end-users in their infectious state.**

The key to the successful, rapid development of an infectious disease molecular diagnostic assay is to utilize non-infectious, manufactured controls. These controls should adequately represent the virus genetically and function in the appropriate assay format and sample matrix. In addition, these controls should evaluate the entire process from viral nucleic acid extraction through amplification and detection and not just a portion of the workflow (process control).

## THE SAFEST, TRUE FULL-PROCESS CONTROL ON THE MARKET

SeraCare's AccuPlex recombinant material serves as a true molecular process control for your diagnostic assays. Compatible with multiplexed RT-PCR and NGS-based assays, AccuPlex custom recombinant materials are constructed with a replication-deficient mammalian virus, producing a safe, non-infectious material (Figure 1). With a protein coat and lipid bilayer, these mammalian virus-based reference materials resemble the complexity of virus targets found in patient samples.

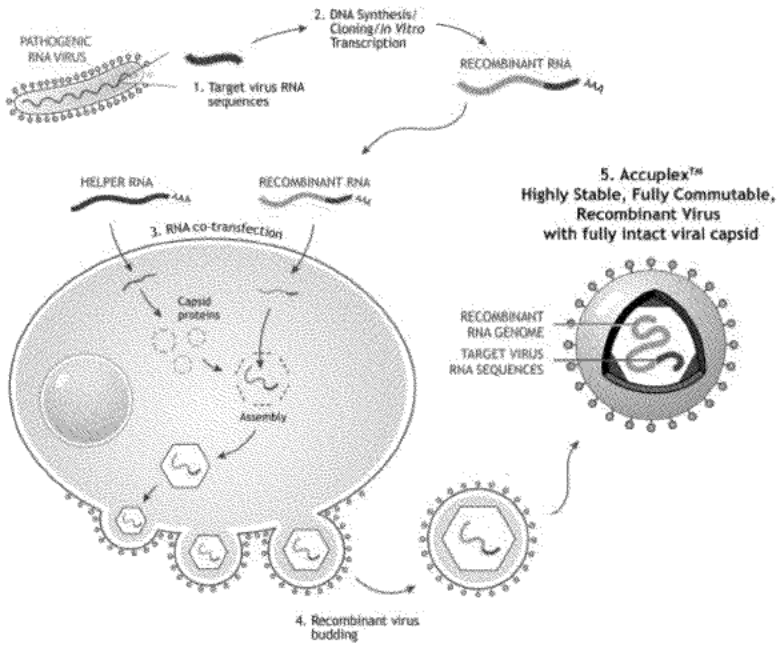



**FIGURE 1:**
1) RNA sequence from the pathogenic virus of interest is chosen. 2) DNA synthesis and cloning occur to produce the recombinant RNA. 3) Recombinant RNA and helper RNA are co-transfected into the mammalian cells, allowing the encapsulation of recombined RNA. 4) Exocytosis of the mature enveloped RNA virus with the RNA sequence of the virus of interest.

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## ABOUT SERACARE

TRUSTED SUPPLIER TO THE DIAGNOSTIC TESTING INDUSTRY FOR OVER 30 YEARS.

HIGH-QUALITY CONTROL PRODUCTS, RAW BIOLOGICAL MATERIALS, AND IMMUNOASSAY REAGENTS.

INNOVATIVE TOOLS AND TECHNOLOGIES TO PROVIDE ASSURANCE IN DIAGNOSTIC ASSAY PERFORMANCE AND TEST RESULTS.

FOR MORE INFORMATION, PLEASE VISIT OUR WEBSITE: WWW.SERACARE.COM.

## MOST 'PATIENT SAMPLE-LIKE' MATERIAL EVALUATES ENTIRE WORKFLOW

Unlike other technologies that package the viral RNA into a bacteriophage, the AccuPlex recombinant closely resembles the wild-type mammalian pathogenic virus. This enables the release of the viral genome at a similar rate to the wild-type virus during the nucleic acid sample preparation process. AccuPlex recombinant material mimics a real patient sample in your workflow, serving as a full-process control for your assay.

| Technology | Packaged Insert Size | Analyte | Complex Viral Structure | Replication Deficient | Flexible Sequence Design | True Process Control |
|---|---|---|---|---|---|---|
| **AccuPlex** | **4 kb** | **Virus** | **Yes** | **Yes** | **Yes** | **Yes** |
| Cultured virus | Full genome | Virus | Yes | No | No | Yes |
| MS-2 | 1 kb | Bacteriophage | No | Yes | Yes | No |

## ACCUPLEX SOLVES ASSAY DEVELOPMENT CHALLENGES

If you're developing diagnostics for emerging viral diseases and have the challenge of including safe, non-infectious controls in your test kit, partner with SeraCare's talented R&D team to produce your custom AccuPlex recombinant virus material (DNA or RNA-based). Utilizing your sequences of interest and product specifications, we will develop a custom solution which meets your unique requirements.

**SeraCare's AccuPlex Solution:**

- Non-infectious and replication deficient, enables safe and effective handling of positive material
- Fully-extractable with a real viral protein coat; serves as a full-process control
- Accepts multiple sequences from same or different RNA viruses, customizable to your sequences of interest
- Digital PCR (ddPCR) QC step allows for a wide range of titer levels, offers flexible concentrations
- Compatible with any sample matrix (e.g. DBS, buffer, serum)
- Stability studies confirm product is stable at 4 °C, room temperature, and elevated temperatures

## RELATED PRODUCTS

| Material # | Product | Target Regions | Fill Size |
|---|---|---|---|
| 0505-0034 | AccuPlex Zika Reference Material | Entire genome | 1 X 1.5 mLl vial |
| 0505-0001 | AccuPlex rEbola GP/NP Reference Material | Glycoprotein (GP), nucleoprotein (NP) and VP24 regions | 5 X 0.25 mL vial |
| 2410-0327 | AccuSpan HCV RNA Linearity Panel | 5' UTR region | 8 x 1.2 mL |
| 2410-0318 | AccuSpan Zika RNA Linearity Panel | Entire genome | 7 x 1.5 mL |

**Inquire about custom AccuPlex recombinant products for your diagnostics development needs.**

## LEARN MORE

To learn more about AccuPlex™Recombinant Viral Technology and SeraCare's products for infectious disease diagnostics, visit www.seracare.com/accuplex. Contact us at +1.508.244.6400 and 800.676.1881 or email info@seracare.com.

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/27/2020 6:12:29 PM
**To:** Russell Herbert (b) (6) :@LGCGroup.com]
**CC:** Eric Morreale (b) (6) :@LGCGroup.com]; Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Darren Cook (b) (6) .@LGCGroup.com]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: LGC - Seracare - COVID-19 Reference Material - IVD Communications
**Attachments:** Seracare Coronavirus communication_ v2.docx; AccuPlex Product Sheet.pdf

Hi Uwe,

I wanted to let you know that the (b) (4) kit utilized a control that is different from the CDC design. See attached.

Hi Russell, Let me know if you sent the quote, I may have missed it.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-7692
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---

**From:** Russell Herbert (b) (6) :@LGCGroup.com>
**Sent:** Thursday, February 27, 2020 5:53 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Eric Morreale (b) (6) :@LGCGroup.com>
**Subject:** LGC - Seracare - COVID-19 Reference Material - IVD Communications

Tim

Timely information from my colleague at Seracare – I have forwarded this to you with a customer communication and also the product sheet with all information you were asking.

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His contact details are below and I made him aware I was sending this over.

Hope it is useful

Regards

Russell Herbert | Director Global Sales | Biosearch Technologies
Strategic Accounts | Healthcare & Diagnostic Market
Cell: (b) (6) @LGCGroup.com

Attached are the 2 pieces I'd like to speak to. The word document is the standard email communication we're sending directly to relevant IVD customer contacts; the second is a product sheet overview of AccuPlex technology.

We're also in the process of making a COVID-19 specific product sheet. We anticipate to have that ready in a week or so and will send it to you once we have it.

Please let me know if you need any more information on my end.

Thanks,

Eric

**Eric Morreale, Ph.D.**
*Director, Marketing and Product Management*
Clinical Diagnostics Business Unit
Phone: (b) (6)
Mobile: +(b) (6)
Fax: +1 508-244-6541
SeraCare Life Sciences is now part of LGC Group.
***Science for a Safer World***

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/29/2020 9:53:44 PM
**To**: Taylor, Jill (HEALTH) [jill.taylor@health.ny.gov]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: St. George, Kirsten (HEALTH) [kirsten.st.george@health.ny.gov]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Briggs, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef1ca1039ccd4540b5899e3474749330-Joseph.Brig]; Bisht, Himani [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031ee031c9284e7d8e6363cf29546683-HXB]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Drs. Taylor and St. George,

You are most welcome! We are curious, what is your lab's weekly capacity for Coronavirus test volume? We are trying to keep track of this number nationwide.

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Saturday, February 29, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issue an Emergency Use Authorization.

Thank you so much Uwe. Being able to work with you and your FDA colleagues has been a privilege. We are grateful that the FDA is with us as we work to protect our citizens.
Very best wishes,
Jill

Sent from my iPhone

On Feb 29, 2020, at 9:35 PM, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov> wrote:

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Drs. Taylor and St. George,

It is a pleasure to inform you that your submission for the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel has been issued an Emergency Use Authorization.

Attached please find the electronic version of the signed letter. Please confirm the receipt of the letter.

Congratulations, it has been a pleasure to work with you and your team.

Kind regards,
Uwe Scherf

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>
**Sent:** Saturday, February 29, 2020 6:02 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara

AMERICAN OVERSIGHT

<Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** RE: Material to discuss for 1 PM
**Importance:** High

Here is the new letter

Please let me know if it OK or if you need adjustments

Best, Kirsten

**Kirsten St. George, MAppSc, PhD**
Chief, Viral Diseases, Wadsworth, NYSDOH
Clinical Professor, Biomedical Sciences, U. Albany, SUNY
Albany, NY, USA
1-518-474 4177
Kirsten.St.George@health.ny.gov
https://www.wadsworth.org/senior-staff/kirsten-st-george

<image001.png.secure>

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:09 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Subject:** RE: Material to discuss for 1 PM

*ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.*

Dear Kirsten

Please find attached Draft EUA request cover letter you can use.

You can delete the hard copy part as you EUA submission is already logged in

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov

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<image003.jpg.secure>

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<image007.jpg.secure>

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:56 PM
**To:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Briggs, Joseph <Joseph.Briggs@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Material to discuss for 1 PM

Kristen,

We would like to go over the following documents with you during our 1 PM call:

Intended Use

Instructions for Use

And discuss the Fact Sheets

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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<NYS DOH EUA Letter of Authorization 02292020 FINAL.pdf.secure>

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/27/2020 4:11:52 PM
**To**: Kerr, Liz [(b) (6) -@thermofisher.com]; Shearstone, Peter E. [(b) (6) @thermofisher.com]
**CC**: Tanzella, Kelli [Kelli.Tanzella@thermofisher.com]; Schumaker, Michael [(b) (6) -@thermofisher.com]; Du, Faith P. (b) (6) @thermofisher.com]; Varma, Kamini H. (b) (6) @thermofisher.com]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Meeting with Dr. Tim Stenzel, FDA OIR

Hi Liz,

(b) (4)

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Kerr, Liz (b) (6) -@thermofisher.com>
**Sent:** Thursday, February 27, 2020 4:02 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shearstone, Peter E. <(b) (6) @thermofisher.com>
**Cc:** Tanzella, Kelli <Kelli.Tanzella@thermofisher.com>; Schumaker, Michael <(b) (6) r@thermofisher.com>; Du, Faith P. (b) (6) @thermofisher.com>; Varma, Kamini H. <(b) (6) @thermofisher.com>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** Re: Meeting with Dr. Tim Stenzel, FDA OIR

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Tim, Peter,

(b) (4) [redacted]

- Liz

**Elizabeth Kerr, Ph.D.**
GSD Insights, Transformation and Portfolio Leader
Life Sciences Solutions

Thermo Fisher Scientific
180 Oyster Point Blvd | South San Francisco, CA 94080 USA
Tel: (b) (6) | Mobile (b) (6)
(b) (6) @thermofisher.com | thermofisher.com

---

**From:** "Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov>
**Date:** Thursday, February 27, 2020 at 9:52 AM
**To:** "Shearstone, Peter E." <(b) (6) @thermofisher.com>
**Cc:** "Kerr, Liz" (b) (6) @thermofisher.com>, "Tanzella, Kelli" <Kelli.Tanzella@thermofisher.com>, "Schumaker, Michael" (b) (6) @thermofisher.com>, "Du, Faith P." (b) (6) @thermofisher.com>, "Varma, Kamini H." <(b) (6) @thermofisher.com>, "Kuhnert-Tallman, Wendi L (CDC)" <wdk1@cdc.gov>
**Subject:** RE: Meeting with Dr. Tim Stenzel, FDA OIR

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For today. I am only interested in (b) (4) [redacted]

---

**From:** Shearstone, Peter E. <(b) (6) @thermofisher.com>
**Date:** February 27, 2020 at 12:43:33 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Kerr, Liz (b) (6) @thermofisher.com>, Tanzella, Kelli <Kelli.Tanzella@thermofisher.com>, Schumaker, Michael (b) (6) r@thermofisher.com>, Du, Faith P. (b) (6) @thermofisher.com>, Varma, Kamini H. (b) (6) @thermofisher.com>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** RE: Meeting with Dr. Tim Stenzel, FDA OIR

Tim,

Just got off the phone with Liz. She is pulling together the answers for you ASAP.

(b) (4) [redacted]

Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451

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Office: (b) (6) Mobile: (b) (6)
Internal extension (b) (6)
(b) (6) @thermofisher.com

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 12:30 PM
**To:** Kerr, Liz (b) (6) @thermofisher.com>; Tanzella, Kelli <Kelli.Tanzella@thermofisher.com>; Schumaker, Michael <(b) (6) @thermofisher.com>; Du, Faith P. (b) (6) @thermofisher.com>; Shearstone, Peter E. <(b) (6) @thermofisher.com>
**Cc:** Varma, Kamini H. <(b) (6) @thermofisher.com>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Subject:** Re: Meeting with Dr. Tim Stenzel, FDA OIR

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Hi Peter,

(b) (4)

Thanks!

Best,
Tim

---

**From:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**When:** February 26, 2020 at 2:00:00 PM EST
**Required:** Tanzella, Kelli <Kelli.Tanzella@thermofisher.com>, Du, Faith P. <(b) (6) @thermofisher.com>, Kerr, Liz <(b) (6) @thermofisher.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>, Schumaker, Michael (b) (6) @thermofisher.com>
**Optional:** Varma, Kamini H. <(b) (6) @thermofisher.com>
**Subject:** Meeting with Dr. Tim Stenzel, FDA OIR
**Location:** WebEx call and Tim Cell

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

Meeting number (access code): (b) (6)
Meeting password: (b) (6)

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Join meeting

**Join by phone**
Tap to call in from a mobile device (attendees only)
1-888-579-0888 United States Toll Free
+1-408-758-9898 United States Toll
Global call-in numbers | Toll-free calling restrictions

**Join by video system, application or Skype for business**
Dial 921157888@webex.com
You can also dial 173.243.2.68 and enter your meeting number.

If you are a host, go here to view host information.

Need help? Go to http://help.webex.com

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/28/2020 10:55:42 AM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Fwd: 2019-nCoV EUA Template

Hi Uwe,

(b) (5), (b) (4) [redacted]

Best,
Tim

---

**From:** Krueger, Brian <(b) (6) [redacted]@LabCorp.com>
**Date:** February 28, 2020 at 10:12:50 AM EST
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Eisenberg, Marcia <Eisenbm@LabCorp.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019-nCoV EUA Template

Thank you Tamara, (b) (4) [redacted] (b) (4) [redacted]

-Brian

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---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:23:00 AM
**To:** Krueger, Brian <(b) (6) [redacted]@LabCorp.com>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Eisenberg, Marcia <Eisenbm@LabCorp.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** [External] FW: [External] 2019-nCoV EUA Template

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Dear Brian,

AMERICAN OVERSIGHT

Additional SARS-CoV2 viral RNA is available from (b) (4) [redacted]. Attached is the product information sheet for your convenience.

Best regards,

**Tamara Feldblyum, M.S., Ph.D.**
*Branch Chief,*
*Viral Respiratory and STI Branch*
Division of Microbiology Devices | Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3106 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6195
Tamara.Feldblyum@fda.hhs.gov




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**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Friday, February 28, 2020, 6:38 AM
**To:** Bisht, Himani
**Cc:** Sapsford, Kim E
**Subject:** Re: [External] 2019-nCoV EUA Template

Hi Himani,

We are receiving (b) (4)

Sincerely,

-Brian Krueger, PhD

---

**From:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 10:12:58 PM
**To:** Krueger, Brian <(b) (6) @LabCorp.com>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** [External] 2019-nCoV EUA Template

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Dear Brian,

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I am providing you our recent feedback regarding two studies; please see below.

Limit of detection:

Analytical Sensitivity (LoD) using viral genomic RNA or inactivated virus preferably in clinical matrix as described in the EUA Template (if BSL-3 facilities are available live virus can also be used in this study). If viral genomic RNA is used in the LoD study, the clinical or simulated matrix should be mixed with the lysis buffer from the extraction kit validated for use with your test prior to the addition of RNA to mitigate the risk of RNA degradation in clinical or simulated matrix. The sample to lysis buffer ratio should be the same as when extracting and purifying nucleic acids from clinical specimens. The volume of the initial viral genomic RNA dilutions used to build the contrived specimens for testing should be kept as low as possible to maximumly preserve the characteristics of the natural clinical specimen matrixes. If lysis buffer is not used for your assay, then other methods to prevent RNA degradation may be helpful (e.g., use of RNasin). For the initial dilution of viral genomic RNA, the diluent should be able to maintain RNA stability e.g., using certified RNase-free consumables and reagents, carrier RNA or tRNA, etc.

Clinical Evaluation – Contrived clinical study:
You should test 50 negative and 50 positive contrived clinical samples. The samples should be prepared by spiking SARS-CoV2 viral RNA or inactivated virus into individual clinical specimens collected from patients with signs and symptoms of respiratory infection (if BSL-3 facilities are available live virus can also be used to prepare contrived clinical samples). Left-over archived specimens may be used to prepare the mock clinical samples. Half (25) of the contrived positive samples should be prepared by spiking the SARS-CoV2 at 1X – 2x LoD and the remaining contrived positive samples should span the testing range of your assay and not higher than 5x LoD. Consider mixing the clinical matrix with the lysis buffer from the extraction kit validated for use with your test prior to the addition of viral RNA to mitigate the risk of RNA degradation. The sample to lysis buffer ratio should be the same as when extracting and purifying nucleic acids from clinical specimens. The volume of the initial viral genomic RNA dilutions used to build the contrived clinical specimens for testing should be kept as low as possible to maximumly preserve the characteristics of the natural clinical specimen matrix.

I will send remaining FDA comments in the interactive review Template soon.

Note: Please contact FDA if you are interested in obtaining the extracted viral genomic RNA.

Best regards,
Himani

**Himani Bisht, Ph.D.**
*Interdisciplinary Scientist*

Viral Respiratory and HPV Branch
Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3202 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6189| Fax: (301)-847-8512
Himani.Bisht@fda.hhs.gov






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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/27/2020 3:45:18 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: (b) (4), (b) (5)

Still waiting. Peter is working on it and has promised me an update today. BARDA was fine after the call with Elizabeth.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 3:44 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** RE: (b) (4), (b) (5)

Were you able to find out where they are on test development/validation?

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 3:41 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** RE: (b) (4), (b) (5)

(b) (4), (b) (5)

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Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 3:34 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** RE (b) (4), (b) (5) [redacted]

Does that mean (b) (4), (b) (5) [redacted]

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 3:31 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** RE: (b) (4), (b) (5) [redacted]

Reported directly to me.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 3:31 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** (b) (4), (b) (5)

(b) (4), (b) (5)

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 6:29:56 PM
**To:** Eisenberg, Marcia [Eisenbm@LabCorp.com]
**CC:** Krueger, Brian (b) (6) @LabCorp.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: 2019 nCoV

Thank you Marcia! Hi Brian,

Fantastic. I am at CDC HQ now and can talk. My cell is (b) (6) .

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Sent:** Monday, February 24, 2020 5:51 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Krueger, Brian <(b) (6) @LabCorp.com>
**Subject:** Re: 2019 nCoV

Hi Tim
So great to hear from you.
We have our submission number after a few exchanges with the agency via email on our validation design. I am copying Dr. Brian Krueger. He and I can be available and welcome your help.

On Feb 24, 2020, at 4:37 PM, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov> wrote:

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***EXTERNAL:*** This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Hi Marcia,

I am told LabCorp is developing an assay. Could you put me in touch with the correct R&D leader to discuss? We want to do anything we can to help speed the development of an EUA.

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/26/2020 10:04:32 AM
**To:** Shearstone, Peter E. [(b) (6) @thermofisher.com]; Lloyd, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338a759166e74b13a5c9b385cde90eb9-Lindsay.Llo]
**CC:** Campbell, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24dd067ea9494177b7b3ab45546d6e3b-Jennifer.Ca]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: February 21st Meeting

Sorry. Was in meetings. Thought my cell was going to be called. +1(b) (6)

---

**From:** Shearstone, Peter E. <(b) (6) @thermofisher.com>
**Date:** February 26, 2020 at 10:01:32 AM EST
**To:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Cc:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: February 21st Meeting

Thanks Lindsay.
Jennifer – Dr. Stenzel agreed to meet with us regarding the EUA for COVID-19 test we are developing.
He suggested to us any time before 10am EST and after 11am EST. We tried for 930am and he did not show unfortunately.
Can he meet at 2pm EST today?

Best,
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) Mobile: (b) (6)
Internal extension (b) (6)
(b) (6) @thermofisher.com

---

**From:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 9:58 AM
**To:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Cc:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>
**Subject:** RE: February 21st Meeting

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Copying Jennifer.

---

**From:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Sent:** Wednesday, February 26, 2020 9:47 AM

AMERICAN Operation

**To:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Subject:** RE: February 21st Meeting

Lindsay,

Good morning. Who is Dr. Stenzel's administrative support person?
I scheduled a meeting with him today at 9:30am EST regarding our EUA for COVID-19 and he has not arrived yet.

Thanks,
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) Mobile: (b) (6)
Internal extension (b) (6)
(b) (6) @thermofisher.com

---

**From:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 11:14 AM
**To:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Cc:** Thomas, Ashley <Ashley.Thomas@fda.hhs.gov>
**Subject:** RE: February 21st Meeting

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Peter –

Ashley Thomas is the POC for Dr. Woodcock. I will copy her and attach the original email you sent us so they have the background.

Thanks!

Lindsay

---

**From:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Sent:** Wednesday, February 12, 2020 10:53 AM
**To:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Subject:** February 21st Meeting

Dear Lindsay,

Good morning. Hope it's a good day for you.
We are setting our discussion topics and determined that the coronavirus and its progress would be top of mind.
We'd like to talk about, among other things, our capabilities to manufacture vaccines and drug products to support its prevention.
Seeing that we did not invite Dr. Janet Woodcock from CDER is it possible she may have availability or perhaps one of her team?
I am sorry to surprise you with this but our company provides many services and we would like a productive discussion to help.

Thanks for helping. If you would rather I reach out to her office any contact information would be great.

AMERICAN OVERSIGHT

Best,
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) Mobile: (b) (6)
Internal extension (b) (6)
(b) (6) @thermofisher.com

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 6:28:28 PM
**To**: Eisenberg, Marcia [Eisenbm@LabCorp.com]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: 2019 nCoV

Hi Marcia,

Thanks for the offer but I don't need that, at least at this time. Uwe and team may though. I leave it to them to ask.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Sent:** Monday, February 24, 2020 5:56 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: 2019 nCoV

If you thought it was useful to see any of the design, preliminary data etc let me know.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 4:37:01 PM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Subject:** [External] 2019 nCoV

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Hi Marcia,

I am told LabCorp is developing an assay. Could you put me in touch with the correct R&D leader to discuss? We want to do anything we can to help speed the development of an EUA.

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/26/2020 11:54:47 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits

I will make sure you get the call in number. See my next email too for your 12 noon briefing.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 11:54 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits

I might be able to join a 3 PM call.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 26, 2020 at 11:51:22 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits

Hi Jeff,

There was some concern in speaking with Scott just now that based on a CDC call yesterday that some labs may destroy their existing kits and we want to stop that immediately.

AMERICAN OVERSIGHT

The call with all the PHLs will be at 3 pm today. Scott would still like to keep the 4:30 pm call.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 11:49 AM
**To:** Scott.Becker@aphl.org
**Cc:** Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits

Please hold for additional follow on information.

For now, do not destroy your existing CDC 2019 nCoV Coronavirus EUA kits.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
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- ALL slides that follow are draft – graphics still being worked on.
- Please send comments before 11am Monday



AMERICAN OVERSIGHT

(b) (4), (b) (5)



AMERICAN OVERSIGHT

(b) (4), (b) (5)



AMERICAN OVERSIGHT

(b) (4), (b) (5)



AMERICAN OVERSIGHT

(b) (4), (b) (5)



AMERICAN OVERSIGHT

(b) (4), (b) (5)



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(b) (4), (b) (5)



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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/21/2020 2:23:08 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Coronavirus and MERS culturing

Yes, you are correct. I do not have the CBER contact. It was Pillai who let me know. I will go through Uwe as well. I don't have the CBER contact.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 2:21 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: Coronavirus and MERS culturing

Tim,

Isn't CBER who's handling this?

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 21, 2020 at 2:13:21 PM EST
**To:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Coronavirus and MERS culturing

AMERICAN OVERSIGHT

Hi Pillai,

Great to meet you today! I wanted to reach out and have copied Jeff to find out more details about the coronavirus and mers cultures. We have a number of test developers who cannot complete validation of their EUA assays until they have at least mock samples made with virus to test.

How soon will virus be available?
Can we connect developers with someone here at the agency so they can coordinate access?

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
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**Center for Devices and Radiological Health**
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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/25/2020 4:26:25 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Re: Availability of CDC Designed Kits

Dan really likes the (b) (5) And Dan asked me to go to the lab task force group. I am in the lab task force office now, they are on a conference call. Will bring it up as soon as conf call is over.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 25, 2020 at 4:16:10 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Availability of CDC Designed Kits

FYI. Going to talk to who I can find now.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:15 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Pallansch, Mark (CDC) <map1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>

AMERICAN OVERSIGHT

**Cc:** Thomas, Jennifer (CDC) <fsu8@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** Availability of CDC Designed Kits

Hi,

(b) (5)



Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 12:53:47 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC:** Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: nCoV PEUA Assignments-Priority List.xlsx
**Attachments:** nCoV PEUA Assignments-Priority List.xlsx

Deliberative / Pre-decisional

Hi Uwe,

Thanks so much! (b) (5) [redacted]

Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 12:49 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** nCoV PEUA Assignments-Priority List.xlsx

AMERICAN OVERSIGHT INVESTIGATION

Tim,

Attached the priority list:

(b) (5)



Uwe

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/26/2020 11:52:20 AM
**To:** Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits

FYI

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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Jennifer.Campbell@fda.hhs.gov

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 11:49 AM
**To:** Scott.Becker@aphl.org
**Cc:** Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits

Please hold for additional follow on information.

For now, do not destroy your existing CDC 2019 nCoV Coronavirus EUA kits.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

AMERICAN OVERSIGHT

**Jennifer Campbell**
*Administrative Assistant*

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CDRH | Food and Drug Administration
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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 9:07:13 PM
**To:** Krueger, Brian [(b) (6) @LabCorp.com]; Eisenberg, Marcia [Eisenbm@LabCorp.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: 2019 nCoV

You are most welcome.

---

**From:** Krueger, Brian <(b) (6) @LabCorp.com>
**Date:** February 24, 2020 at 9:06:28 PM EST
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019 nCoV

Ok, we will get in touch with utmb, thanks!

Get Outlook for Android

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 8:57:38 PM
**To:** Krueger, Brian <(b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Subject:** [External] RE: 2019 nCoV

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Great to connect Brian. Also I just heard that UTMB has extracted RNA that is ready to ship.

---

**From:** Krueger, Brian <(b) (6) @LabCorp.com>
**Date:** February 24, 2020 at 7:04:56 PM EST
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019 nCoV

Hey Tim,

Give me a call if you're still free to chat.

(b) (6)

-Brian

Get Outlook for Android

AMERICAN OVERSIGHT

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:29:56 PM

**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Cc:** Krueger, Brian <(b) (6) @LabCorp.com>
**Subject:** [External] RE: 2019 nCoV

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Thank you Marcia! Hi Brian,

Fantastic. I am at CDC HQ now and can talk. My cell is (b) (6)

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
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**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
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Jennifer.Campbell@fda.hhs.gov

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---

**From:** Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Sent:** Monday, February 24, 2020 5:51 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Krueger, Brian <(b) (6) @LabCorp.com>
**Subject:** Re: 2019 nCoV

Hi Tim
So great to hear from you.
We have our submission number after a few exchanges with the agency via email on our validation design. I am copying Dr. Brian Krueger. He and I can be available and welcome your help.

On Feb 24, 2020, at 4:37 PM, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov> wrote:

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Hi Marcia,

I am told LabCorp is developing an assay. Could you put me in touch with the correct R&D leader to discuss? We want to do anything we can to help speed the development of an EUA.

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
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AMERICAN OVERSIGHT

Interagency Strategy Recommendation from MCM TF Diagnostics WG:

(b)(5) DRAFT

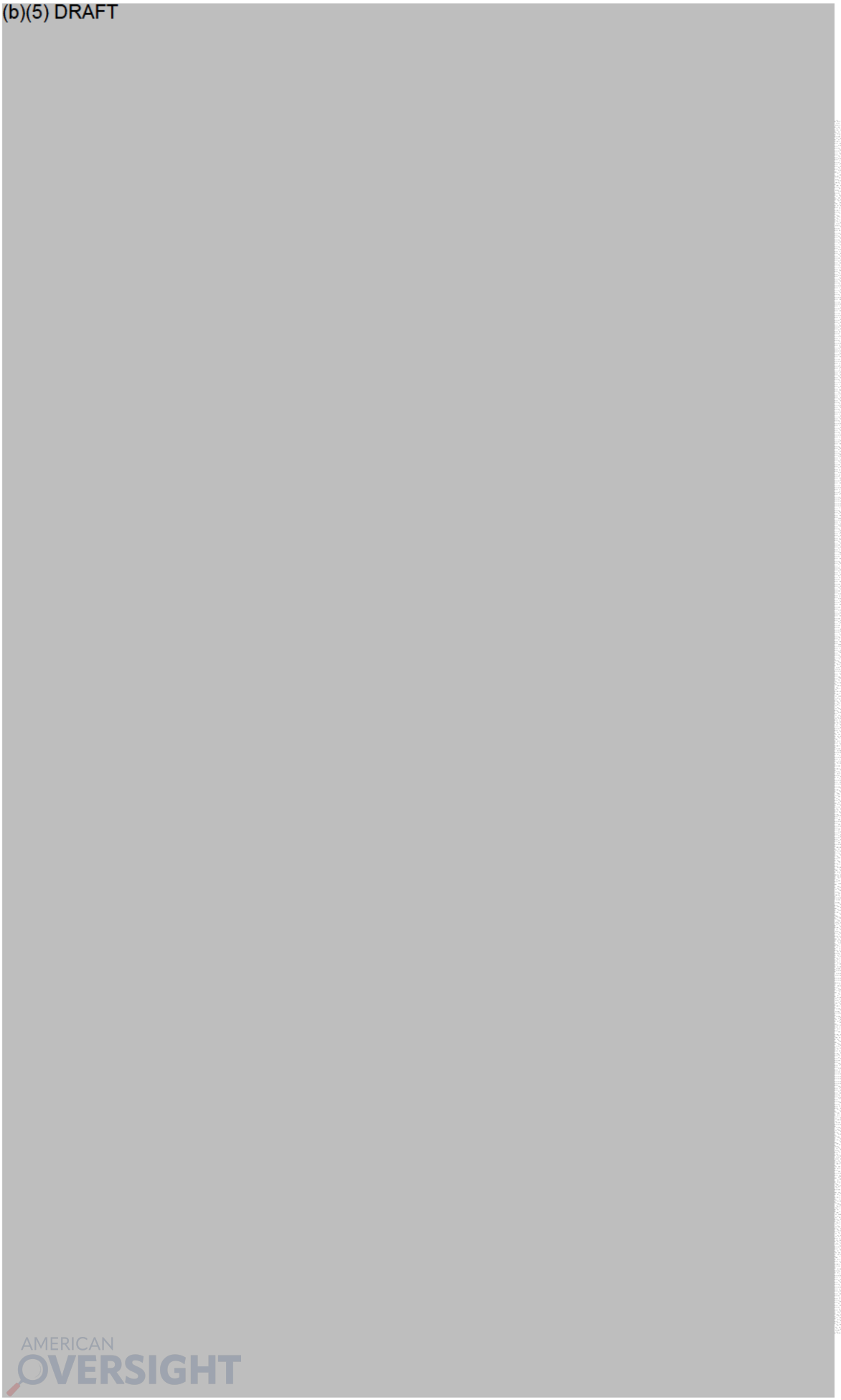
[redacted]

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AMERICAN OVERSIGHT

(b)(5) DRAFT



AMERICAN OVERSIGHT

(b)(5) DRAFT

[redacted]

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AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 4:08:28 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: CDC Update to patient population

Deliberative / Pre-decisional

Hi Ellen,

Agreed. We require something in writing. We were just told that they wanted something like the MERS authorization for 2019-nCoV.

Just called Uwe and he is in a meeting with the Commissioner which you may be in as well. Call when you can. Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 3:34 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: CDC Update to patient population

Deliberative / Pre-decisional

Tim,

I am confused. (b) (5) [redacted]

(b) (5) [redacted]

AMERICAN OVERSIGHT

Thanks,
Ellen

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 2:52 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** CDC Update to patient population

Deliberative / Pre-decisional

Hi Ellen,

I believe the (b) (5) See highlighted text below and attached.

(b) (5)

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/21/2020 2:13:21 PM
**To**: Pillai, Segaran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d5e546783d4445fa315d858e0c92d47-Segaran.Pil]
**CC**: Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Coronavirus and MERS culturing

Hi Pillai,

Great to meet you today! I wanted to reach out and have copied Jeff to find out more details about the coronavirus and mers cultures. We have a number of test developers who cannot complete validation of their EUA assays until they have at least mock samples made with virus to test.

How soon will virus be available?
Can we connect developers with someone here at the agency so they can coordinate access?

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/18/2020 9:55:46 AM
**To**: Iademarco, Michael (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60a2bbf679974a56950bbb13b73d2549-HHS-mai9-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: CDC Coronavirus assay question.

Hi Michael,

I have a question for the CDC and don't know who to ask and am hoping you can help.

(b) (5)

[redacted]

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 9:10:50 AM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Draft CDC EUA 2019-nCoV Letter of Authorization 2-24-20.doc

Hi Ellen,

That is what I thought. I am in the listening mode and passing information along to you.

Jeff, Could you call my cell when you get a minute?

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 9:08 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Draft CDC EUA 2019-nCoV Letter of Authorization 2-24-20.doc

Tim,

(b) (5)

Ellen

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 8:55 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Draft CDC EUA 2019-nCoV Letter of Authorization 2-24-20.doc

Hi Ellen and Jeff,

(b) (5)

[redacted]

Thanks!

Best,
Tim

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/25/2020 4:15:20 PM
**To**: Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Smith, Lia H (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cda5acfaea1403d98eeed026beb76bd-HHS-loh5-cd]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Pallansch, Mark (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2941652b4c784575b079ef1164b4f089-HHS-map1-cd]; Carroll, Darin S (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1e41f0ca9984d0ea6d434fd7dc0908d-HHS-zuz4-cd]
**CC**: Thomas, Jennifer (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dae2359951c41afabbc243e6697d8fb-HHS-fsu8-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Availability of CDC Designed Kits

Hi,

We just got off the phone with IDT. The have the following kits available for sale today of the CDC designed kits.

(b) (4) kits with (b) (4) reactions, (b) (4) kits with (b) (4) reactions, and (b) (4) kits with (b) (4) reactions in hands. They can be shipped in 1-2 days.

The CDC Test Panel includes fluorescently labeled hydrolysis probes that contain Black Hole Quencher® (BHQ®), a proprietary chemistry owned by Biosearch Technologies.
IDTDNA has an alternative fluorescent hydrolysis probe quencher chemistry (ZEN™ Double-Quenched Probe technology) being used in their kits.

Can we?

(b) (5)

[redacted]

AMERICAN OVERSIGHT

https://www.genomeweb.com/pcr/co-diagnostics-sars-cov-2-assay-garners-ce-mark

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 12:42:31 PM
**To**: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
**CC**: Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Hi Dr. Redfield,

Just wanted to make sure you have this Enforcement Discretion email for the surveillance testing program. The CDC has the green light from this email for that activity as of last Saturday night shortly after you and Dr. Hahn spoke Saturday.

Happy to discuss.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 9:46 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

AMERICAN OVERSIGHT

Dear Wendi,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

Today, February 22, 2020, CDRH/FDA was informed that CDC would need enforcement discretion from FDA, until approval of a new EUA, for certain public health surveillance testing activities that do not fall within the currently authorized intended use of the assay (EUA200001) – namely, CDC has identified an urgent need to partner with designated jurisdictions and surveillance sites across the United States to perform testing to identify possible transmission of SARS-CoV-2 among individuals without a clear epidemiologic link (contact with known cases or history of recent travel to mainland China).

At this time, there are no adequate, approved, and available alternative tools that can detect SARS-CoV-2 during the acute phase of infection in the United States in symptomatic individuals without the epidemiological risk factors. In addition, unlike typical surveillance activities, individuals who test positive or inconclusive for SARS-CoV-2 using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel will be notified of their test result and followed up accordingly.

Our understanding of the facts and the public health concerns at issue here are that there is currently no other test available to respond to this emergency, significant public health concerns are presented by the infectious disease, the proposed testing may help to prevent the spread of the infectious disease, and the testing activity will help to support situational awareness and guide the public health response to COVID-19. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the following conditions: that all patients must be adequately informed about the status of this testing and the potential implications of agreeing to this testing, and that CDC will act promptly to submit an application for a new EUA to authorize the testing described above.

If you have any questions, please contact Uwe Scherf or me.

Sincerely,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov






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AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/22/2020 7:53:51 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Fwd: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

Hi Wendi,

I wanted to correct/clarify about the request for confirmation of the number of PHLs who have validated the CDC EUA assay. That request came from FDA leadership. The Secretary's requests regarding the EUA are below and we have received all the information we needed from the CDC for our response to the Secretary's request. Thank you!

Best,
Tim

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 22, 2020 at 5:25:57 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers
**Importance:** High

Uwe, Kim, and Toby,

Good evening. Secretary Azar has requested a great deal of data from FDA (particularly regarding the supply chain, number of firms we have contacted, numbers of firms manufacturing certain products OUS and domestically, etc.). As part of this, we want to provide some of the notable information about diagnostic tests and EUAs. Can you review the four points below by 9 am on Monday morning? Feel free to add anything else you think is responsive and helpful.

Sorry for the quick turnaround (once again).

Thanks very much for your help.

Best,

Jennifer

## FDA Response to COVID-19 By-the-Numbers

Diagnostic Tests

- Granted 1 Emergency Use Authorization, to the CDC, as of 2/21/20
- This test was developed within about a month.

AMERICAN OVERSIGHT

- CDC submitted the EUA package to FDA on 2/3/2020; on 2/4/2020, FDA issued an EUA to enable emergency use of the test.
- Provided the Emergency Use Authorization template to 70 developers of diagnostics for this outbreak as of 2/21/20

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 12:21:42 PM
**To**: jsb6@cdc.com
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Hi Joe,

See email to Wendi on Saturday night. You have a green light to start the Sentinel Surveillance program under Enforcement Discretion until the EUA for it is finalized.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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---

**From:** Stenzel, Timothy
**Sent:** Monday, February 24, 2020 10:53 AM
**To:** Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Hi Dan,

Just want to make you have this Enforcement Discretion email for the surveillance testing. The CDC has the green light from this email as of last Saturday night shortly after Dr. Redfield and Dr. Hahn spoke Saturday.

Happy to discuss.

Thanks!

AMERICAN OVERSIGHT

Best,

Tim

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 22, 2020 at 9:45:55 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Dear Wendi,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

Today, February 22, 2020, CDRH/FDA was informed that CDC would need enforcement discretion from FDA, until approval of a new EUA, for certain public health surveillance testing activities that do not fall within the currently authorized intended use of the assay (EUA200001) – namely, CDC has identified an urgent need to partner with designated jurisdictions and surveillance sites across the United States to perform testing to identify possible transmission of SARS-CoV-2 among individuals without a clear epidemiologic link (contact with known cases or history of recent travel to mainland China).

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Ellen

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**Sent:** 2/22/2020 7:44:58 PM
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Re: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

Hi Jennifer, Just confirmed with Uwe, we have everything we need from the CDC to finish our responses to the Secretary. Uwe and his team are drafting them. Best, Tim

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 22, 2020 at 7:36:35 PM EST
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Subject:** Re: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

Thanks Jennifer. I just arrived in Atlanta. We have reached out to the CDC for confirmation of numbers and I connected with Wendi, if you remember her from the CDC org chart, by voice a few minutes ago to ask them to confirm the information we have. Best, Tim

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**Date:** February 22, 2020 at 5:25:57 PM EST
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Jennifer

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Diagnostic Tests

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 8:57:38 PM
**To:** Krueger, Brian [(b) (6) @LabCorp.com]; Eisenberg, Marcia [Eisenbm@LabCorp.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: 2019 nCoV

Great to connect Brian. Also I just heard that UTMB has extracted RNA that is ready to ship.

---

**From:** Krueger, Brian <(b) (6) @LabCorp.com>
**Date:** February 24, 2020 at 7:04:56 PM EST
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019 nCoV

Hey Tim,

Give me a call if you're still free to chat.

(b) (6)

-Brian

Get Outlook for Android

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:29:56 PM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Cc:** Krueger, Brian <(b) (6) @LabCorp.com>
**Subject:** [External] RE: 2019 nCoV

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Thank you Marcia! Hi Brian,

Fantastic. I am at CDC HQ now and can talk. My cell is (b) (6).

Thanks!

Best,
***Tim***

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Sent:** Monday, February 24, 2020 5:51 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Krueger, Brian <(b) (6) @LabCorp.com>
**Subject:** Re: 2019 nCoV

Hi Tim
So great to hear from you.
We have our submission number after a few exchanges with the agency via email on our validation design. I am copying Dr. Brian Krueger. He and I can be available and welcome your help.

On Feb 24, 2020, at 4:37 PM, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov> wrote:

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Hi Marcia,

I am told LabCorp is developing an assay. Could you put me in touch with the correct R&D leader to discuss? We want to do anything we can to help speed the development of an EUA.

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 5:03:07 PM
**To:** Tucker, Angela [(b) (6) @roche.com]
**CC:** Cline, Richeal (b) (6) @roche.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: 2019 nCoV

Perfect. Thanks Angela.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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**From:** Tucker, Angela <(b) (6) @roche.com>
**Sent:** Monday, February 24, 2020 4:59 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Cline, Richeal <(b) (6) @roche.com>
**Subject:** Re: 2019 nCoV

Of course, Tim. Would calling you in ca 30 minutes work for you? 5:30 p.m. ET?

Angela G. Tucker
Vice President, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588-2722

Phone: +(b) (6)
Cell: + (b) (6)
Fax: +1 925 225-0207
Email: (b) (6) @roche.com

AMERICAN OVERSIGHT
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On Mon, Feb 24, 2020 at 1:53 PM Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov> wrote:

Hi Richeal,

I understand and thanks for the connection to Angela!

Hi Angela,

Would you have any time for a brief call today or tomorrow? You can reach me on my FDA cell (b) (6) I am on East Coast time.

Thanks in advance!

Best,

*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
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**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**

Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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**From:** Cline, Richeal (b) (6) @roche.com>
**Sent:** Monday, February 24, 2020 4:48 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Angela Tucker (b) (6) @roche.com>
**Subject:** Re: 2019 nCoV

Dear Tim

AMERICAN OVERSIGHT

We are developing an assay for our cobas 6800/8800 platform and have a Pre-EUA in review. When we spoke on Wednesday you asked about development on the (b) (4) [redacted]

I've copied Angela Tucker, Head of Regulatory for Roche Molecular Diagnostics who can be your point of contact.

Looking forward to seeing you tomorrow.

Best regards,

Richeal

On Mon, Feb 24, 2020 at 4:34 PM Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov> wrote:

> Hi Richeal,
>
> I am told Roche is developing an assay for the Cobas. Could you put me in touch with the correct R&D leader at Roche to discuss? We want to do anything we can to help speed the development.
>
> Thanks in advance!
>
> Best,
>
> *Tim*
>
> **Timothy T. Stenzel, MD, PhD**
> *Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
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>
> **Center for Devices and Radiological Health**
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**Richeal M. Cline**

Global Head Quality & Regulatory

Roche Diagnostics

9115 Hague Rd

Indianpolis, IN 46250-0457

Office: (b) (6)

Cell: +

mailt e.com

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**Sent**: 2/22/2020 7:36:34 PM
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**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Re: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

Thanks Jennifer. I just arrived in Atlanta. We have reached out to the CDC for confirmation of numbers and I connected with Wendi, if you remember her from the CDC org chart, by voice a few minutes ago to ask them to confirm the information we have. Best, Tim

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 22, 2020 at 5:25:57 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers
**Importance:** High

Uwe, Kim, and Toby,

Good evening. Secretary Azar has requested a great deal of data from FDA (particularly regarding the supply chain, number of firms we have contacted, numbers of firms manufacturing certain products OUS and domestically, etc.). As part of this, we want to provide some of the notable information about diagnostic tests and EUAs. Can you review the four points below by 9 am on Monday morning? Feel free to add anything else you think is responsive and helpful.

Sorry for the quick turnaround (once again).

Thanks very much for your help.

Best,

Jennifer

AMERICAN OVERSIGHT

# FDA Response to COVID-19 By-the-Numbers

Diagnostic Tests

- Granted 1 Emergency Use Authorization, to the CDC, as of 2/21/20
- This test was developed within about a month.
- CDC submitted the EUA package to FDA on 2/3/2020; on 2/4/2020, FDA issued an EUA to enable emergency use of the test.
- Provided the Emergency Use Authorization template to 70 developers of diagnostics for this outbreak as of 2/21/20

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 8:55:40 PM
**To:** Tucker, Angela [(b) (6) @roche.com]
**CC:** Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Richeal Cline [(b) (6) @roche.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Re: 2019 nCoV

Thanks for the update Angela. I also just heard from Uwe that UTMB has extracted RNA that is ready to ship. Best, Tim

---

**From:** Tucker, Angela <(b) (6) @roche.com>
**Date:** February 24, 2020 at 7:07:12 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Richeal Cline (b) (6) @roche.com>
**Subject:** Re: 2019 nCoV

Apologies, Tim. It seems our information was slightly out of date. We did in fact receive live virus here on Friday. Due to the time difference I cannot tell you today if material was also received in Switzerland, but we are following up with them first thing in the morning and I will let you know. We truly appreciate your willingness to help move any obstacles.

Thank you,
Angela

Angela G. Tucker
Vice President, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588-2722

Phone: (b) (6)
Cell: +(b) (6)
Fax: +1 925 225-0207
Email: (b) (6) @roche.com

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On Mon, Feb 24, 2020 at 3:42 PM Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov> wrote:

> Hi Angela,
>
> Thanks again for the quick call. We are sorry to hear that (b) (4) has not yet shipped you live virus.
>
> The CDC can send you live virus now. Please coordinate with Dr. Kuhnert-Tallman who will take it from here.

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Thanks!

Best,

*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*

*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**

Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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CDRH | Food and Drug Administration
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Jennifer.Campbell@fda.hhs.gov

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/18/2020 11:08:12 AM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Manufacturing of EUA CDC Assay

Thanks Uwe. Great!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 11:02 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Manufacturing of EUA CDC Assay

Tim,

Here the information:

The materials provided by CDC are [all manufactured at CDC]

1. 2019-nCoVEUA-01 Box #1: Primers and Probes for the following targets:
a. 2019-nCoV_N1
b. 2019-nCoV_N2
c. 2019-nCoV_N3
d. Human RNase P
2. 2019-nCoV Positive Control (nCoVPC)

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Other materials needed to run the test but not provided by CDC in their 2019-nCoV panel:

1. Human Specimen Control (HSC) –manufactured by CDC [need to be ordered separately]
2. RT-qPCR Enzyme Master Mix – manufactured by ThermoFisher
3. Two different extraction kits (manual & automated) - manufactured by Qiagen
4. The 7500 Fast Dx Real-Time PCR Systems with SDS 1.4 software - RCR instrument by Applied Biosystems

Plus regular equipment and consumables used in the laboratory.

Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 10:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Manufacturing of EUA CDC Assay

Hi Uwe,

Can you send me the list of assay components that the CDC uses to manufacture their assay? Probes, primers, buffers, enzymes, etc.

We are wondering if anything is manufactured outside the CDC and if so where and by what companies?

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/26/2020 10:22:33 AM
**To:** Shearstone, Peter E. (b) (6) @thermofisher.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: February 21st Meeting

Great. Yes, I am currently available at that time.

---

**From:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Date:** February 26, 2020 at 10:14:19 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: February 21st Meeting

Call you at 2pm EST on your cell. Thanks.
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) | Mobile: (b) (6)
Internal extension (b) (6)
(b) (6) @thermofisher.com

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 10:05 AM
**To:** Shearstone, Peter E. (b) (6) @thermofisher.com>; Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Cc:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>
**Subject:** RE: February 21st Meeting

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Sorry. Was in meetings. Thought my cell was going to be called. (b) (6)

---

**From:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Date:** February 26, 2020 at 10:01:32 AM EST
**To:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Cc:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: February 21st Meeting

Thanks Lindsay.
Jennifer – Dr. Stenzel agreed to meet with us regarding the EUA for COVID-19 test we are developing.
He suggested to us any time before 10am EST and after 11am EST. We tried for 930am and he did not show unfortunately.
Can he meet at 2pm EST today?

AMERICAN OVERSIGHT

Best,
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) | Mobile: (b) (6)
Internal extension (b)(6)
(b) (6) @thermofisher.com

---

**From:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 9:58 AM
**To:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Cc:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>
**Subject:** RE: February 21st Meeting

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Copying Jennifer.

---

**From:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Sent:** Wednesday, February 26, 2020 9:47 AM
**To:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Subject:** RE: February 21st Meeting

Lindsay,

Good morning. Who is Dr. Stenzel's administrative support person?
I scheduled a meeting with him today at 9:30am EST regarding our EUA for COVID-19 and he has not arrived yet.

Thanks,
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) | Mobile: (b) (6)
Internal extension (b) (6)
(b) (6) @thermofisher.com

---

**From:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 11:14 AM
**To:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Cc:** Thomas, Ashley <Ashley.Thomas@fda.hhs.gov>
**Subject:** RE: February 21st Meeting

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CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Peter –

Ashley Thomas is the POC for Dr. Woodcock. I will copy her and attach the original email you sent us so they have the background.

Thanks!

Lindsay

---

**From:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Sent:** Wednesday, February 12, 2020 10:53 AM
**To:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Subject:** February 21st Meeting

Dear Lindsay,

Good morning. Hope it's a good day for you.
We are setting our discussion topics and determined that the coronavirus and its progress would be top of mind.
We'd like to talk about, among other things, our capabilities to manufacture vaccines and drug products to support its prevention.
Seeing that we did not invite Dr. Janet Woodcock from CDER is it possible she may have availability or perhaps one of her team?
I am sorry to surprise you with this but our company provides many services and we would like a productive discussion to help.

Thanks for helping. If you would rather I reach out to her office any contact information would be great.

Best,
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) | Mobile: (b) (6)
Internal extension (b) (6)
(b) (6) @thermofisher.com

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/25/2020 1:36:54 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Deliberative/Predecisional

Still, it would be good to know if (b) (5) [redacted]

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 1:35 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Jeff,

Sorry I made mistake, (b)(4) [redacted]
(b)(4) [redacted]

AMERICAN OVERSIGHT

Uwe

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 1:21 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Uwe – can you/someone on your team please (b) (5)

Tim – can you please talk with (b) (5)
(b) (5)

Jeff

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 1:05 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

If the kits of the company are available, (b) (5)

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 12:51 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Deliberative/PreDecisional

(b) (5)

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 25, 2020 at 12:11:07 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen

AMERICAN OVERSIGHT

<Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

(b) (5)

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 25, 2020 at 11:24:51 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Tim, Ellen, Jeff,

Based on the attached information it looks like that the CDC primer is commercially available at IDT Integrated Technology:

# 2019-nCoV CDC qPCR Probe Assays

IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes. Three of the primer/probe sets in this panel target different locations on the 2019-nCoV/SARS-CoV-2 Nucleocapsid gene (N-gene). These 3 primer/probe sets must be run concurrently with the internal control (4th assay), which targets the human RNase P gene. Altogether, there are 4 qPCR assays per patient sample.

Components are premixed to the CDC recommended working concentration and delivered in IDTE, pH 7.5. Stocked kits are available in 3 reaction sizes of 50, 100, and 500 reactions, with custom sizes available (see section below. Kits are shipped within 1–2 business days at ambient temperature.

https://www.idtdna.com/pages/education/decoded/article/assays-and-sequences-for-2019-ncov-detection-and-vaccine-development

Uwe

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 6:57:38 PM
**To**: Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

And this is the second email you asked for. Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-7692
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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Stenzel, Timothy
**Sent:** Monday, February 24, 2020 12:43 PM
**To:** Redfield, Robert R (CDC) <olx1@cdc.gov>
**Cc:** Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Hi Dr. Redfield,

Just wanted to make sure you have this Enforcement Discretion email for the surveillance testing program. The CDC has the green light from this email for that activity as of last Saturday night shortly after you and Dr. Hahn spoke Saturday.

Happy to discuss.

Thanks!

Best,
*Tim*

AMERICAN OVERSIGHT

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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Office of Product Evaluation and Quality

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 9:46 PM
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Dear Wendi,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

Today, February 22, 2020, CDRH/FDA was informed that CDC would need enforcement discretion from FDA, until approval of a new EUA, for certain public health surveillance testing activities that do not fall within the currently authorized intended use of the assay (EUA200001) – namely, CDC has identified an urgent need to partner with designated jurisdictions and surveillance sites across the United States to perform testing to identify possible transmission of SARS-CoV-2 among individuals without a clear epidemiologic link (contact with known cases or history of recent travel to mainland China).

At this time, there are no adequate, approved, and available alternative tools that can detect SARS-CoV-2 during the acute phase of infection in the United States in symptomatic individuals without the epidemiological risk factors. In addition, unlike typical surveillance activities, individuals who test positive or inconclusive for SARS-CoV-2 using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel will be notified of their test result and followed up accordingly.

Our understanding of the facts and the public health concerns at issue here are that there is currently no other test available to respond to this emergency, significant public health concerns are presented by the infectious disease, the proposed testing may help to prevent the spread of the infectious disease, and the testing activity will help to support situational awareness and guide the public health response to COVID-19. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the following conditions: that all patients must be adequately informed about the status of this testing and the

AMERICAN OVERSIGHT

potential implications of agreeing to this testing, and that CDC will act promptly to submit an application for a new EUA to authorize the testing described above.

If you have any questions, please contact Uwe Scherf or me.

Sincerely,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 8:55:46 AM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: 2/24/20 6 AM update

Hi Uwe,

Thanks, if the MERS CDC EUA authorization letter is handy, I would like to review. The CDC is asking for the same sort of authorization now.

Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
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Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 8:50 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2/24/20 6 AM update

Good morning Tim,

We are meeting at 9 to get the latest update on the status of the Developers, will get the update right after the meeting. Uwe

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 8:45 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/24/20 6 AM update

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Morning Uwe,

Hope you are doing well. Could I get a list of all the developers interested in the EUA, perhaps with those who are furthest along tagged?

We would like to get more testing available as soon as possible and I while I am working on making positive material more available it might be good for me to connect with developers. I would also like to understand what they require to get started and what they require to complete their EUA validations.

Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:54 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/24/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/24/20 6 AM update:

**Status of activities on diagnostics:**

(b) (5)

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(b) (5)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 4:53:04 PM
**To:** Cline, Richeal (b) (6) @roche.com]
**CC:** Angela Tucker (b) (6) @roche.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: 2019 nCoV

Hi Richeal,

I understand and thanks for the connection to Angela!

Hi Angela,

Would you have any time for a brief call today or tomorrow? You can reach me on my FDA cell (b) (6) I am on East Coast time.

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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**From:** Cline, Richeal (b) (6) @roche.com>
**Sent:** Monday, February 24, 2020 4:48 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Angela Tucker (b) (6) @roche.com>
**Subject:** Re: 2019 nCoV

Dear Tim

We are developing an assay for our cobas 6800/8800 platform and have a Pre-EUA in review. When we spoke on Wednesday you asked about development on the cobas Liat (PoC instrument). We currently have no plans to develop an assay for cobas Liat.

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I've copied Angela Tucker, Head of Regulatory for Roche Molecular Diagnostics who can be your point of contact.

Looking forward to seeing you tomorrow.

Best regards,
Richeal

On Mon, Feb 24, 2020 at 4:34 PM Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov> wrote:

> Hi Richeal,
>
> I am told Roche is developing an assay for the Cobas. Could you put me in touch with the correct R&D leader at Roche to discuss? We want to do anything we can to help speed the development.
>
> Thanks in advance!
>
> Best,
>
> *Tim*
>
> **Timothy T. Stenzel, MD, PhD**
> *Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
> *Office of Product Evaluation and Quality*
>
> **Center for Devices and Radiological Health**
> **U.S. Food and Drug Administration**
> Timothy.Stenzel@fda.hhs.gov
>
> **Jennifer Campbell**
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--

**Richeal M. Cline**
Global Head Quality & Regulatory
Roche Diagnostics
9115 Hague Rd
Indianpolis, IN 46250-0457

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Office: (b) (6)
Cell: (b) (6)
mailto:(b) (6) @roche.com

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 6:56:36 PM
**To**: Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Wendi, This is the email you asked for. Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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---

**From:** Stenzel, Timothy
**Sent:** Monday, February 24, 2020 10:53 AM
**To:** Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Hi Dan,

Just want to make you have this Enforcement Discretion email for the surveillance testing. The CDC has the green light from this email as of last Saturday night shortly after Dr. Redfield and Dr. Hahn spoke Saturday.

Happy to discuss.

Thanks!

Best,
Tim

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**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 22, 2020 at 9:45:55 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Dear Wendi,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

Today, February 22, 2020, CDRH/FDA was informed that CDC would need enforcement discretion from FDA, until approval of a new EUA, for certain public health surveillance testing activities that do not fall within the currently authorized intended use of the assay (EUA200001) – namely, CDC has identified an urgent need to partner with designated jurisdictions and surveillance sites across the United States to perform testing to identify possible transmission of SARS-CoV-2 among individuals without a clear epidemiologic link (contact with known cases or history of recent travel to mainland China).

At this time, there are no adequate, approved, and available alternative tools that can detect SARS-CoV-2 during the acute phase of infection in the United States in symptomatic individuals without the epidemiological risk factors. In addition, unlike typical surveillance activities, individuals who test positive or inconclusive for SARS-CoV-2 using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel will be notified of their test result and followed up accordingly.

Our understanding of the facts and the public health concerns at issue here are that there is currently no other test available to respond to this emergency, significant public health concerns are presented by the infectious disease, the proposed testing may help to prevent the spread of the infectious disease, and the testing activity will help to support situational awareness and guide the public health response to COVID-19. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the following conditions: that all patients must be adequately informed about the status of this testing and the potential implications of agreeing to this testing, and that CDC will act promptly to submit an application for a new EUA to authorize the testing described above.

If you have any questions, please contact Uwe Scherf or me.

Sincerely,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/20/2020 6:57:33 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Uwe Scherf (Uwe.Scherf@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: Problems with CDC coronavirus test delay expanded US screening

Hi Kim and Uwe,

Am curious. Does this match what the CDC has let us know? I can send a note to the CDC or happy to have you do so. Copy me?

Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
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**Jennifer Campbell**
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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 6:56 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Problems with CDC coronavirus test delay expanded US screening

On it

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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Center for Devices and Radiological Health
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Timothy.Stenzel@fda.hhs.gov

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 5:27 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Problems with CDC coronavirus test delay expanded US screening
**Importance:** High

Please see the story in POLITICO Pro below. According to the article, APHL is saying that only 3 of the public health labs have been able to verify use of the CDC test. That number is less than the (b) (4) labs number that CDC gave us (e.g., sent to ~110 labs of which (b) (4) could not verify for N3 and (b) (4) could not verify for N1). Can OHT7 follow up with CDC on the veracity of what APHL is reporting?

The article also states that CDC will distribute a second test and will need it approved by the FDA first, according to CDC.

Jeff

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 5:19 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** FW: Problems with CDC coronavirus test delay expanded US screening

FYI

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

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**From:** POLITICO Pro <politicoemail@politicopro.com>
**Sent:** Thursday, February 20, 2020 5:04 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Problems with CDC coronavirus test delay expanded US screening

## Problems with CDC coronavirus test delay expanded US screening

By David Lim

02/20/2020 05:03 PM EST

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators

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during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

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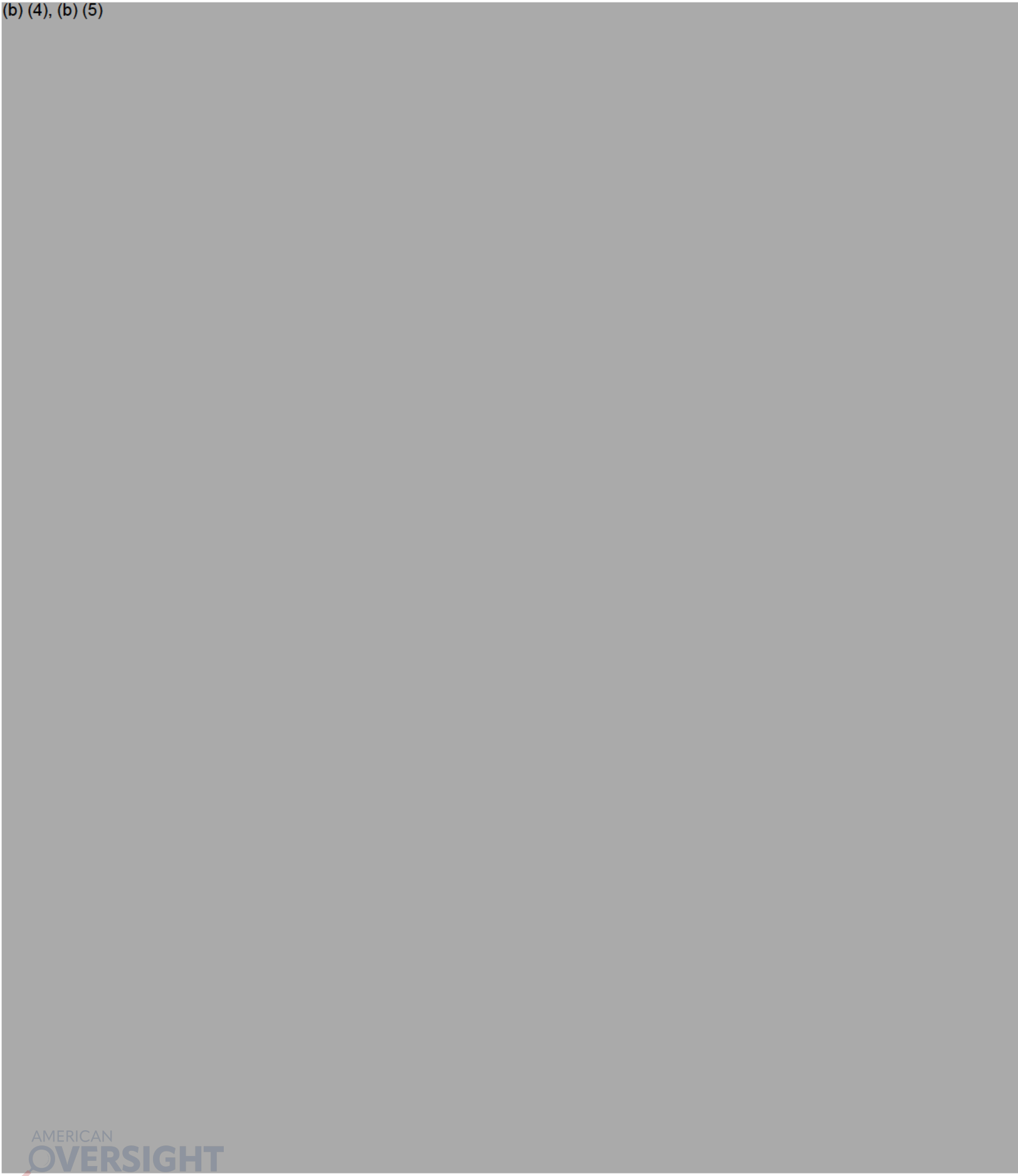
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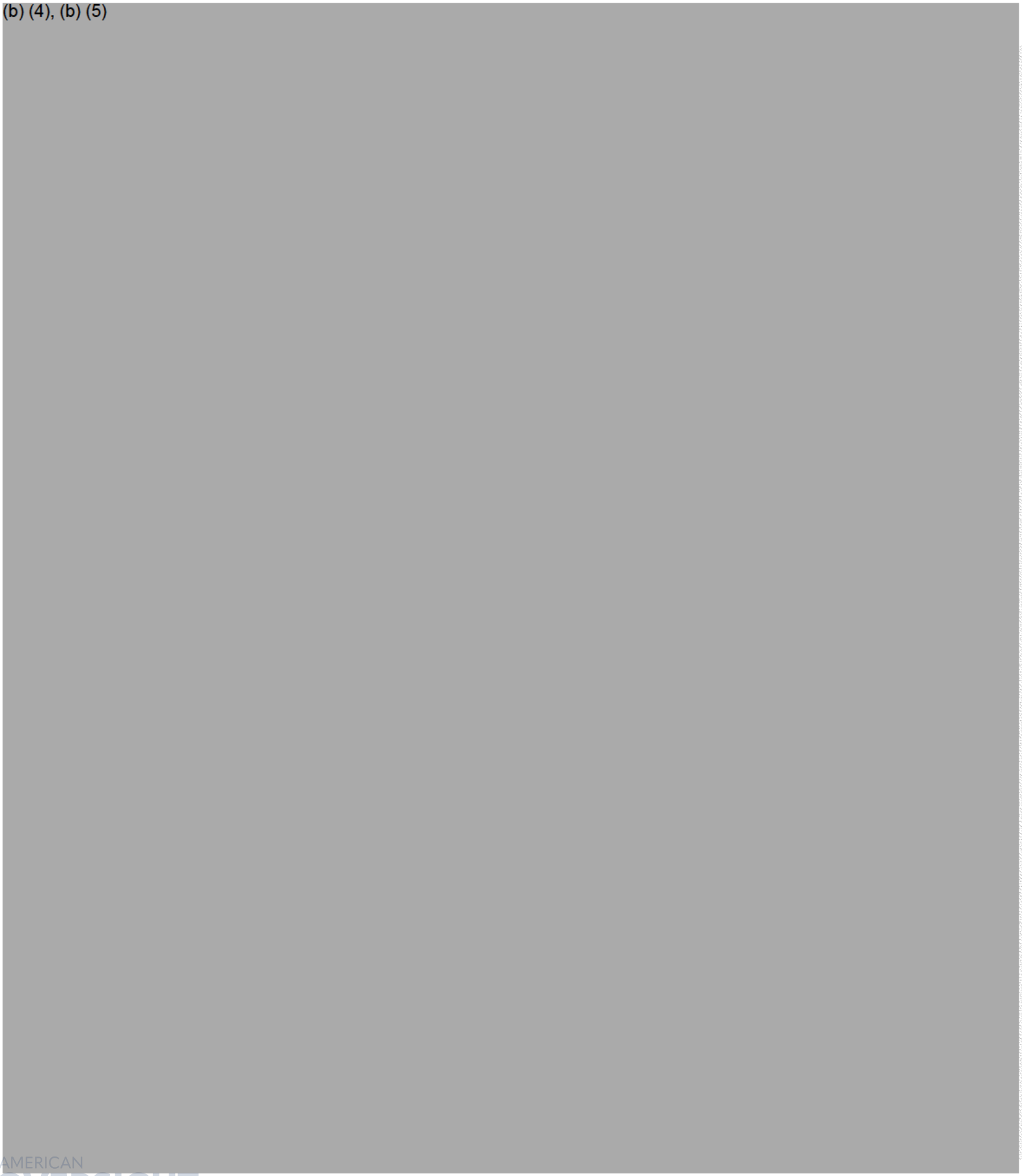
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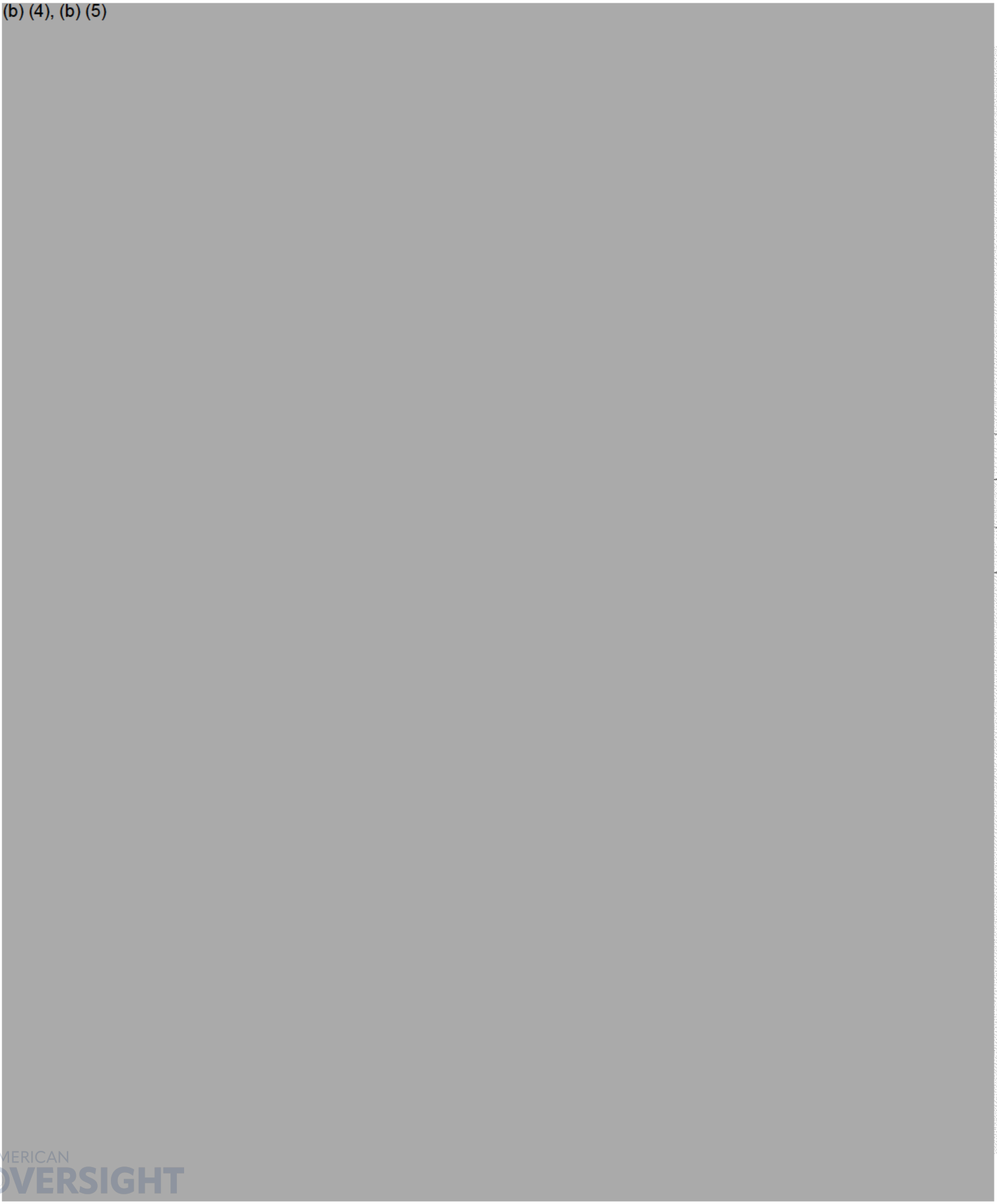

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(b) (4), (b) (5)



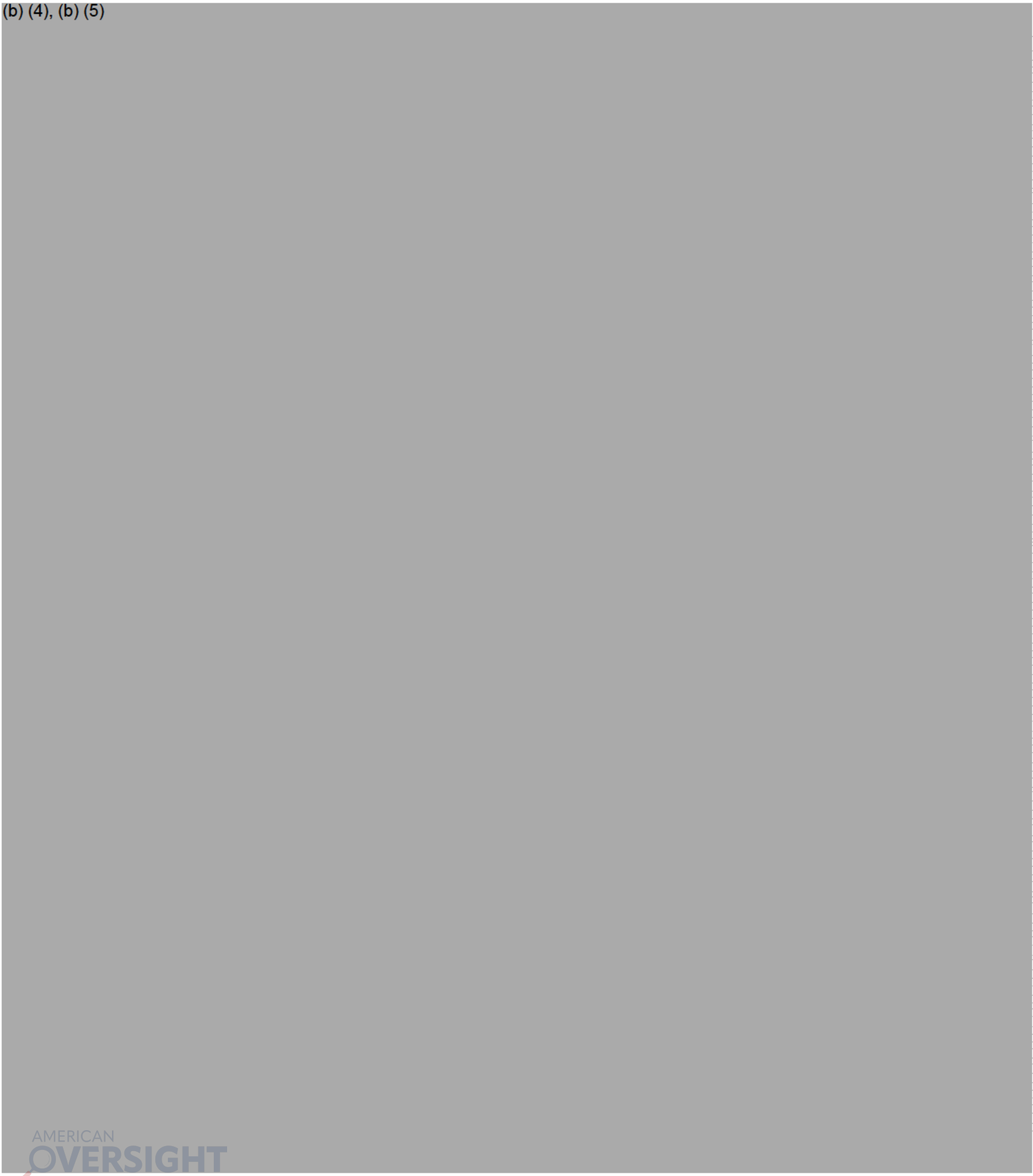
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(b) (4), (b) (5)



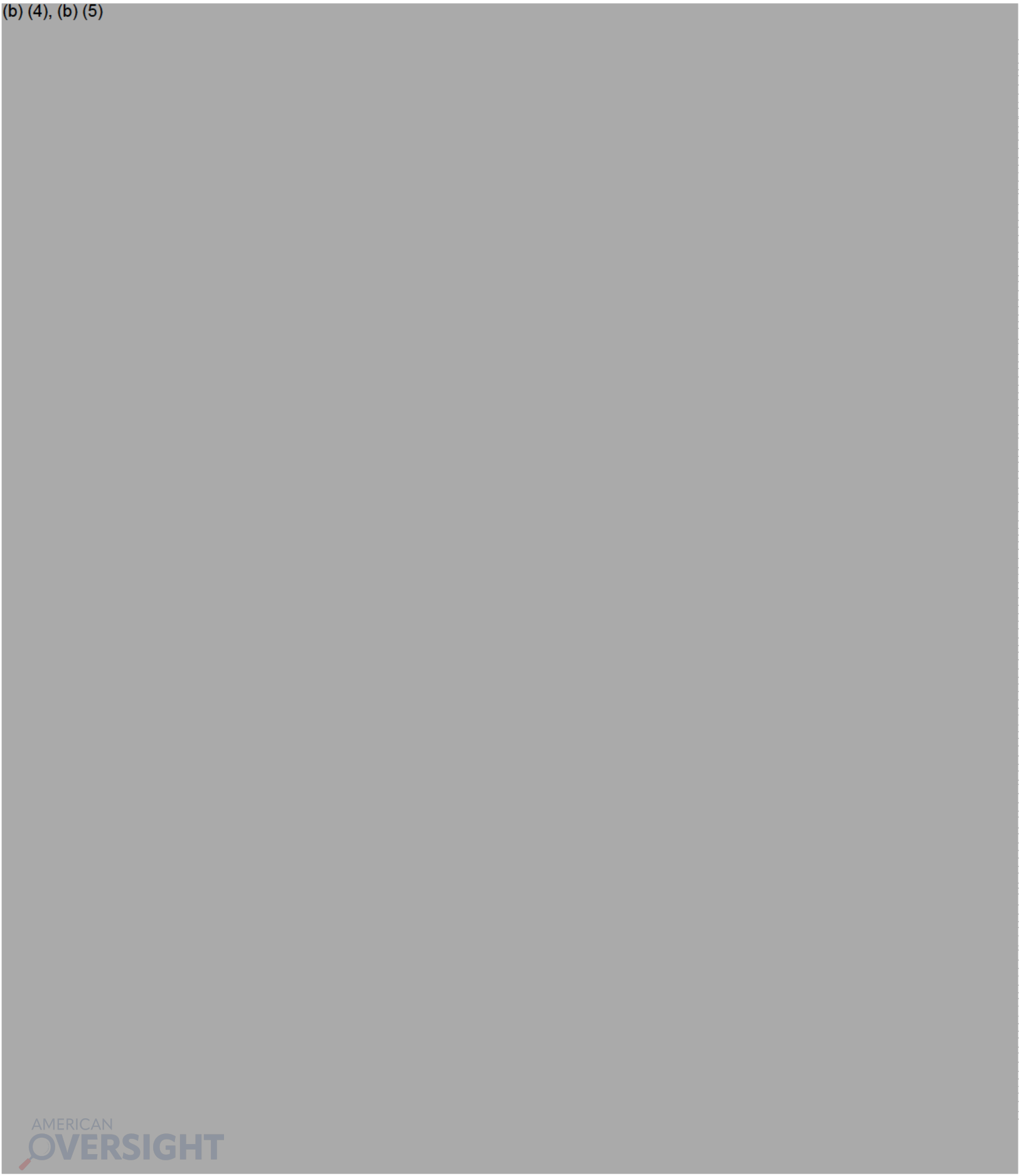
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(b) (4), (b) (5)



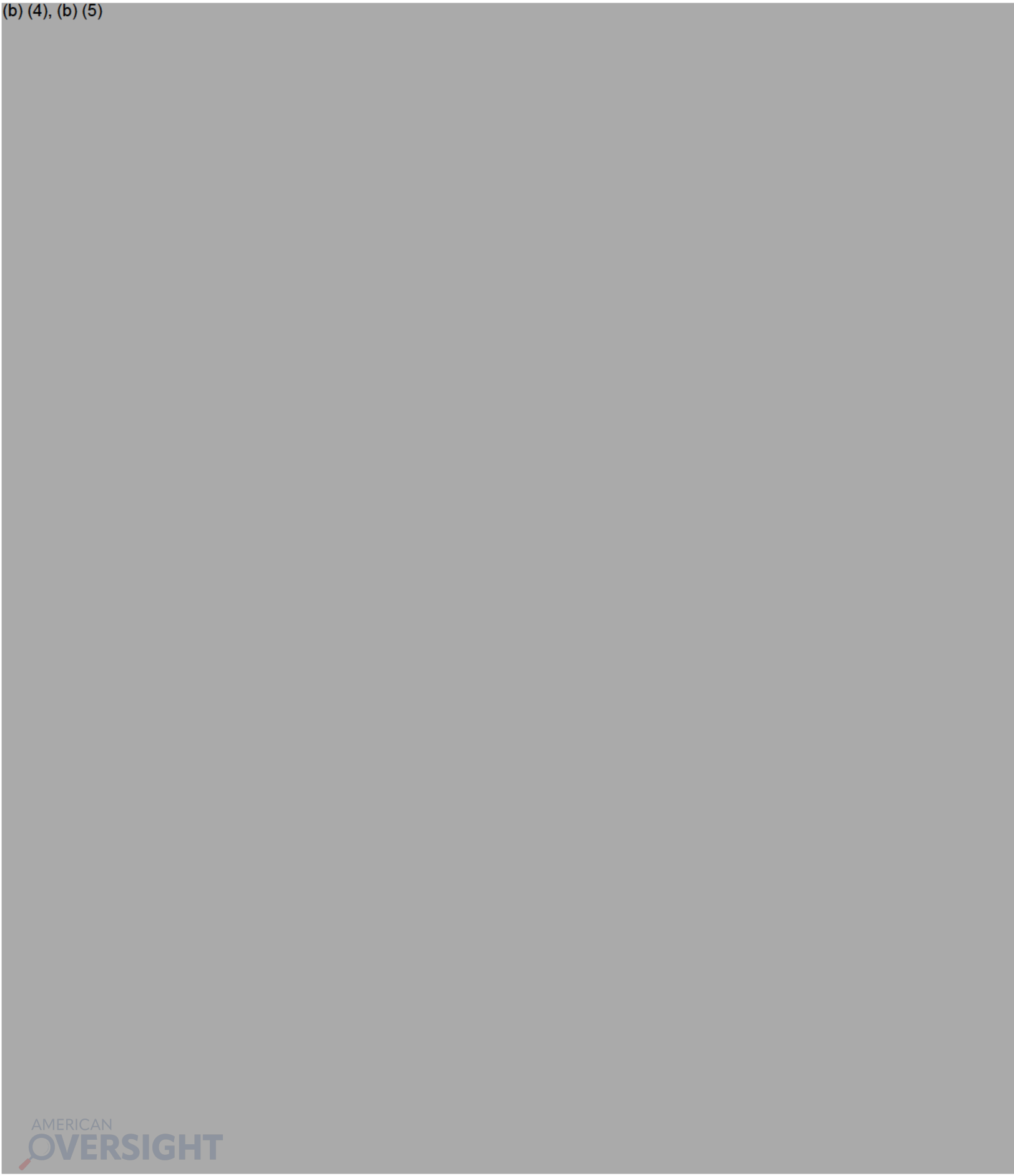
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(b) (4), (b) (5)



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(b) (4), (b) (5)



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(b) (4), (b) (5)

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(b) (4), (b) (5)

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/24/2020 8:54:48 AM
**To:** Ellen Flannery (Ellen.Flannery@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC:** Shuren, Jeff (Jeff.Shuren@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Draft CDC EUA 2019-nCoV Letter of Authorization 2-24-20.doc
**Attachments:** Draft CDC EUA 2019-nCoV Letter of Authorization 2-24-20.doc

Hi Ellen and Jeff,

(b) (5)

(b) (5) There is a 1 pm meeting today to discuss.

(b) (5)

Thanks!

Best,
Tim

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/23/2020 11:41:29 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Re: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Yes, thank you for making it easy for the CDC.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 23, 2020 at 11:40:10 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Re: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Thank you. And as you saw, CDC got the green light to proceed under enforcement discretion while we work to finalize an EUA.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 23, 2020 at 11:29:32 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

FYI

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 23, 2020 at 11:12:57 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

The following email just went out to CDC. Thank you all for the fast turnabout to get this done.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:09 AM
**To:** Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear Laura,

Attached please find the following documents you submitted on February 21, 2020 to support the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in surveillance activities. These documents have been reviewed and edited by FDA's OCET and OCC.

1. Draft COVID-19 sentinel surveillance
2. Draft SARS-CoV-2 surveillance risk benefit
3. Draft CDC Surveillance EUA Request Cover letter

Please do not hesitate to reach out to me with questions.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 4:39:26 PM
**To**: tim.fenton@thermofisher.com
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: 2019 nCoV

Hi Tim,

Great to see you last week. I was heartened that your company is interested in developing assay.

We want to do anything we can to help speed the development of an EUA. Could you put me in touch with the correct R&D leader to discuss?

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/25/2020 8:12:02 PM
**To:** Krueger, Brian (b) (6) @LabCorp.com]; Eisenberg, Marcia [Eisenbm@LabCorp.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: RE: RE: 2019 nCoV

That is fantastic. Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

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---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Tuesday, February 25, 2020 8:02 PM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: RE: 2019 nCoV

Will do. (b) (4)
(b) (4)

Thanks again for all of your help.

-Brian

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 7:58:51 PM
**To:** Krueger, Brian (b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Subject:** [External] RE: RE: 2019 nCoV

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Thanks Brian for the update. That is great news. If you wouldn't mind continuing to keep me informed of your progress that would be great!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
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---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Sent:** Tuesday, February 25, 2020 11:17 AM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019 nCoV

Hey Tim,

Thank you so much for the UTMB lead. They have sample RNA ready to ship! We should have it Friday!

-Brian

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 9:07:13 PM
**To:** Krueger, Brian (b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Subject:** [External] RE: 2019 nCoV

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You are most welcome.

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Date:** February 24, 2020 at 9:06:28 PM EST

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**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019 nCoV

Ok, we will get in touch with utmb, thanks!

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 8:57:38 PM
**To:** Krueger, Brian (b) (6) @LabCorp.com>; Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Subject:** [External] RE: 2019 nCoV

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Great to connect Brian. Also I just heard that UTMB has extracted RNA that is ready to ship.

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Date:** February 24, 2020 at 7:04:56 PM EST
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019 nCoV

Hey Tim,

Give me a call if you're still free to chat.

(b) (6)

-Brian

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---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:29:56 PM
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Cc:** Krueger, Brian (b) (6) @LabCorp.com>
**Subject:** [External] RE: 2019 nCoV

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Thank you Marcia! Hi Brian,

Fantastic. I am at CDC HQ now and can talk. My cell is (b) (6)

Thanks!

Best,

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*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
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**From:** Eisenberg, Marcia <Eisenbm@LabCorp.com>
**Sent:** Monday, February 24, 2020 5:51 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Krueger, Brian (b) (6) @LabCorp.com>
**Subject:** Re: 2019 nCoV

Hi Tim
So great to hear from you.
We have our submission number after a few exchanges with the agency via email on our validation design. I am copying Dr. Brian Krueger. He and I can be available and welcome your help.

On Feb 24, 2020, at 4:37 PM, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov> wrote:

***EXTERNAL***: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Hi Marcia,

I am told LabCorp is developing an assay. Could you put me in touch with the correct R&D leader to discuss? We want to do anything we can to help speed the development of an EUA.

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

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**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
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Ph: 301-796-7692
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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 4:37:01 PM
**To**: eisenbm@labcorp.com
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: 2019 nCoV

Hi Marcia,

I am told LabCorp is developing an assay. Could you put me in touch with the correct R&D leader to discuss? We want to do anything we can to help speed the development of an EUA.

Thanks in advance!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/26/2020 9:06:56 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Question

Hi Jeff,

About 100 of the 300 CDC labs that do testing are CLIA certified. The Coronavirus labs is CLIA certified. They have expanded into additional space just recently. I will check on that new space now.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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**Jennifer Campbell**
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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 6:17 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Question

Tim,

Do you know whether the CDC labs that make LDTs are CLIA certified or are they exempt from CLIA?

Jeff

AMERICAN OVERSIGHT

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration
Silver Spring, MD 20993

June 10, 2014

Thomas R. Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
Atlanta, GA 30333

Dear Dr. Frieden:

On June 5, 2013, based on a request by the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in patients with signs and symptoms of MERS-CoV infection in conjunction with clinical and epidemiological risk factors, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3), by qualified laboratories.[1] On May 22, CDC submitted a request for an amendment to the Emergency Use Authorization (EUA). In response to that request, and having concluded that revising the June 5, 2013, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), the June 5, 2013, letter authorizing the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay is being reissued in its entirety with the amendments incorporated.[2]

On May 29, 2013, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such an agent or agents - in this case, MERS-CoV.[3] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of

[1] U.S. Food and Drug Administration. *Authorization of Emergency Use of an In Vitro Diagnostic for Detection of Middle East Respiratory Syndrome Coronavirus; Availability.* 78 Fed. Reg. 42779 (July 17, 2013).

[2] The amendments to the June 5, 2013, letter authorize the expanded use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay to include the *in vitro* qualitative detection of genomic RNA from MERS-CoV in clinical specimens collected from individuals meeting certain epidemiological criteria (e.g., contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation) who may or may not exhibit clinical signs and symptoms associated with MERS-CoV infection. The amendments also include a new Fact Sheet for Contacts of MERS Cases and revisions to the Instructions for Use, product insert, and Fact Sheets for Health Care Professionals and Patients.

[3] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

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*in vitro* diagnostics for the detection of MERS-CoV, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[4]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay (as described in the scope section of this letter (Section II)) for the presumptive detection of MERS-CoV in individuals meeting MERS-CoV clinical and/or epidemiological criteria (e.g., clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation) by qualified laboratories, subject to the terms of this authorization.

## I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of MERS-CoV in individuals meeting MERS-CoV clinical and/or epidemiological criteria (e.g., clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation) meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. MERS-CoV can cause a serious or life threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay may be effective in diagnosing MERS-CoV, and that the known and potential benefits of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay, when used for diagnosing MERS-CoV infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for diagnosing MERS-CoV.[5]

## II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of MERS-CoV in individuals meeting MERS-CoV clinical and/or epidemiological criteria (e.g., clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations

[4] U.S. Department of Health and Human Services. *Determination and Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV)*. 78 Fed. Reg. 33842 (June 5, 2013).

[5] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

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where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation).

**The Authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay:**

The CDC Novel Coronavirus 2012 Real-time RT-PCR Assay is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection of MERS-CoV viral RNA from respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputa, lower respiratory aspirates/washes), sera, and stool from individuals meeting MERS-CoV clinical and/or epidemiological criteria (e.g., clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation). The testing procedure consists of nucleic acid extraction followed by rRT-PCR on the FDA cleared Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument.

The CDC Novel Coronavirus 2012 Real-time RT-PCR Assay includes the following primer and probe sets:

| | |
|---|---|
| **NCV.N2** | targets the MERS-CoV nucleocapsid protein gene |
| **NCV.N3** | targets the MERS-CoV nucleocapsid protein gene |
| **NCV.upE**[6] | targets the MERS-CoV region upstream of envelope protein gene |
| **RP**[7] | targets the human Ribonuclease P gene. This primer and probe set is included as a control for specimen quality, to confirm that human nucleic acid was successfully extracted from the clinical specimen. |

The CDC Novel Coronavirus 2012 Real-time RT-PCR Assay also includes the following control materials:

- **Positive Control:** NCV-2012 rRT-PCR Assay Positive Control (VTC)
- **Negative Controls:** Sterile, nuclease-free water, used as No Template Control (NTC)
  1. **PCR No Template Control ($NTC_1$)**
  2. **Extraction control ($NTC_2$)**

The above described CDC Novel Coronavirus 2012 Real-time RT-PCR Assay, when labeled consistently with the labeling authorized by FDA, entitled "CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised with written permission of FDA, is authorized to be distributed to and used by qualified laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

---

[6] This a WHO-recommended MERS-CoV primer and probe set. See Corman VM, et al. Detection of a novel human coronavirus by real-time reverse-transcription polymerase chain reaction. *Euro Surveill* 2012;17(39). Available online at: http://www.eurosurveillance.org/images/dynamic/EE/V17N39/art20285.pdf.

[7] This primer and probe set is not provided in the CDC Novel Coronavirus 2012 rRT-PCR Assay Kit, but it is required for test performance. Laboratories will utilize the Laboratory Response Network (LRN) RNase P Real-time PCR Primer and Probe Set.

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**The above described CDC Novel Coronavirus 2012 Real-time RT-PCR Assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to health care professionals and patients:**

- **Fact Sheet for Health Care Professionals: Interpreting CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Test Results**
- **Fact Sheet for Patients: Understanding Results from the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay**
- **Fact Sheet for Contacts of MERS Cases: Understanding Results from the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay**

As described in section IV below, CDC is also authorized to make available additional information relating to the emergency use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay in the specified population, when used for presumptive detection of MERS-CoV, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay may be effective in the diagnosis of MERS-CoV infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay, when used to diagnose MERS-CoV infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay described above is authorized to diagnose MERS-CoV infection in individuals meeting MERS-CoV clinical and/or epidemiological criteria (e.g., clinical signs and symptoms associated with MERS-CoV infection, contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation).

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

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**III. Waiver of Certain Requirements**

I am waiving the following requirements for the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

**IV. Conditions of Authorization**

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

**CDC**

A. CDC will distribute the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay with the authorized labeling, as may be revised with written permission of FDA, only to qualified laboratories.

B. CDC will provide to the qualified laboratories the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Health Care Professionals, the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Patients, and the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Contacts of MERS Cases.

C. CDC will make available on its website the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Health Care Professionals, the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Patients, and the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Contacts of MERS Cases.

D. CDC will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. CDC will ensure that qualified laboratories using the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay have a process in place for reporting test results to health care professionals and federal, state, and/or local public health authorities, as appropriate.

F. CDC will track adverse events and report to FDA as required under 21 CFR Part 803.

G. Through a process of inventory control, CDC will maintain records of device usage.

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H. CDC will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which CDC becomes aware.

I. CDC is authorized to make available additional information relating to the emergency use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

J. Only CDC may request changes to the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Health Care Professionals, the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Patients, or the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Contacts of MERS Cases. Such requests will be made by contacting FDA concerning FDA review and approval.

**Qualified Laboratories**

K. Qualified laboratories will make available the authorized Fact Sheet for Health Care Professionals, the authorized Fact Sheet for Patients, and the authorized Fact Sheet for Contacts of MERS Cases.

L. Qualified laboratories will perform the assay on an Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with the appropriate software.

M. Qualified laboratories will have a process in place for reporting test results to health care professionals and federal, state, and/or local public health authorities, as appropriate.

N. Qualified laboratories will collect information on the performance of the assay, and report to CDC any suspected occurrence of false positive or false negative results of which qualified laboratories become aware.

**CDC and Qualified Laboratories**

O. CDC and qualified laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

**Conditions Related to Advertising and Promotion**

P. All advertising and promotional descriptive printed matter relating to the use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

Q. All advertising and promotional descriptive printed matter relating to the use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;

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- This test has been authorized by FDA under an Emergency Use Authorization for use by qualified laboratories;
- This test has been authorized only for the detection of MERS-CoV and not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of MERS-CoV under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1).

No advertising or promotional descriptive printed matter relating to the use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay may represent or suggest that this test is safe or effective for the diagnosis of MERS-CoV.

The emergency use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of MERS-CoV is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Enclosures

AMERICAN OVERSIGHT

**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 2:52:23 PM
**To**: Ellen Flannery (Ellen.Flannery@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: CDC Update to patient population
**Attachments**: MERS-CoV_CDC.pdf

Deliberative / Pre-decisional

Hi Ellen,

I believe the CDC will ask for the same language as was used in the MERS EUA. See highlighted text below and attached.

On June 5, 2013, based on a request by the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of Middle East Respiratory Syndrome Corona virus (MERS-Co V) in patients with signs and symptoms of MERS-Co V infection in conjunction with clinical and epidemiological risk factors , pursuant to section 564 ofthe Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3), by qualified laboratories.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/25/2020 8:08:35 PM
**To:** Werner Kroll (b) (6) @quidel.com]
**CC:** Doug Bryant [dbryant@quidel.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: COVID-19 assays

Hi Werner,

Thank you so much for this and apologies for the delay in getting back to you. It has been a very busy day an am still in the EOC.

I like the sound of this below for now as I have not yet got my head around thinking about serology assays and I am still gaining understanding of (b)(4)

You Wrote:

(b)(4)

Two items:

1) UTMB is now shipping extracted viral RNA that can be used for your development work.

2) If you get the UTMB RNA this week or early next week, how soon can you have a finished EUA assay with validation package to submit to the FDA?

Thanks!

Best,
*Tim*

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**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*

*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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**From:** Werner Kroll (b) (6) @quidel.com>
**Sent:** Monday, February 24, 2020 11:54 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Doug Bryant <dbryant@quidel.com>
**Subject:** COVID-19 assays

Hallo Tim,

It was great talking to you on Friday to discuss options and requirements for the development of COVID-19 assays on the Quidel platforms, in specific Lyra for nucleic acid-based assays and (b) (4) and Sofia for the immunoassay-based assays.

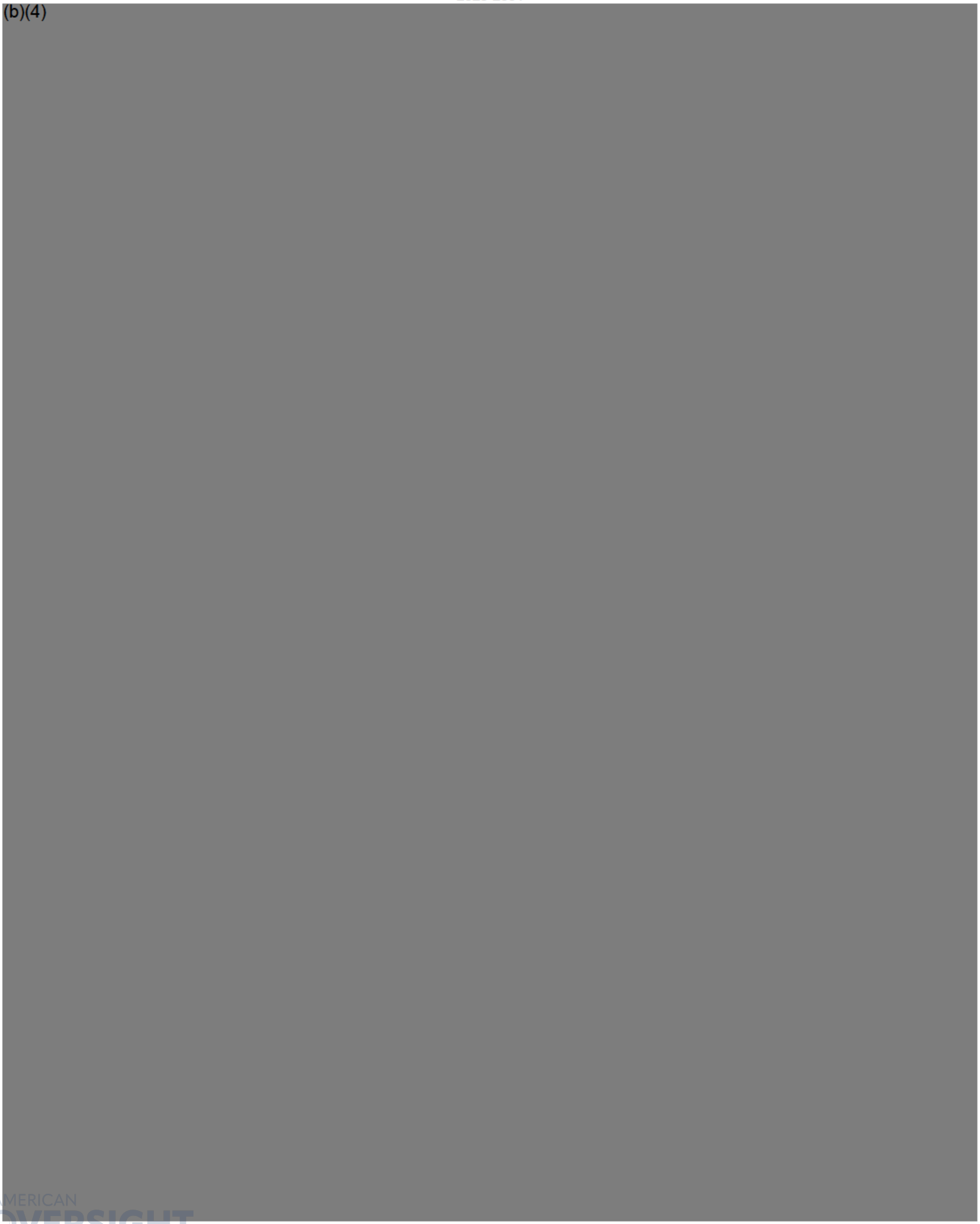
As R&D team we discussed today at Quidel what options we would have to develop such assays, which assumptions we have to make and what timelines are best case options.

(b)(4)

[redacted]

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(b)(4)



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(b)(4)

[redacted]

Please let me know if you need any further information or like to discuss other aspects I have missed in my summary.

Best regards

Werner

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**From:** Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent:** 2/25/2020 7:57:40 PM
**To:** Kerr, Liz (b) (6) @thermofisher.com]; Fenton, Tim [tim.fenton@thermofisher.com]
**CC:** Shearstone, Peter E. (b) (6) @thermofisher.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: 2019 nCoV

Hi Liz,

That would be great. Can we arrange something for in the morning? I am booked 10-11 am Eastern, otherwise I am free at this moment tomorrow.

My cell is (b) (6)

Peter also mentioned that he can help arrange the communication.

Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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**Jennifer Campbell**
*Administrative Assistant*

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**From:** Kerr, Liz (b) (6) @thermofisher.com>
**Sent:** Tuesday, February 25, 2020 1:21 PM
**To:** Fenton, Tim <tim.fenton@thermofisher.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Subject:** Re: 2019 nCoV

Tim,
Thank you for the introduction.

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Dr. Stenzel, I would be happy to facilitate a call with our R&D lead on the Coronavirus qPCR assays as well as one of our regulatory leads. Would you have time later this week, either on Thursday or Friday? If you have someone who helps with your schedule, I am happy to work directly with them as well.

Best regards,
- Liz

**Elizabeth Kerr, Ph.D.**
GSD Insights, Transformation and Portfolio Leader
Life Sciences Solutions

Thermo Fisher Scientific
180 Oyster Point Blvd | South San Francisco, CA 94080 USA
Tel: (650) 246-4028 | Mobile: (650) 814-6532
elizabeth.kerr@thermofisher.com |thermofisher.com

---

**From:** "Fenton, Tim" <tim.fenton@thermofisher.com>
**Date:** Tuesday, February 25, 2020 at 12:20 AM
**To:** "Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov>
**Cc:** "Shearstone, Peter E." (b) (6) @thermofisher.com>, "Kerr, Liz" (b) (6) @thermofisher.com>, "Fenton, Tim" <tim.fenton@thermofisher.com>
**Subject:** RE: 2019 nCoV

Hi Tim – it was nice to meet last week. Appreciate the time and candor in the discussion. I know that one of the key hurdles we face is access to the samples in the US. I'm including here Liz Kerr, our leader of a company-wide task force. Can we work with you on samples? – Tim

**Tim Fenton**
Vice President, Global Government Relations
Thermo Fisher Scientific
(b) (6)

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 4:39 PM
**To:** Fenton, Tim <tim.fenton@thermofisher.com>
**Subject:** 2019 nCoV

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hi Tim,

Great to see you last week. I was heartened that your company is interested in developing assay.

We want to do anything we can to help speed the development of an EUA. Could you put me in touch with the correct R&D leader to discuss?

Thanks in advance!

Best,
*Tim*

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**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**From**: Stenzel, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E181C337CF1D429BAE363600706A5FC4-TIMOTHY.STE]
**Sent**: 2/24/2020 8:42:09 AM
**To**: Bridge, Julia A [jbridge@unmc.edu]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: checking in on 2021 USCAP Timely Topics lecture

Hi Julia,

Great to hear from you and hope you are well! That restaurant is great, hope you son and daughter in law enjoyed it.

I am the acting FDA Liaison to the CDC for Coronavirus and have been at the CDC since Saturday, not sure when I will be going back to DC.

Regarding USCAP, there has only been more and more topics to potentially focus on since we last talked. The two you mention are timely. And AI and ML only seems to grow exponentially. There clearly are some very good LDT labs.

Not sure when your board meeting is, I will have time to talk today most likely after 6 pm Eastern Time. What works for you.

Thanks! ☺

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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---

**From:** Bridge, Julia A <jbridge@unmc.edu>
**Sent:** Sunday, February 23, 2020 4:20 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** checking in on 2021 USCAP Timely Topics lecture

---

Hi Tim,

AMERICAN OVERSIGHT

I hope your year has gone well! Can't believe how fast it all goes!

I will be departing this week for the 2020 USCAP annual meeting in Los Angeles and there may be a brief discussion about your anticipated 2021 presentation at the Board meeting. I wanted to reach out to learn if you had any additional thoughts regarding your presentation.

One thing that seems to be increasingly evident is that pathology (to include laboratory precision medicine) is receiving more highly visible criticism from oncologists and other organizations (some likely warranted due to a few highly visible aggregious news worthy labs) - but others not, but lumped with the bad actors... Interested to learn more about this disconnect and spectrum of views of LDTs and FDA approved assays - merits and limitations ... Also, role of molecular pathologist vs phd geneticist in interpreting somatic cancer results another conflicting topic

Coincidentally (b) (6) (he got married a little over a year ago) - she is an interventional cardiology fellow and has a meeting there. I advised them to try the Chinese restaurant we ate at and they are going there tonight with some of the other fellows!

Wishing you the best always and look forward to hearing back from you on any new insight

Julie

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, January 26, 2019 7:23 AM
**To:** Bridge, Julia A <jbridge@unmc.edu>
**Subject:** RE: a bit more info (hotel?) etc...

Non-UNMC email

Hi Julia,

Wonderful!

I will check my CV to make sure it is up to date and then send along.

AMERICAN OVERSIGHT

A typical title for my talks these days are **FDA Updates** or **FDA Updates on Precision Medicine.** Not extremely exciting so if you have any ideas, please relay. Also, if there is anything specific that you think folks will find more timely and interesting, I am open to adapting my talk. It is a bit far out for setting a specific title or topic so perhaps these generic titles work for now.

No hotel required for March 18 as I am local and will drive down for the day. As long as I am there it would be nice to have a pass for the day so I can attend other events/talks, etc. as well that day.

Thanks!

Best,

*Tim*

Tim Stenzel, MD, PhD

Director

Office of *In Vitro* Diagnostics and Radiological Health

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Email: Timothy.Stenzel@fda.hhs.gov

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AMERICAN OVERSIGHT

**From**: Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent**: 2/28/2020 8:57:13 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Fwd: NYS Wadsworth Center COVID-19 Test

Hi Uwe, How soon can you finish this if you get the right of reference? I will work on the CDC again in the morning. Best, Tim

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 28, 2020 at 8:30:18 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

AMERICAN OVERSIGHT

**From**: Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent**: 2/29/2020 1:01:09 PM
**To**: Robin A Prentice [(b) (6) ; Cowgill, Karen [n-kcowgill@kingcounty.gov]; Mark Rieder [mrieder@uw.edu]; Helen Y Chu [helenchu@uw.edu]; Langley, Gayle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09640f099c74468d9480b73a6d194d5d-HHS-fez7-cd]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Duchin, Jeff [Jeff.Duchin@kingcounty.gov]; Kay, Meagan [Meagan.Kay@kingcounty.gov]
**CC**: Janet Englund (janet.englund@seattlechildrens.org) [janet.englund@seattlechildrens.org]; Lindquist, Scott SL (CDC doh.wa.gov) [scott.lindquist@doh.wa.gov]; Jay A. Shendure (b) (6) Trevor Bedford [trevor@bedford.io]; Istarita [(b) (6)
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: SEATTLE Flu Study Lab Result

Sounds good.

---

**From:** Robin A Prentice <(b) (6)
**Date:** February 29, 2020 at 12:44:15 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Cowgill, Karen <n-kcowgill@kingcounty.gov>, Mark Rieder <(b) (6) >, Helen Y Chu <(b) (6) , Langley, Gayle E (CDC) <fez7@cdc.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Duchin, Jeff <Jeff.Duchin@kingcounty.gov>, Kay, Meagan <Meagan.Kay@kingcounty.gov>
**Cc:** Janet Englund (janet.englund@seattlechildrens.org) <janet.englund@seattlechildrens.org>, Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>, Jay A. Shendure <shendure@uw.edu>, Trevor Bedford <trevor@bedford.io>, Istarita <(b) (6) >
**Subject:** RE: SEATTLE Flu Study Lab Result

AMERICAN OVERSIGHT

**From**: Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent**: 2/28/2020 8:30:23 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Rose, Laura E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daafb82a1d594d1ba4e2cdcd5fc6438a-HHS-zey9-cd]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: NYS Wadsworth Center COVID-19 Test

Hi Dan and Wendi,

This right of reference is important to get this and additional assays based on the CDC through the EUA process quickly. The other two companies we discussed today will be similar.

I believe a simple email stating (b) (5) (b) (5)

Hope this helps.

Thanks in advance!

Best,
Tim

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 7:55:22 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

AMERICAN OVERSIGHT

**From**: Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent**: 2/29/2020 12:35:24 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Re: IDT's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Ok to let IDT know? I don't think I should show them this letter. That would be CDC to do.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 29, 2020 at 12:25:40 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>, Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** IDT's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

AMERICAN OVERSIGHT

**From:** Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent:** 2/29/2020 7:03:54 AM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Fwd: NYS Wadsworth Center COVID-19 Test

Morning Jeff, I will make calls to Wendi and/or Dan early this morning to get CDC's permission. (b) (5)
(b) (5)
(b) (5) Thanks! Tim

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 28, 2020 at 9:08:37 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19 Test

AMERICAN OVERSIGHT

**From**: Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent**: 2/29/2020 6:58:05 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Fwd: SEATTLE Flu Study Lab Result
**Importance**: High

Hi Jeff, Can you call me to discuss this situation? Thanks! Best, Tim

---

**From:** Cowgill, Karen <n-kcowgill@kingcounty.gov>
**Date:** February 28, 2020 at 4:46:43 PM EST
**To:** Mark J Rieder <mrieder@uw.edu>, Helen Y Chu <helenchu@uw.edu>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Langley, Gayle E (CDC) <fez7@cdc.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Duchin, Jeff <Jeff.Duchin@kingcounty.gov>, Kay, Meagan <Meagan.Kay@kingcounty.gov>
**Cc:** Robin A Prentice <(b) (6)>, Janet Englund (janet.englund@seattlechildrens.org) <janet.englund@seattlechildrens.org>, Lindquist, Scott SL (CDC doh.wa.gov) <scott.lindquist@doh.wa.gov>, Jay A. Shendure <(b) (6)>, Trevor Bedford <trevor@bedford.io>, Istarita <(b) (6)>
**Subject:** RE: SEATTLE Flu Study Lab Result
**Importance:** High

AMERICAN OVERSIGHT

**From**: Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent**: 2/29/2020 3:46:09 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: FW: NYS Wadsworth Center COVID-19

Here it is again.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 29, 2020 at 8:49:00 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: NYS Wadsworth Center COVID-19

AMERICAN OVERSIGHT

**From**: Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent**: 2/28/2020 10:55:50 AM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Fwd: 2019-nCoV EUA Template

Hi Uwe,

If they can't get additional viral RNA what can we do? (b) (5)
(b) (5)

(b) (5)

(b) (5) Just a thought.

Best,
Tim

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Date:** February 28, 2020 at 10:12:50 AM EST
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Bisht, Himani <Himani.Bisht@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Eisenberg, Marcia <Eisenbm@LabCorp.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019-nCoV EUA Template

AMERICAN OVERSIGHT

**From**: Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent**: 2/24/2020 10:53:23 AM
**To**: Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]
**CC**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Fwd: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Hi Dan,

Just want to make you have this Enforcement Discretion email for the surveillance testing. The CDC has the green light from this email as of last Saturday night shortly after Dr. Redfield and Dr. Hahn spoke Saturday.

Happy to discuss.

Thanks!

Best,
Tim

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 22, 2020 at 9:45:55 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

AMERICAN OVERSIGHT

**From:** Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent:** 2/24/2020 8:57:46 PM
**To:** Krueger, Brian (b) (6) @LabCorp.com]; Eisenberg, Marcia [Eisenbm@LabCorp.com]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: 2019 nCoV

Great to connect Brian. Also I just heard that UTMB has extracted RNA that is ready to ship.

---

**From:** Krueger, Brian (b) (6) @LabCorp.com>
**Date:** February 24, 2020 at 7:04:56 PM EST
**To:** Eisenberg, Marcia <Eisenbm@LabCorp.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: 2019 nCoV

AMERICAN OVERSIGHT

**From**: Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent**: 2/24/2020 8:55:48 PM
**To**: Tucker, Angela (b) (6) @roche.com]
**CC**: Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Richeal Cline (b) (6) @roche.com]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Re: 2019 nCoV

Thanks for the update Angela. I also just heard from Uwe that UTMB has extracted RNA that is ready to ship. Best, Tim

---

**From:** Tucker, Angela (b) (6) @roche.com>
**Date:** February 24, 2020 at 7:07:12 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Richeal Cline (b) (6) @roche.com>
**Subject:** Re: 2019 nCoV

AMERICAN OVERSIGHT

**From:** Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent:** 2/25/2020 7:19:44 AM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Fwd: Co-Diagnostics SARS-CoV-2 Assay Garners CE Mark | GenomeWeb

Hi Uwe,

Has this firm requested the EUA template and/or reached out to you?

Sorry if you sent me a link already to all the companies.

Thanks in advance! :)

Best,
Tim

---

**From:** Tim Stenzel (b) (6)
**Date:** February 25, 2020 at 6:48:52 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Co-Diagnostics SARS-CoV-2 Assay Garners CE Mark | GenomeWeb

AMERICAN OVERSIGHT

**From**: Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent**: 2/25/2020 12:50:43 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Deliberative/PreDecisional

The CDC has not received kits from IDT yet, (b) (5) (b) (5) I or someone else can call IDT to find out for sure. I'm going into my last lab manufacture tour now.

If IDT can ship kits today, (b) (5) (b) (5)

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 25, 2020 at 12:11:07 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

AMERICAN OVERSIGHT

**From**: Timothy.Stenzel@fda.hhs.gov [Timothy.Stenzel@fda.hhs.gov]
**Sent**: 2/22/2020 7:53:59 PM
**To**: Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]
**BCC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Fwd: For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers

Hi Wendi,

I wanted to correct/clarify about the request for confirmation of the number of PHLs who have validated the CDC EUA assay. That request came from FDA leadership. The Secretary's requests regarding the EUA are below and we have received all the information we needed from the CDC for our response to the Secretary's request. Thank you!

Best,
Tim

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 22, 2020 at 5:25:57 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** For Review/Edits by 9 am on Monday (2/24) - Info re EUA for COVID-19 By The Numbers
**Importance:** High

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 10:08:26 PM
**To**: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
**Subject**: RE: White House Request-Due 0900 tomorrow (Wednesday)

Perfect thanks, Uwe

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 10:06 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: White House Request-Due 0900 tomorrow (Wednesday)

OK thx I will include

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 10:06 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: White House Request-Due 0900 tomorrow (Wednesday)

Michael, this will work, since we only provide the number and not information on the individual companies. So we are good.

Uwe

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 10:00 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: White House Request-Due 0900 tomorrow (Wednesday)

Can we add this? Or is it confidential?

<< File: CoV Diagnostics USG Interagency One-pager v6_FDA.docx >>

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 9:36 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Scherf, Uwe

AMERICA'S FRONTLINE DOCTORS OVERSIGHT

<Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: White House Request-Due 0900 tomorrow (Wednesday)

Michael, Rosemary,

Diagnostics look good, no comments. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 8:21 PM
**To:** Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** FW: White House Request-Due 0900 tomorrow (Wednesday)
**Importance:** High

Hi – please take a look and send me any comments before the deadline if possible thx -m

Understanding is that this is a briefing for the White House Task Force – currently scheduled to meet at 4pm on Thursday. After that brief, a subset will go in to brief POTUS. Drs. Fauci (and likely Kadlec) will be doing the briefing for the *Task Force*.

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**From:** Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>
**Sent:** Tuesday, February 4, 2020 7:31 PM
**To:** Embry, Alan C (NIH) <(b) (6) @niaid.nih.gov>; Jennifer Kishimori <jennifer.m.kishimori.mil@mail.mil>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Biggins, Julia (MIL) <julia.e.biggins.ctr@mail.mil>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Marston, Hilary D (NIH) <(b) (6) @nih.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>
**Cc:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Armstrong, Kimberly (OS) <Kimberly.Armstrong@hhs.gov>; Tse, Brian (OS) <Brian.Tse@hhs.gov>; Donabedian, Armen (OS) <armen.donabedian@hhs.gov>; Donis, Ruben (OS) <Ruben.Donis@hhs.gov>
**Subject:** RE: White House Request-Due 0900 tomorrow (Wednesday)

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All,

Thanks for your patience as we worked through a number of rapid-fire tasks today. I've attached the following documents for your review:

1)Therapeutics one pager
2)Vaccines one pager
3)Diagnostics one pager
4)Two overview slides: talking points and graphic

Please add information that is missing and return the documents by 0900 tomorrow (Wednesday). I'll adjudicate comments and make edits once I receive input from each Agency. I understand that all need to go through ASPR and NIAID clearance tomorrow.

Thanks again for your input and your patience as we polished these documents as much as possible today.

Best,
Christy
<< File: CoV Diagnostics USG Interagency One-pager v6.docx >> << File: 2019_nCoV_Tx_One_Pager_v4 02042020.docx >> << File: Vaccines-1-pager v1ad.docx >> << File: ASPR-WH Slide Deck_v5.pptx >>
--
Christy L. Ventura, Ph.D.
Tunnell Government Services
Executive Secretary, 2019-nCoV Medical Countermeasures Task Force
Project Manager, CBRN/BARDA/ASPR/HHS
O'Neill 23L05
Office: (b) (6)
Cell: (b) (6)

---

**From:** Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
**Sent:** Monday, February 3, 2020 10:24 PM
**To:** Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Tse, Brian (OS/ASPR/BARDA) <Brian.Tse@hhs.gov>; Donabedian, Armen (OS/ASPR/BARDA) <armen.donabedian@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>
**Cc:** Marston, Hilary (NIH/NIAID) [E] (b) (6) @nih.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>; Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>
**Subject:** White House Request-Due COB tomorrow (Tuesday)

All,

We have received a request from the White House Task Force. We need to provide the S1 with three one-pagers, one each for diagnostics, vaccines, and therapeutics. ASPR also wants a single slide showing product development for all three, close collaboration between agencies, etc. we will also put together a slightly longer deck with more detail around the one-pagers.

I've asked Rosemary to coordinate the diagnostic one-pager.

BARDA will take the pen on the one pager, but we are going to have pieces coming in from DoD and NIAID. The attached word document is a very rough outline. Below is what we are thinking in terms of specifics:

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<< File: outline1 hm.docx >>
*mRNA – blurb on moderna, listing other mRNA (e.g.,* (b) (4) ***NIAID***

*Adenovirus – blurb on* (b) (4) *listing other adeno (e.g.,* (b) (4) *)* ***BARDA***
*nanoparticle– blurb on* (b) (4) ***NIAID***
*Live-attenuated – blurb on* (b) (4) ***NAIID***
*Others as needed.*

***Therapeutics –*** *by type.*
*Here I'm thinking just a slide with boxes for broad-spectrum antivirals, host-targeted, approved/repurposed and mAbs* ***(BARDA)***
*Another slide on potential timeline for remdesivir trial, including Chinese enrollment.* ***(JPEO)***

*Broad-spectrum antiviral –* (b) (4) *(big focus – JPEO),* (b) (6) ***based on*** (b) (6) ***content)***
*Host-targeted –****BARDA***
*Approved-FDA –* (b) (4) ***NIAID***
*mAbs:*
- (b) (4) – ***BARDA***
- (b) (4) – ***NIAID***
- (b) (4) – ***NIAID***
- (b) (4) – ***NIAID***

I recognize the challenge in this approach, but just do not see a better approach with the time we have. I need the first draft of the one pagers by about noon tomorrow, so we can start dropping in pieces and working on the flow. I've copied Hilary so she can weigh in with any thoughts.

**Brian,**

Could I ask you to pull together the one pager for the therapeutics, with Kim or her designee providing the specific information on host-target Regeneron efforts? And could I also lean on you to take an initial stab (working with Amy) on what a single comprehensive view might look like? I have no idea where to even start.

**Ruben,**

Could I ask you to pull together the vaccine one-pager?

For all of these, we're going for bullet format, lots of white space.

We can chat tomorrow a.m., but I wanted to get this out to you tonight in case some of you had time/wanted to get a jump.

Thanks.

Robert

**Robert Johnson, Ph.D.**
Director, Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research and Development Authority
**BARDA**
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
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# FACT SHEET FOR HEALTHCARE PROVIDERS

**CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel** **XXX x, 202** **2019 Novel Coronavirus (2019-nCoV)**

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Centers for Disease Control and Prevention (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Testing is to be conducted on specimens from people who meet CDC criteria for 2019-nCoV testing, available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section). The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel should be ordered only to presumptively detect 2019-nCoV infection. If outside the U.S., testing should follow appropriate public health authority consultation and/or guidance for the diagnosis and reporting of 2019-nCoV infection. All information and guidance, including for 2019-nCoV laboratory testing, may change as more data is gathered on this virus. Please check the CDC's 2019 Novel Coronavirus, webpage (see links provided in "Where can I go for updates and more information" section) regularly for the most current information.

**All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel**

**What are the symptoms of 2019-nCoV?**
Most patients with confirmed 2019-nCoV infection appear to develop fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with 2019-nCoV infection. Signs and symptoms may appear any time from 2 to 14 days after exposure to 2019-nCoV virus. The median incubation period is unknown at this time.

Public health officials have identified cases of 2019-nCoV in the United States, which may pose risks for public health. To date most cases of 2019-nCoV infection outside of China have been directly or indirectly linked through residence in or travel to Wuhan City, China or close contact with an individual suspected or confirmed to be ill with 2019-nCoV. Please check the CDC webpage for the most up to date information.

Comment [SKE1]: CDC please update with new information as as appropriate – we should include that human-to-human transmission with close contacts has been observed.

**This test is to be performed only using respiratory specimens collected from individuals who meet CDC criteria for 2019-nCoV testing.**

**What do I need to know about 2019-nCoV testing?**
Current information on 2019-nCoV infection for healthcare providers, including case definitions and infection control, is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel can be used to test upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, bronchoalveolar lavage, sputum, lower respiratory tract aspirate, nasopharyngeal wash/aspirate or nasal aspirate).
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel should be ordered for the presumptive detection of 2019-nCoV in individuals who meet CDC criteria for 2019-nCoV testing.
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized for use in laboratories designated by CDC as qualified, and in the U.S., certified under CLIA to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions following CDC *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007).*

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with 2019-nCoV as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with*

**Report Adverse events,** including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 ([ HYPERLINK "https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home" ]) or by calling **1-800-FDA-1088**



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*2019 Novel Coronavirus (2019-nCoV)*. These specimens are only shipped for analysis to laboratories designated by CDC as qualified for analysis. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV) (*see links provided in "Where can I go for updates and more information" section).

**What does it mean if the specimen tests positive for 2019-nCoV?**
A positive test result for 2019-nCoV indicates that RNA from 2019-nCoV was detected, and the patient is presumptively infected with 2019-nCoV and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for quarantine of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially 2019-nCoV infected patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the recommended standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

**What does it mean if the specimen tests negative for 2019-nCoV?**
A negative test result for this test means that 2019-nCoV RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out 2019-nCoV infection and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of 2019-nCoV infection.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with 2019-nCoV infection. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that 2019-nCoV infection is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If 2019-nCoV infection is still suspected based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities.

Risks to a patient of a false negative include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of 2019-nCoV within the community, or other unintended adverse events.

**What is an EUA?**
The United States (U.S.) FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of in vitro diagnostics (IVDs) under EUA for the detection and/or diagnosis of 2019-nCoV.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. However, based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of 2019-nCoV.

The EUA for this test is in effect for the duration of the 2019-nCoV emergency, unless terminated or revoked (after which the test may no longer be used). An FDA approved or cleared IVD should be used instead of an IVD under EUA, when applicable and available.

**Comment [RVB2]:** Seems to be contradictive. "must" follow "recommended". If they are recommended why would they have to follow?

**Report Adverse events,** including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 ([ HYPERLINK "https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home" ]) or by calling **1-800-FDA-1088**



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| FACT SHEET FOR HEALTHCARE PROVIDERS | 2019 Novel Coronavirus (2019-nCoV) |
|---|---|
| CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel XXX x, 202 | |

## Where can I go for updates and more information?

**CDC webpages:**

**General:** [ HYPERLINK "https://www.cdc.gov/nCoV" ]
**Healthcare Professionals:**
[ HYPERLINK "https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html" ]
**Information for Laboratories:** [ HYPERLINK "https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html" ]
**Laboratory Biosafety:** [ HYPERLINK "https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html" ]
**Isolation Precautions in Healthcare Settings:**
[ HYPERLINK "https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html" \l "a4" ]
**Specimen Collection:** [ HYPERLINK "https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html" ]

**FDA webpages:**

**General:** [ HYPERLINK "http://www.fda.gov/novelcoronavirus" ]

**Report Adverse events,** including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 ([ HYPERLINK "https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home" ]) or by calling **1-800-FDA-1088**



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# FACT SHEET FOR PATIENTS

**CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel** **XXX x, 202** **2019 Novel Coronavirus (2019-nCoV)**

You are being given this Fact Sheet because your sample(s) were tested for the 2019 novel coronavirus (2019-nCoV) using the Centers for Disease Control and Prevention (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Testing was done because you meet CDC criteria for 2019-nCoV testing.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of 2019-nCoV infection. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on 2019-nCoV please visit the CDC 2019 Novel Coronavirus webpage:**
- [ HYPERLINK "https://www.cdc.gov/nCoV" ]

**What is 2019-nCoV Infection?**
2019-nCoV infection is caused by the 2019-nCoV. The 2019-nCoV infection can cause severe respiratory illness in humans and was recently idenitifed in Wuhan, China. Limited information is available to characterize the spectrum of clinical illness associated with 2019-nCoV. 2019-nCoV likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, sneezing, difficulty breathing, etc.).

**What is the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel?**

The test is designed to detect 2019-nCoV in respiratory specimens, for example nasal or oral swabs.

**Why was my sample tested?**
Your sample(s) were tested because your healthcare provider believes you may have been exposed to 2019-nCoV based on your signs and symptoms (e.g., fever, cough, sneezing, difficulty breathing), and because:

- You live in or have recently traveled to a place where 2019-nCoV infection is known to occur, and/or
- Because you have been in close contact with an individual suspected of or confirmed to have 2019-nCoV infection.

The sample(s) collected from you were tested to help find out whether you may be infected with 2019-nCoV.

**What are the known and potential risks and benefits of the test?**
Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Risk that the test result is incorrect (see below for more information).

Potential benefits include:

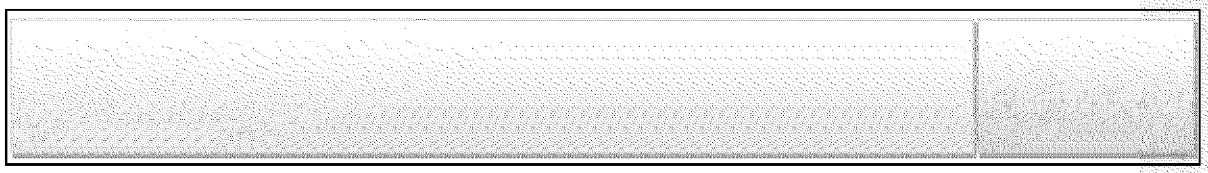
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of 2019-nCoV to your family and others in your community.

**What does it mean if I have a positive 2019-nCoV test result?**

**Where can I go for updates and more information?** The most up-to-date information on 2019-nCoV is available at the CDC General webpage: [ HYPERLINK "https://www.cdc.gov/nCoV" ]. In addition, please also contact your healthcare provider with any questions/concerns.



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If you have a positive test result, it is very likely that you are infected with 2019-nCoV. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). However, your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, such as symptoms, possible exposures, and geographic location of places you have recently traveled.

**What does it mean if I have a negative test result?**
A negative test result means that 2019-nCoV was not found in your sample. For 2019-nCoV, a negative test result for a sample collected while a person has symptoms usually means that 2019-nCoV did not cause your recent illness.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with 2019-nCoV infection, meaning you could possibly still have an infection with 2019-nCoV even though the test is negative. Therefore, while a negative test most likely means you do not have 2019-nCoV infection, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

**Is this test FDA-approved or cleared?**
No. This test is not yet approved or cleared by the United States (U.S.) FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of in vitro diagnostics under EUA for the detection and/or diagnosis of 2019-nCoV. This EUA will remain in effect (meaning this test can be used) for the duration of the 2019-nCoV emergency, unless it is terminated or revoked by FDA (after which the test may no longer be used).

**Comment [SKE1]:** CDC are you okay with this language?

**Where can I go for updates and more information?** The most up-to-date information on 2019-nCoV is available at the CDC General webpage: [ HYPERLINK "https://www.cdc.gov/nCoV" ]. In addition, please also contact your healthcare provider with any questions/concerns.



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/31/2020 8:44:00 PM
**To**: Humes, Rosemary (OS) (Rosemary.Humes@hhs.gov) [Rosemary.Humes@hhs.gov]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: DUE today: USG Strategy needed for Diagnostics 2019-nCoV

Dear Rosemary,

See below in red DMD's response to your questions. Regarding the proposed goals: they look great.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Friday, January 31, 2020 11:04 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Beanan, Maureen J (NIH) (b) (6) @mail.nih.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>; Munster, Vincent J (NIH) (b) (6) @nih.gov>; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>
**Cc:** Huynh, Chuong Q (OS) <Chuong.Huynh@hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>
**Subject:** DUE today: USG Strategy needed for Diagnostics 2019-nCoV

Sorry - Change of plan, drafts due COB today.

---

**From:** Humes, Rosemary (OS/ASPR/BARDA)
**Sent:** Friday, January 31, 2020 10:58 AM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>; Marston, Hilary (NIH/NIAID) [E] (b) (6) @nih.gov>; Munster, Vincent (NIH/NIAID) [E] (b) (6) @nih.gov>; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>; Carroll, Darin (CDC/DDID/NCEZID/OD) <zuz4@cdc.gov>
**Cc:** Huynh, Chuong (OS/ASPR/BARDA) <Chuong.Huynh@hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD)

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<wdk1@cdc.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>
**Subject:** USG Strategy needed for Diagnostics 2019-nCoV

CoV Dx Team,
I have been asked to coordinate the drafting of a USG strategy for CoV diagnostics, this will be used to brief up, including possibly to the NSC. Some of you will remember we had to do this for Zika in 2016. As expected , turn around is short, expectation is to have this ready early next week. Vaccine and Therapeutics groups are doing same, it is my understanding that everything will be vetted and approved through the official 2019-nCoV MCM Task Force that includes senior representative from every agency.

Using what we did for Zika as a template, I have started drafting, and will share draft later today, but wanted to give you a heads up so you can start working.
To speed things along, I ask:
1. Review the proposed goals below – are these acceptable – please suggest edits/revisions. Send your input back today - just at the WG level now, vetting with leadership will come later.
2. Please provide by ~~Monday morning~~ COB today a draft brief summary of what you are currently doing, and what you plan to do if funding is made available.

Current activities
(b) (5)

Plan if funding is available
- (b) (5)

3. Please provide ~~Monday morning~~ COB today by a list of any key challenges (other than access to samples/viruses) that you think need to be highlighted.
- Development of reference material for traceability purposes
- Develop material for initial laboratory verification purposes

We are also working on some landscape graphics to include.
Let me know if you have any questions. Thanks so much for your understanding and responsiveness!!
Rosemary

**Proposed goals:**
(b) (5)

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(b) (5)

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
Cell: (b) (6)

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/31/2020 8:30:23 PM
**To:** Humes, Rosemary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6de8a41cc8d54da69787255ca964affa-HHS-Rosemar]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: DUE today: USG Strategy needed for Diagnostics 2019-nCoV

Dear Rosemary,

See below in red DMD's response to your questions. Regarding the proposed goals they look.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Friday, January 31, 2020 11:04 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Beanan, Maureen J (NIH) (b) (6) @mail.nih.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>; Munster, Vincent J (NIH) (b) (6) @nih.gov>; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>
**Cc:** Huynh, Chuong Q (OS) <Chuong.Huynh@hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>
**Subject:** DUE today: USG Strategy needed for Diagnostics 2019-nCoV

Sorry - Change of plan, drafts due COB today.

---

**From:** Humes, Rosemary (OS/ASPR/BARDA)
**Sent:** Friday, January 31, 2020 10:58 AM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>; Marston, Hilary (NIH/NIAID) [E] (b) (6) @nih.gov>; Munster, Vincent (NIH/NIAID) [E] (b) (6) @nih.gov>; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>; Carroll, Darin (CDC/DDID/NCEZID/OD) <zuz4@cdc.gov>

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**Cc:** Huynh, Chuong (OS/ASPR/BARDA) <Chuong.Huynh@hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>
**Subject:** USG Strategy needed for Diagnostics 2019-nCoV

CoV Dx Team,
I have been asked to coordinate the drafting of a USG strategy for CoV diagnostics, this will be used to brief up, including possibly to the NSC. Some of you will remember we had to do this for Zika in 2016. As expected , turn around is short, expectation is to have this ready early next week. Vaccine and Therapeutics groups are doing same, it is my understanding that everything will be vetted and approved through the official 2019-nCoV MCM Task Force that includes senior representative from every agency.

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To speed things along, I ask:

(b) (5)

Current activities

(b) (5)

Plan if funding is available

- (b) (5)

3. Please provide ~~Monday morning~~ COB today by a list of any key challenges (other than access to samples/viruses) that you think need to be highlighted.
- Development of reference material for traceability purposes
- Develop material for initial laboratory verification purposes

We are also working on some landscape graphics to include.
Let me know if you have any questions. Thanks so much for your understanding and responsiveness!!
Rosemary

**Proposed goals:**

(b) (5)

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(b) (5)

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
Cell: (b) (6)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/26/2020 3:03:34 PM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Yes, please, would be a good sign that these document have been finalized by CDC and FDA.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 3:01 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Ok, sounds good to me. Do you want me to reply to Julie with regard to their responses to our comments to the draft PI and the Product Information Sheet?
Li

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 2:59 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

We left is too wage and did not really request the description of the (b) (5)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 2:55 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

I am also ok with the responses to our comments from the CDC, except for t(b) (5)

(b) (5)

Do we need to mention this recommendation again?

Li

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 2:46 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Just finished up my review and have to say they addressed our questions quite nicely(b) (5) Looks like with the comments regarding the screen shots we are done.

**Uwe**

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 2:40 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

The items they have addressed look good to me – for the screen shots could we have a footnote to highlight that these are just representative and not the actual names?

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
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Kim.Sapsford@fda.hhs.gov






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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, January 26, 2020 2:20 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Li,

We've updated the PI and have answered most of your questions – it will take us some time to update all of the screen shots. We've also updated the product information sheet for your review. Please let us know if you have questions.

Thanks,
Julie

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 4:03 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Steve and Julie,

Please find attached our feedback on the draft package insert (minus the performance sections). Let us know if you have any questions.

We have looked at the spreadsheet list of clinical specimens that CDC has tested to date with the CDC 2019-nCoV real-time RT-PCR panel and have some questions about the specimens included to help us better understand the data:

(b) (5)

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(b) (5)

[redacted]

Also attached are our feedback on the draft "Product Information Sheet" for your consideration.

Best Regards,
Li

**Li Li**
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 762-6200 | Fax: (301) 847-8512
li.li2@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 24, 2020 7:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

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Hi Kim and Li,

I am forwarding our draft Package Insert minus performance data sections for a first look. We will forward the one-pager product information sheet once we have that draft.

I am also forwarding a list of clinical specimens that CDC has tested with the panel so far. (b) (5) [redacted]

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:29 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

FDA agree with use of "Product Information Sheet" rather than Instructions for Use and do not have any additional comments on the box/vial labels.
Please make sure to submit the developed product information sheet as part of your labeling package with the EUA submission (should include Instructions for use, product information sheet, final box/vial labels) and make sure it includes instructions to the end user for obtaining the full Instructions for Use document.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 5:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Sorry with attachment!!

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara

AMERICAN OVERSIGHT

<Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM

**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

BLASTn analysis queries with the 2019-nCoV rRT-PCR assays primers and probes will be performed against public domain nucleotide sequences (more detail regarding parameters are included in the attached document). Database search parameters will follow a strategy to demonstrate the potential for cross-reactivity depending on the target of the design.

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1. BLASTn analysis query excluding all coronavirus sequences.

1. BLASTn analysis query including coronaviruses, but excluding human SARS and bat SARS coronaviruses

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) AND (b) (4) or AND/OR (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
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gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)

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<sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/31/2020 8:21:17 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FW: Regulatory discretion - Need to confirm process and next steps

Jeff, Elizabeth and Ellen,

CDC's 1st request for testing sites came in, Chicago and Richmond. DMD acknowledged the receipt.

Uwe

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 7:03 PM
**To:** Patel, Anita (CDC) <bop1@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Weldon, William C (CDC) <wiw4@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Anita,

DMD acknowledge the receipt of this information.

Thanks, Uwe

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Date:** January 31, 2020 at 5:57:26 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Weldon, William C (CDC) <wiw4@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe and Kim,
Please see below for the locations for the first two lab locations.
Best,
Anita

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:49 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

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Here is the info:

Illinois Dept of Public Health-Chicago Laboratory
Attn: Matt Charles
2121 West Taylor (2nd floor)
Chicago, IL 60612
Phone: 217-220-1739
matt.charles@illinois.gov

California Department of Public Health
Attn: Debra Wadford
850 Marina Bay Parkway
Richmond, CA 94804
Debra.wadford@cdph.ca.gov
Phone: 510-685-2965

**Wendi Kuhnert-Tallman**
**phone - 404-639-3103**

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:40 PM
**To:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe,
We greatly appreciate FDA's rapid review of CDC's request. CDC will send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford once locations are confirmed.

We will notify our lab team of the note below and let you know if there are any additional questions.
Thanks again -
Best,
Anita

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:01 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Dear Anita,

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FDA and CDC have been working interactively together on CDC's request for an Emergency Use Authorization (EUA) for its 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens. At this time, there is no *in vitro* diagnostic test approved, cleared or authorized for such use.

On January 30th, CDC notified FDA that it would like to distribute the test to certain laboratories so that they can use the test prior to issuance of an EUA. This would help to address the significant public health concerns raised by the infectious disease at this early stage, and may help to prevent the spread of the infectious disease by addressing the high testing demands currently being faced by CDC.

We understand that CDC would like to distribute the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit, and any components, to laboratories designated by CDC as qualified and, in the United States, such laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. We also understand that CDC will ask each of the state laboratories to send positive samples and (b) (5) negative samples to CDC for further validation testing.

Based on our understanding of the facts and the public health concerns at issue here – specifically, that there is currently no other test available to respond to this emergency and that CDC is actively pursuing EUA authorization – at this time, FDA does not intend to object to the distribution and use of this test as described above. We ask that you please send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford (Kim.Sapsford@fda.hhs.gov) and the Director of the Division of Microbiology Devices, Uwe Scherf (Uwe.Scherf@fda.hhs.gov).

Kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Hi Liz,
When we spoke last week, we considered options to rapidly make lab reagents available for 2019-nCoV testing. We are actively working to get the EUA submitted. However, we are now at a point where CDC would like for reagents to test for 2019-nCoV to be placed at public health labs at the state/local level. I have a draft request asking to use existing statutory authority 564B for us to preposition the reagents for testing and also to request regulatory discretion for these test to be used in limited laboratories.

AMERICAN OVERSIGHT

Is there a specific process in which we need to make this ask? I believe you mentioned this may just be an email – if so, should I run this by you or Uwe to double check the accuracy of how and what we are asking? Also, who should this request be made to?

We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
4044332667

+ Wendi who is now overseeing lab activities for the response.

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/1/2020 4:16:12 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: NSC request nCoV MCM Task Force strategy

I will thanks. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 3:02 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: NSC request nCoV MCM Task Force strategy

My comments in the attached – do you want to add yours and then respond to Michael – I think he provides them back

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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AMERICAN OVERSIGHT

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Saturday, February 01, 2020 1:45 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: NSC request nCoV MCM Task Force strategy

Hi – have u seen this doc? (says they (b) (5) I don't see u on the email chain)

Would u want to / have time to join the strategy call on Monday @ 1 -2 PM

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Saturday, February 1, 2020 8:59 AM
**To:** Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Kishimori, Jennifer M COL USARMY OSD OUSD P-R (USA) <jennifer.m.kishimori.mil@mail.mil>
**Cc:** Hassell, David (OS) <David.Hassell@hhs.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Embry, Alan C (NIH) (b) (6) @niaid.nih.gov>; Armstrong, Kimberly (OS) <Kimberly.Armstrong@hhs.gov>; Donis, Ruben (OS) <Ruben.Donis@hhs.gov>; Donabedian, Armen (OS) <armen.donabedian@hhs.gov>; Ventura, Christy L (OS) <Christy.Ventura@hhs.gov>
**Subject:** RE: NSC request nCoV MCM Task Force strategy

Colleagues,
Please see updated Diagnostics version (v1a) attached. If you are already reviewed the earlier version, the only change is the addition of bullet points from FDA.
Rosemary

---

**From:** Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>
**Sent:** Friday, January 31, 2020 9:10 PM
**To:** Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>; Marston, Hilary (NIH/NIAID) [E] (b) (6) @nih.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Kishimori, Jennifer M COL USARMY OSD OUSD P-R (USA) <jennifer.m.kishimori.mil@mail.mil>
**Cc:** Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Embry, Alan (NIH/NIAID) [E] (b) (6) @niaid.nih.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Donabedian, Armen (OS/ASPR/BARDA) <armen.donabedian@hhs.gov>
**Subject:** RE: NSC request nCoV MCM Task Force strategy

Attaching the Vaccine Strategy draft document as well.
Christy
<< File: nCoV vaccine strategy v3.docx >>
--
Christy L. Ventura, Ph.D.
Tunnell Government Services
Executive Secretary, 2019-nCoV Medical Countermeasures Task Force
Project Manager, CBRN/BARDA/ASPR/HHS
O'Neill 23L05
Office: (b) (6)
Cell: (b) (6)

AMERICAN OVERSIGHT

**From:** Ventura, Christy (OS/ASPR/BARDA) (CTR)
**Sent:** Friday, January 31, 2020 8:53 PM
**To:** Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>; Marston, Hilary (NIH/NIAID) [E] (b) (6) @nih.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Kishimori, Jennifer M COL USARMY OSD OUSD P-R (USA) <jennifer.m.kishimori.mil@mail.mil>
**Cc:** Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Embry, Alan (NIH/NIAID) [E] (b) (6) @niaid.nih.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Donabedian, Armen (OS/ASPR/BARDA) <armen.donabedian@hhs.gov>
**Subject:** RE: NSC request nCoV MCM Task Force strategy
**Importance:** High

Colleagues,

Attached are the initial drafts of the Therapeutics strategy and the Diagnostics strategy documents for your review. I will forward the Vaccines strategy document when I receive it. Please share with the SMEs whom you want to join us on the Strategy call on Monday.

We would like to have your initial comments and edits back NLT noon on Sunday (2/2) so that I can compile them and share with Robert and the group in advance of the teleconferen << File: CoV Therapeutics USG Interagency Strategy v1.docx >> << File: CoV Diagnostics USG Interagency Strategy v1.docx >> ce on Monday.

Thank you,
Christy
--
Christy L. Ventura, Ph.D.
Tunnell Government Services
Executive Secretary, 2019-nCoV Medical Countermeasures Task Force
Project Manager, CBRN/BARDA/ASPR/HHS
O'Neill 23L05
Office: (b) (6)
Cell: (b) (6)

**From:** Ventura, Christy (OS/ASPR/BARDA) (CTR)
**Sent:** Friday, January 31, 2020 8:42 AM
**To:** Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>; Marston, Hilary (NIH/NIAID) [E] (b) (6) @nih.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Kishimori, Jennifer M COL USARMY OSD OUSD P-R (USA) <jennifer.m.kishimori.mil@mail.mil>
**Cc:** Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; anita.patel@cdc.gov; Embry, Alan (NIH/NIAID) [E] (b) (6) @niaid.nih.gov>
**Subject:** NSC request nCoV MCM Task Force strategy

All,

AMERICAN OVERSIGHT

The NSC has requested the nCoV MCM Task Force's strategy for MCM development for 2019-nCoV. We propose using the attached Strategy for Zika Vaccine Development that was used in 2016 as the template for the nCoV Strategy for MCM Development. If you are all in agreement on this approach, BARDA will initiate a

draft today and send to all of you for review. In parallel, we will work with NIAID and DoD to update the figures and tables in the document. If you have information or updates to incorporate, please share them with Robert and me today (they can also be incorporated in the review stage).

We are targeting Tues 2/4 at 0900 to receive all written comments from Task Force leads and their SMEs, and Wed 2/5 at 1500 to have a finalized document. To accomplish this task as efficiently as possible, we would like to have a smaller Task Force Working Group call on Monday to discuss the draft. Ideally, the Strategy Working Group will be composed of all of the Task Force leads and the SMEs that you identify as being essential to this task. Please send me the names of the 2-4 SMEs from your team whom you would like to include in the Strategy Working Group today so that I can schedule the discussion.

We apologize for the tight timeline on this request.

Best,
Christy

<< File: HHS-DoD Vaccine Sub-Plan 2 22.docx >> --

Christy L. Ventura, Ph.D.
Tunnell Government Services
in support of CBRN/BARDA/ASPR/HHS
O'Neill 23L05
Office: (b) (6)
Cell: (b) (6)

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/26/2020 3:02:37 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

This comment came originally from CDC as a place holder to update the screen shots. Li in your response just remind CDC that by their own suggestion update the screen shots. [Original comment from Steve Burke]

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 2:56 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

I would prefer for them to update the screen shots to reflect the 2019-nCoV panel assays.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 2:40 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

The items they have addressed look good to me – for the screen shots could we have a footnote to highlight that these are just representative and not the actual names?

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, January 26, 2020 2:20 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Li,

We've updated the PI and have answered most of your questions – it will take us some time to update all of the screen shots. We've also updated the product information sheet for your review. Please let us know if you have questions.

Thanks,
Julie

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 4:03 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Steve and Julie,

Please find attached our feedback on the draft package insert (minus the performance sections). Let us know if you have any questions.

We have looked at the spreadsheet list of clinical specimens that CDC has tested to date with the CDC 2019-nCoV real-time RT-PCR panel and have some questions about the specimens included to help us better understand the data:

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

[redacted]

Also attached are our feedback on the draft "Product Information Sheet" for your consideration.

Best Regards,
Li

**Li Li**
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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li.li2@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 24, 2020 7:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

AMERICAN OVERSIGHT

I am forwarding our draft Package Insert minus performance data sections for a first look. We will forward the one-pager product information sheet once we have that draft.

I am also forwarding a list of clinical specimens that CDC has tested with the panel so far. (b) (5) [redacted]

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:29 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

FDA agree with use of "Product Information Sheet" rather than Instructions for Use and do not have any additional comments on the box/vial labels.
Please make sure to submit the developed product information sheet as part of your labeling package with the EUA submission (should include Instructions for use, product information sheet, final box/vial labels) and make sure it includes instructions to the end user for obtaining the full Instructions for Use document.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 5:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>;

AMERICAN OVERSIGHT

Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Sorry with attachment!!

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

AMERICAN OVERSIGHT

Dear Steve,

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

AMERICAN OVERSIGHT

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

BLASTn analysis queries with the 2019-nCoV rRT-PCR assays primers and probes will be performed against public domain nucleotide sequences (more detail regarding parameters are included in the attached document). Database search parameters will follow a strategy to demonstrate the potential for cross-reactivity depending on the target of the design.

1. BLASTn analysis query excluding all coronavirus sequences.
1. BLASTn analysis query including coronaviruses, but excluding human SARS and bat SARS coronaviruses

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

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**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) AND (b) (4) or AND/OR (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
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gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

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Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
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gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>

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**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/24/2020 11:33:36 AM
**To**: Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Julie, Steve and Steve,

FDA also agrees with your pre-positioning proposal to distribute tests and control to the LRN labs and public health labs before the EUA authorization.

One nuance, are you also planning to provide the device outside of the US?

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:29 AM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

FDA agree with use of "Product Information Sheet" rather than Instructions for Use and do not have any additional comments on the box/vial labels.

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Please make sure to submit the developed product information sheet as part of your labeling package with the EUA submission (should include Instructions for use, product information sheet, final box/vial labels) and make sure it includes instructions to the end user for obtaining the full Instructions for Use document.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

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Sorry with attachment!!

**Kim Sapsford-Medintz, Ph.D.**
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**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

BLASTn analysis queries with the 2019-nCoV rRT-PCR assays primers and probes will be performed against public domain nucleotide sequences (more detail regarding parameters are included in the attached document). Database search parameters will follow a strategy to demonstrate the potential for cross-reactivity depending on the target of the design.

1. BLASTn analysis query excluding all coronavirus sequences.
1. BLASTn analysis query including coronaviruses, but excluding human SARS and bat SARS coronaviruses

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
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gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM

**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

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Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) AND (b) (4) or AND/OR (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

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**Steve Burke, Ph.D., RAC**
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*CDC Influenza Division (Battelle Contractor)*
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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases

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are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/2/2020 2:13:48 PM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: draft CDC EUA template

Thanks Julie, you guys are amazing. Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 2, 2020 2:07 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template

Thank you Uwe! We will send all of the documents listed below to you. We are not sharing the already agreed upon labeling to streamline the clearance process.

We will be back in touch today later this afternoon.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 1:55 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template

Julie,

They look good, only one final point: The standalone paragraph:

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*Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens from the same patient may be necessary to detect the virus.*

Is now redundant since the updated language with '(types and time points) ' has been added in the paragraph starting: "Negative results ……..

So I deleted the redundant paragraph. See file attached.

These are all the documents we need.

As mentioned earlier the documents we would expect to see in the EUA request package are:

- CDC Cover Letter
- EUA Template
- Labeling:
  - Final Instructions for Use/Package Insert (let us know which you choose)
  - Final Product Information Sheet
  - Final Verification Requirements
  - Final Box and Vial Labels
- Fact Sheets:
  - HCP Fact Sheet
  - Patient Fact Sheet
- Appendix – include any line data and additional information (bioinformatic analysis) used to support the summary information in the EUA template

Thanks, Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 2, 2020 12:32 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Good morning all,

Thank you for reviewing the EUA template so quickly. We appreciate your feedback and have incorporated all of your suggested changes in the EUA template and the instructions for use. I've attached the tracked changes versions and clean versions of both.

We would like to send the documents, understanding that the LoD table will need to go into the EUA template and the instructions for use, for CDC clearance this afternoon. Is that acceptable to you? What other documents do you need from us?

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 9:34 AM

AMERICAN OVERSIGHT

**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Dear Julie,

Please find attached DMD's comments in the EUA template, looks good, we just need the LoD data. We inserted them in the clean version for ease of viewing. Once the LoD is finalized we recommend dropping the EUA template performance section into your instructions for use performance section.

We would also like to request the following limitation addition/change in the IFU:

New:

- Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has only been established in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).

And maybe strengthen the negative results one by combining two of the current limitations with the addition in green:

- Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.

Julie, also when are you planning to send the complete package for CDC clearance – in parallel with our review or after we have reviewed and say it is good.

Let us know if have any questions.

Best regards
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 2, 2020 12:10 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>

AMERICAN OVERSIGHT

**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** draft CDC EUA template

Hi all,

Here is the latest version of the CDC EUA template. We believe that the only data set missing is the limit of detection study, which we will have for you tomorrow, likely in the afternoon. I've attached both a tracked changes version which captures all of our combined edits and a clean version from which we can work if you agree with all of our combined edits.

Please let us know if there are additional questions. We will be available all day tomorrow to discuss.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 5:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Dear Julie,

Please find attached the final redline (FYI) and clean Patient and HCP facts sheets for you to send forward for CDC clearance.
In addition, below is an outline of the main items we would expect to see in the EUA request package:

- CDC Cover Letter
- EUA Template
- Labeling:
  - Final Instructions for Use/Package Insert (let us know which you choose)
  - Final Product Information Sheet
  - Final Verification Requirements
  - Final Box and Vial Labels
- Fact Sheets:
  - HCP Fact Sheet
  - Patient Fact Sheet
- Appendix – include any line data and additional information (bioinformatic analysis) used to support the summary information in the EUA template

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Saturday, February 01, 2020 3:13 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Hi Kim,

Here are some edits and comments from our epidemiologists. Please let me know if they are acceptable or if we need to discuss.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 4:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Dear Julie,

Please find attached the HCP and Patient Fact Sheets, there were a number of changes resulting from the updated intended use and the additional internal review at FDA so I haven't didn't include a redline – but let me know if you need it I can send it along.

Let me know if you have any questions
Best regards
Kim

AMERICAN OVERSIGHT

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 31, 2020 3:27 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Clean instruction for use and question regarding in silico analyses
**Importance:** High

Hi all,

Attached is the clean instructions for use without the performance data. There is one screen shot that needs to be replaced.

We have another question regarding the presentation of the in silico analyses (also attached). We have discussed the approach, and we'd like your feedback on how you would like the data summarized. The data will be sent as an appendix with the submission along with the rest of our data.

We appreciate your help!
Thanks,
Julie

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/24/2020 8:18:42 AM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Agree. We will also bring this up with OCET this morning at the 10 AM meeting. Uwe

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 7:51 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Agree, I am OK if the 1-pager referrers to the complete PI.

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 9:31 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

I am ok with "Product information sheet". This 1-page document will refer to the Instructions for Use that will be published on the FDA EUA site.
Li

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 8:47 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Are we okay with "Product information sheet" rather than "Instructions for Use" to describe the 1-page they plan to include in the box? Seems okay to me but wasn't sure if there was another more common name we have seen.

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 5:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Sorry with attachment!!

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

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Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara

AMERICAN OVERSIGHT

<Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

BLASTn analysis queries with the 2019-nCoV rRT-PCR assays primers and probes will be performed against public domain nucleotide sequences (more detail regarding parameters are included in the attached document). Database search parameters will follow a strategy to demonstrate the potential for cross-reactivity depending on the target of the design.

1. BLASTn analysis query excluding all coronavirus sequences.
1. BLASTn analysis query including coronaviruses, but excluding human SARS and bat SARS coronaviruses

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

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Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

AMERICAN OVERSIGHT

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

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Do you want (b) (4) AND (b) (4) or AND/OR (b) (4) (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

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Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/2/2020 2:01:09 PM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: draft CDC EUA template
**Attachments**: EUA20000x CDC_Authorization Letter DRAFT 02012020 JR (OCC 2-2-2020)_MB.doc

Julie

See my last email regarding the PI and here an updated letter of authorization matching the language in the declaration

Also, just to confirm:

- CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Executive Summary

Is the EUA review template, correct?

Thanks, Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 2, 2020 1:54 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Hi all,

I know that you are all very busy but I just want to confirm that you are OK with me sending the following documents through CDC clearance today (without the LoD table):

- CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Cover Letter 02FEB20
- CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Executive Summary
- EUA20000x CDC HCP FS Draft_02012020: CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers (Appendix A)
- EUA20000x CDC Patient FS Draft_02012020: CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Patients (Appendix B)
- Appendix E_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Instructions for Use

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- EUA20000x CDC_Authorization Letter DRAFT 01312020_CDC: FDA letter of authorization

Thanks!
Julie

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI)
**Sent:** Sunday, February 2, 2020 12:32 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Good morning all,

Thank you for reviewing the EUA template so quickly. We appreciate your feedback and have incorporated all of your suggested changes in the EUA template and the instructions for use. I've attached the tracked changes versions and clean versions of both.

We would like to send the documents, understanding that the LoD table will need to go into the EUA template and the instructions for use, for CDC clearance this afternoon. Is that acceptable to you? What other documents do you need from us?

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 9:34 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Dear Julie,

Please find attached DMD's comments in the EUA template, looks good, we just need the LoD data. We inserted them in the clean version for ease of viewing. Once the LoD is finalized we recommend dropping the EUA template performance section into your instructions for use performance section.

We would also like to request the following limitation addition/change in the IFU:

New:

- Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has only been established in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).

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And maybe strengthen the negative results one by combining two of the current limitations with the addition in green:

- Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.

Julie, also when are you planning to send the complete package for CDC clearance – in parallel with our review or after we have reviewed and say it is good.

Let us know if have any questions.

Best regards
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 2, 2020 12:10 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** draft CDC EUA template

Hi all,

Here is the latest version of the CDC EUA template. We believe that the only data set missing is the limit of detection study, which we will have for you tomorrow, likely in the afternoon. I've attached both a tracked changes version which captures all of our combined edits and a clean version from which we can work if you agree with all of our combined edits.

Please let us know if there are additional questions. We will be available all day tomorrow to discuss.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 5:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>

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**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Dear Julie,

Please find attached the final redline (FYI) and clean Patient and HCP facts sheets for you to send forward for CDC clearance.
In addition, below is an outline of the main items we would expect to see in the EUA request package:

- CDC Cover Letter
- EUA Template
- Labeling:
  - Final Instructions for Use/Package Insert (let us know which you choose)
  - Final Product Information Sheet
  - Final Verification Requirements
  - Final Box and Vial Labels
- Fact Sheets:
  - HCP Fact Sheet
  - Patient Fact Sheet
- Appendix – include any line data and additional information (bioinformatic analysis) used to support the summary information in the EUA template

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Saturday, February 01, 2020 3:13 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>

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**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Hi Kim,

Here are some edits and comments from our epidemiologists. Please let me know if they are acceptable or if we need to discuss.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 4:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Dear Julie,

Please find attached the HCP and Patient Fact Sheets, there were a number of changes resulting from the updated intended use and the additional internal review at FDA so I haven't didn't include a redline – but let me know if you need it I can send it along.

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 31, 2020 3:27 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Clean instruction for use and question regarding in silico analyses
**Importance:** High

Hi all,

Attached is the clean instructions for use without the performance data. There is one screen shot that needs to be replaced.

We have another question regarding the presentation of the in silico analyses (also attached). We have discussed the approach, and we'd like your feedback on how you would like the data summarized. The data will be sent as an appendix with the submission along with the rest of our data.

We appreciate your help!
Thanks,
Julie

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/31/2020 7:34:14 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Kim, do not worry, it is just a little delicate. You are doing a marvelous job. Thanks, Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** January 31, 2020 at 7:32:12 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Sorry Uwe
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 7:05 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Fwd: Regulatory discretion - Need to confirm process and next steps

Kim, please let me acknowledge the receipt of the information.
Thanks, Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** January 31, 2020 at 6:44:18 PM EST
**To:** Patel, Anita (CDC) <bop1@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Weldon, William C (CDC) <wiw4@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

AMERICAN OVERSIGHT

Dear Anita,

Thank you for providing the locations and contact information for the first too locations

Best regards
Kim

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Date:** January 31, 2020 at 5:57:26 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Weldon, William C (CDC) <wiw4@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe and Kim,
Please see below for the locations for the first two lab locations.
Best,
Anita

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:49 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Here is the info:

Illinois Dept of Public Health-Chicago Laboratory
Attn: Matt Charles
2121 West Taylor (2nd floor)
Chicago, IL 60612
Phone: 217-220-1739
matt.charles@illinois.gov

California Department of Public Health
Attn: Debra Wadford
850 Marina Bay Parkway
Richmond, CA 94804
Debra.wadford@cdph.ca.gov
Phone: 510-685-2965

**Wendi Kuhnert-Tallman**
**phone - 404-639-3103**

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:40 PM
**To:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH)

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<Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe,
We greatly appreciate FDA's rapid review of CDC's request. CDC will send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford once locations are confirmed.

We will notify our lab team of the note below and let you know if there are any additional questions.
Thanks again -
Best,
Anita

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:01 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Dear Anita,

FDA and CDC have been working interactively together on CDC's request for an Emergency Use Authorization (EUA) for its 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens. At this time, there is no *in vitro* diagnostic test approved, cleared or authorized for such use.

On January 30th, CDC notified FDA that it would like to distribute the test to certain laboratories so that they can use the test prior to issuance of an EUA. This would help to address the significant public health concerns raised by the infectious disease at this early stage, and may help to prevent the spread of the infectious disease by addressing the high testing demands currently being faced by CDC.

We understand that CDC would like to distribute the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit, and any components, to laboratories designated by CDC as qualified and, in the United States, such laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. We also understand that CDC will ask each of the state laboratories to send positive samples and (b) (5) negative samples to CDC for further validation testing.

Based on our understanding of the facts and the public health concerns at issue here – specifically, that there is currently no other test available to respond to this emergency and that CDC is actively pursuing EUA authorization – at this time, FDA does not intend to object to the distribution and use of this test as described above. We ask that you please send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford (Kim.Sapsford@fda.hhs.gov) and the Director of the Division of Microbiology Devices, Uwe Scherf (Uwe.Scherf@fda.hhs.gov).

Kind regards,
Uwe

AMERICAN OVERSIGHT

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Hi Liz,
When we spoke last week, we considered options to rapidly make lab reagents available for 2019-nCoV testing. We are actively working to get the EUA submitted. However, we are now at a point where CDC would like for reagents to test for 2019-nCoV to be placed at public health labs at the state/local level. I have a draft request asking to use existing statutory authority 564B for us to preposition the reagents for testing and also to request regulatory discretion for these test to be used in limited laboratories.

Is there a specific process in which we need to make this ask? I believe you mentioned this may just be an email – if so, should I run this by you or Uwe to double check the accuracy of how and what we are asking? Also, who should this request be made to?

We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
4044332667

+ Wendi who is now overseeing lab activities for the response.

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/26/2020 2:47:47 PM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

No problem, I just wanted to make sure you also have a chance to provide feedback.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 1:56 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Uwe,

Thanks for forwarding the e-mail. Unfortunately I cannot review the documents right now. I will be out 2 - 8 pm. I will review when I get back. However, if others can review and get back to CDC earlier, please do not wait for me.

Tamara

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 1:01 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Li & Tamara, this just came in from CDC

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, January 26, 2020 12:55 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E

AMERICAN OVERSIGHT

<Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

We have made some edits to the fact sheets for your consideration. Please take a look and let us know your feedback.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:18 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>

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**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) AND (b) (4) or AND/OR (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM

**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064

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At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/2/2020 1:59:54 PM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject**: RE: draft CDC EUA template

Will confirm

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 1:59 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** FW: draft CDC EUA template
**Importance:** High

Is the Executive Summary the same as the EUA Tamplate?
Li

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 02, 2020 1:54 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Hi all,

I know that you are all very busy but I just want to confirm that you are OK with me sending the following documents through CDC clearance today (without the LoD table):

- CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Cover Letter 02FEB20
- CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Executive Summary

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- EUA20000x CDC HCP FS Draft_02012020: CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers (Appendix A)
- EUA20000x CDC Patient FS Draft_02012020: CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Fact Sheet for Patients (Appendix B)
- Appendix E_CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Instructions for Use
- EUA20000x CDC_Authorization Letter DRAFT 01312020_CDC: FDA letter of authorization

Thanks!
Julie

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI)
**Sent:** Sunday, February 2, 2020 12:32 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Good morning all,

Thank you for reviewing the EUA template so quickly. We appreciate your feedback and have incorporated all of your suggested changes in the EUA template and the instructions for use. I've attached the tracked changes versions and clean versions of both.

We would like to send the documents, understanding that the LoD table will need to go into the EUA template and the instructions for use, for CDC clearance this afternoon. Is that acceptable to you? What other documents do you need from us?

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 9:34 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Dear Julie,

Please find attached DMD's comments in the EUA template, looks good, we just need the LoD data. We inserted them in the clean version for ease of viewing. Once the LoD is finalized we recommend dropping the EUA template performance section into your instructions for use performance section.

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We would also like to request the following limitation addition/change in the IFU:

New:

- Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has only been established in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).

And maybe strengthen the negative results one by combining two of the current limitations with the addition in green:

- Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.

Julie, also when are you planning to send the complete package for CDC clearance – in parallel with our review or after we have reviewed and say it is good.

Let us know if have any questions.

Best regards
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 2, 2020 12:10 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** draft CDC EUA template

Hi all,

Here is the latest version of the CDC EUA template. We believe that the only data set missing is the limit of detection study, which we will have for you tomorrow, likely in the afternoon. I've attached both a tracked changes version which captures all of our combined edits and a clean version from which we can work if you agree with all of our combined edits.

Please let us know if there are additional questions. We will be available all day tomorrow to discuss.

Thanks,
Julie

AMERICAN OVERSIGHT

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 5:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Dear Julie,

Please find attached the final redline (FYI) and clean Patient and HCP facts sheets for you to send forward for CDC clearance.
In addition, below is an outline of the main items we would expect to see in the EUA request package:

- CDC Cover Letter
- EUA Template
- Labeling:
  - Final Instructions for Use/Package Insert (let us know which you choose)
  - Final Product Information Sheet
  - Final Verification Requirements
  - Final Box and Vial Labels
- Fact Sheets:
  - HCP Fact Sheet
  - Patient Fact Sheet
- Appendix – include any line data and additional information (bioinformatic analysis) used to support the summary information in the EUA template

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Saturday, February 01, 2020 3:13 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Hi Kim,

Here are some edits and comments from our epidemiologists. Please let me know if they are acceptable or if we need to discuss.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 4:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Dear Julie,

Please find attached the HCP and Patient Fact Sheets, there were a number of changes resulting from the updated intended use and the additional internal review at FDA so I haven't didn't include a redline – but let me know if you need it I can send it along.

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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Kim.Sapsford@fda.hhs.gov




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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 31, 2020 3:27 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Clean instruction for use and question regarding in silico analyses
**Importance:** High

Hi all,

Attached is the clean instructions for use without the performance data. There is one screen shot that needs to be replaced.

We have another question regarding the presentation of the in silico analyses (also attached). We have discussed the approach, and we'd like your feedback on how you would like the data summarized. The data will be sent as an appendix with the submission along with the rest of our data.

We appreciate your help!
Thanks,
Julie

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/25/2020 4:15:53 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Landscape slides for NSC - need your review

Actually, Quest requested the template via Don, and Don forwarded me the email. I sent out last night the review template to Quest Diagnostics, at around 7:30 PM and cced you on the email. They have the template and we should mention them.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 4:12 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

Should I also mention Quest Diagnostics interest – I have not heard back from them yet if is it okay to share their information with BARDA – I can wait and update her when Quest responds

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 4:09 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

Also, please add Faison, Tremel (OS/ASPR/BARDA) Tremel.Faison@hhs.gov as cc on the email, she is our MOU liaison and has complained being outside of the loop. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 4:03 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

Thank you both – I will make the edit and respond to Rosemary now

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:14 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

AMERICAN OVERSIGHT

Michael and Kim,

I think it would be much better to add this additional qualifier to point 3. (b) (5) So we should add this to the slide.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 1:55 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

Hi – my 2 cents - (b) (5)

This is first I am hearing of this meeting w/NSC – if it is a PCC then they will want agency representation at assistant secretary level – especially if it is an in-person only meeting – so we will have to ensure FDA representative is fully prepped. If there is a call in it's typically in the SCIF by SVTC – so still a challenge to get folks in the room b/c of clearances. thx

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 1:52 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

(b) (5)

What about this addition?

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 1:45 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

Dear Michael and Uwe

In the case of CDC – because of (b) (5)

Maybe I can ask Rosemary to put a clarification as a footnote (b) (5)

What do you think?

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

AMERICAN OVERSIGHT

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 1:33 PM

**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

Hi – I obviously defer to you whether the slides r OK.

Just my ignorance – but on slide 3 where it states (b) (5)

---

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Saturday, January 25, 2020 1:12 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Weldon, William C (CDC) <wiw4@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beanan, Maureen J (NIH) (b) (6) @mail.nih.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>; Munster, Vincent J (NIH) (b) (6) @nih.gov>; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Cc:** Lee, John S (OS) <John.Lee@hhs.gov>
**Subject:** Landscape slides for NSC - need your review

Coronavirus team,
BARDA and NIH have been asked to provide the interagency MCM slides for a meeting with the NSC. I have updated the Dx set, attached for your review. Only slides 3+4 will go forward to NSC, the others are informational to help us track what's going on. At the request of leadership, the published assays and reagents have been separated from Dx assays in development for reagent/kit distribution.
WHO removed the links to the assays from Charite, HKU and China CDC. The Charite and HKU groups, with PHE and others, just jointly published information on their assay in Eurosurveillance (https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.3.2000045)

Please reply:
Slides 3+4 - are these OK, is anything missing?
Other slides: any corrections or new info to add?

Many thanks for your continued support in meeting the expectations for information,
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
BB: (b) (6)

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/22/2020 3:23:57 PM
**To:** Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Li,

Agree, this is an important point to discuss internally before we go into the afternoon meeting. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 2:49 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Tomorrow, we can also discuss internally regarding whether we should ask CDC to (b) (5) .
Li

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 2:42 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

My comments to the EUA template (including exchanges between Kim and Julie/Steve B. from CDC) are in the attached.

I also reviewed the example of (b) (5) . They seem pretty straight forward and make sense. However, we should ask (b) (5)

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Li

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 11:43 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** FW: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

BLASTn analysis queries with the 2019-nCoV rRT-PCR assays primers and probes will be performed against public domain nucleotide sequences (more detail regarding parameters are included in the attached document). Database search parameters will follow a strategy to demonstrate the potential for cross-reactivity depending on the target of the design.

1. BLASTn analysis query excluding all coronavirus sequences.
1. BLASTn analysis query including coronaviruses, but excluding human SARS and bat SARS coronaviruses

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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Kim.Sapsford@fda.hhs.gov






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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

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Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) AND (b) (4) or AND/OR (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

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Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
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gky2@cdc.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
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gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases

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are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/30/2020 10:20:59 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject**: RE: Regulatory discretion - Need to confirm process and next steps

Just send the info, happy to talk on the phone as well, Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 10:19 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Thank you. I've emailed you the meeting information.

Also, if you can answer the questions in my first email that would be great or we can talk now if you have a minute. I can call you on your cell.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** January 30, 2020 at 10:15:53 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Yes, I am available at 2 PM tomorrow. Uwe

**Uwe Scherf, M.Sc., Ph.D.**

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 10:15 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Uwe,

Also, are you available tomorrow at 2PM to discuss the CDC EUA with Ellen, myself, and folks from the Commissioner's Office? We'll be discussing the VALID Act EUA provision and CDC's concerns, as well.

Jeff

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** January 30, 2020 at 10:04:53 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

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Uwe,

Per the update today our review of the clinical data is finalized. Have we (b) (5)

Sorry for all the questions. Also, happy to talk in the AM before 8:30 AM.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** January 30, 2020 at 7:25:05 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

I am online, can be reached at (b) (6) for any questions. Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 7:18 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Regulatory discretion - Need to confirm process and next steps

I can talk now — (b) (6)

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** January 30, 2020 at 7:14:43 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Regulatory discretion - Need to confirm process and next steps

Hi Jeff,

CDC is asking (bottom of email chain) the following:

(b) (5)

Thanks,
Ellen

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**Ellen J. Flannery, J.D.**

*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 7:03 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

See the message below. Per our last exchange, (b) (5) . Please let me know how you plan to proceed. Thanks, Liz

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** January 30, 2020 at 7:00:06 PM EST
**To:** Patel, Anita (CDC) <bop1@cdc.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

I will consider this email a request, and we will respond accordingly. Thanks.

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Date:** January 30, 2020 at 6:58:24 PM EST
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Villanueva, Julie M (CDC) <jfv3@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Meant wendi not wendy ☺

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD)
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>

AMERICAN OVERSIGHT

**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Hi Liz,
When we spoke last week, we considered options to rapidly make lab reagents available for 2019-nCoV testing. We are actively working to get the EUA submitted. However, we are now at a point where CDC would like for reagents to test for 2019-nCoV to be placed at public health labs at the state/local level. I have a draft request asking to use existing statutory authority 564B for us to preposition the reagents for testing and also to request regulatory discretion for these test to be used in limited laboratories.

Is there a specific process in which we need to make this ask? I believe you mentioned this may just be an email – if so, should I run this by you or Uwe to double check the accuracy of how and what we are asking? Also, who should this request be made to?

We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
4044332667

+ Wendy who is now overseeing lab activities for the response.

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/2/2020 1:54:31 PM
**To**: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Burke, Stephen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d17a0f3f59584d64969b15a71b26744a-HHS-gky2-cd]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Goldberg, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=669c6aaf23b14e5fbc202960bb10734f-GOLDBERGB]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: draft CDC EUA template
**Attachments**: PI - CDC 2019-nCoV rRT-PCR Dx Panel_draft 31JAN20 CLEAN DMD_SR (002) 02FEB20-DMD.docx; PI - CDC 2019-nCoV rRT-PCR Dx Panel_draft 31JAN20 CLEAN DMD_SR (002) 02FEB20 CLEAN_DMD.docx

Julie,

They look good, only one final point: The standalone paragraph:

*Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens from the same patient may be necessary to detect the virus.*

Is now redundant since the updated language with '(types and time points) ' has been added in the paragraph starting: "Negative results ……..

So I deleted the redundant paragraph. See file attached.

These are all the documents we need.

As mentioned earlier the documents we would expect to see in the EUA request package are:

- CDC Cover Letter
- EUA Template
- Labeling:
  - Final Instructions for Use/Package Insert (let us know which you choose)
  - Final Product Information Sheet
  - Final Verification Requirements
  - Final Box and Vial Labels
- Fact Sheets:
  - HCP Fact Sheet
  - Patient Fact Sheet
- Appendix – include any line data and additional information (bioinformatic analysis) used to support the summary information in the EUA template

AMERICA'S FRONTLINE DOCTORS OVERSIGHT

Thanks, Uwe

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 2, 2020 12:32 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Good morning all,

Thank you for reviewing the EUA template so quickly. We appreciate your feedback and have incorporated all of your suggested changes in the EUA template and the instructions for use. I've attached the tracked changes versions and clean versions of both.

We would like to send the documents, understanding that the LoD table will need to go into the EUA template and the instructions for use, for CDC clearance this afternoon. Is that acceptable to you? What other documents do you need from us?

Thanks,
Julie

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 9:34 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Dear Julie,

Please find attached DMD's comments in the EUA template, looks good, we just need the LoD data. We inserted them in the clean version for ease of viewing. Once the LoD is finalized we recommend dropping the EUA template performance section into your instructions for use performance section.

We would also like to request the following limitation addition/change in the IFU:

New:

- Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has only been established in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).

And maybe strengthen the negative results one by combining two of the current limitations with the addition in green:

- Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.

AMERICAN OVERSIGHT

Julie, also when are you planning to send the complete package for CDC clearance – in parallel with our review or after we have reviewed and say it is good.

Let us know if have any questions.

Best regards
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 2, 2020 12:10 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** draft CDC EUA template

Hi all,

Here is the latest version of the CDC EUA template. We believe that the only data set missing is the limit of detection study, which we will have for you tomorrow, likely in the afternoon. I've attached both a tracked changes version which captures all of our combined edits and a clean version from which we can work if you agree with all of our combined edits.

Please let us know if there are additional questions. We will be available all day tomorrow to discuss.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 5:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

AMERICAN OVERSIGHT

Dear Julie,

Please find attached the final redline (FYI) and clean Patient and HCP facts sheets for you to send forward for CDC clearance.
In addition, below is an outline of the main items we would expect to see in the EUA request package:

- CDC Cover Letter
- EUA Template
- Labeling:
  - Final Instructions for Use/Package Insert (let us know which you choose)
  - Final Product Information Sheet
  - Final Verification Requirements
  - Final Box and Vial Labels
- Fact Sheets:
  - HCP Fact Sheet
  - Patient Fact Sheet
- Appendix – include any line data and additional information (bioinformatic analysis) used to support the summary information in the EUA template

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Saturday, February 01, 2020 3:13 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

AMERICAN OVERSIGHT

Hi Kim,

Here are some edits and comments from our epidemiologists. Please let me know if they are acceptable or if we need to discuss.

Thanks,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 4:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Dear Julie,

Please find attached the HCP and Patient Fact Sheets, there were a number of changes resulting from the updated intended use and the additional internal review at FDA so I haven't didn't include a redline – but let me know if you need it I can send it along.

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 31, 2020 3:27 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>

AMERICAN OVERSIGHT

**Subject:** Clean instruction for use and question regarding in silico analyses
**Importance:** High

Hi all,

Attached is the clean instructions for use without the performance data. There is one screen shot that needs to be replaced.

We have another question regarding the presentation of the in silico analyses (also attached). We have discussed the approach, and we'd like your feedback on how you would like the data summarized. The data will be sent as an appendix with the submission along with the rest of our data.

We appreciate your help!
Thanks,
Julie

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/25/2020 4:05:26 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
**Subject**: RE: Landscape slides for NSC - need your review

Hold on,

What do you think about this wording:

(b) (5)

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 4:03 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

Thank you both – I will make the edit and respond to Rosemary now

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

AMERICAN OVERSIGHT
FDA U.S. FOOD & DRUG ADMINISTRATION

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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:14 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

Michael and Kim,

I think it would be much better to add this additional qualifier to point 3. (b) (5) So we should add this to the slide.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 1:55 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

Hi – my 2 cents -(b) (5)

This is first I am hearing of this meeting w/NSC – if it is a PCC then they will want agency representation at assistant secretary level – especially if it is an in-person only meeting – so we will have to ensure FDA representative is fully prepped. If there is a call in it's typically in the SCIF by SVTC – so still a challenge to get folks in the room b/c of clearances. thx

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 1:52 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

AMERICAN OVERSIGHT

(b) (5)

What about this addition?

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 1:45 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

Dear Michael and Uwe

In the case of CDC – because of (b) (5)

Maybe I can ask Rosemary to put a clarification as a footnote "(b) (5)

What do you think?

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

AMERICAN OVERSIGHT

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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 1:33 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Landscape slides for NSC - need your review

Hi – I obviously defer to you whether the slides r OK.

Just my ignorance – but on slide 3 where it states "(b) (5)

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Saturday, January 25, 2020 1:12 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Weldon, William C (CDC) <wiw4@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beanan, Maureen J (NIH) (b) (6) @mail.nih.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>; Munster, Vincent J (NIH) (b) (6) @nih.gov>; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Cc:** Lee, John S (OS) <John.Lee@hhs.gov>
**Subject:** Landscape slides for NSC - need your review

Coronavirus team,
BARDA and NIH have been asked to provide the interagency MCM slides for a meeting with the NSC. I have updated the Dx set, attached for your review. Only slides 3+4 will go forward to NSC, the others are informational to help us track what's going on. At the request of leadership, the published assays and reagents have been separated from Dx assays in development for reagent/kit distribution.
WHO removed the links to the assays from Charite, HKU and China CDC. The Charite and HKU groups, with PHE and others, just jointly published information on their assay in Eurosurveillance (https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.3.2000045)

Please reply:
Slides 3+4 - are these OK, is anything missing?
Other slides: any corrections or new info to add?

Many thanks for your continued support in meeting the expectations for information,
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
BB: (b) (6)

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/31/2020 7:02:34 PM
**To**: Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Weldon, William C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0eefd1a4745a4051a5193d7b7d00defc-HHS-wiw4-cd]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Regulatory discretion - Need to confirm process and next steps

Dear Anita,

DMD acknowledge the receipt of this information.

Thanks, Uwe

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Date:** January 31, 2020 at 5:57:26 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Weldon, William C (CDC) <wiw4@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe and Kim,
Please see below for the locations for the first two lab locations.
Best,
Anita

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:49 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Here is the info:

Illinois Dept of Public Health-Chicago Laboratory
Attn: Matt Charles
2121 West Taylor (2nd floor)
Chicago, IL 60612
Phone: 217-220-1739
matt.charles@illinois.gov

California Department of Public Health
Attn: Debra Wadford
850 Marina Bay Parkway
Richmond, CA 94804

AMERICAN OVERSIGHT

Debra.wadford@cdph.ca.gov
Phone: 510-685-2965

**Wendi Kuhnert-Tallman**
**phone - 404-639-3103**

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:40 PM
**To:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe,
We greatly appreciate FDA's rapid review of CDC's request. CDC will send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford once locations are confirmed.

We will notify our lab team of the note below and let you know if there are any additional questions.
Thanks again -
Best,
Anita

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:01 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Dear Anita,

FDA and CDC have been working interactively together on CDC's request for an Emergency Use Authorization (EUA) for its 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens. At this time, there is no *in vitro* diagnostic test approved, cleared or authorized for such use.

On January 30th, CDC notified FDA that it would like to distribute the test to certain laboratories so that they can use the test prior to issuance of an EUA. This would help to address the significant public health concerns raised by the infectious disease at this early stage, and may help to prevent the spread of the infectious disease by addressing the high testing demands currently being faced by CDC.

We understand that CDC would like to distribute the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit, and any components, to laboratories designated by CDC as qualified and, in the United States, such laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. We also understand that CDC will ask each of the state laboratories to send positive samples and (b) (5) negative samples to CDC for further validation testing.

AMERICAN OVERSIGHT

Based on our understanding of the facts and the public health concerns at issue here – specifically, that there is currently no other test available to respond to this emergency and that CDC is actively pursuing EUA authorization – at this time, FDA does not intend to object to the distribution and use of this test as described above. We ask that you please send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford (Kim.Sapsford@fda.hhs.gov) and the Director of the Division of Microbiology Devices, Uwe Scherf (Uwe.Scherf@fda.hhs.gov).

Kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

Hi Liz,
When we spoke last week, we considered options to rapidly make lab reagents available for 2019-nCoV testing. We are actively working to get the EUA submitted. However, we are now at a point where CDC would like for reagents to test for 2019-nCoV to be placed at public health labs at the state/local level. I have a draft request asking to use existing statutory authority 564B for us to preposition the reagents for testing and also to request regulatory discretion for these test to be used in limited laboratories.

Is there a specific process in which we need to make this ask? I believe you mentioned this may just be an email – if so, should I run this by you or Uwe to double check the accuracy of how and what we are asking? Also, who should this request be made to?

We would like to submit this to you tomorrow. Please call my cell when you get a moment if this is easier to talk through.
Best,
Anita
4044332667

+ Wendi who is now overseeing lab activities for the response.

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/31/2020 6:59:49 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: Regulatory discretion - Need to confirm process and next steps

Thanks

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** January 31, 2020 at 6:58:53 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Just acknowledge receipt. Thanks!

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 6:56 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Fwd: Regulatory discretion - Need to confirm process and next steps

Ellen , are you recommending a certain wording for DMD's response or just to acknowledge the received of the information. Please advise.

Uwe

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Date:** January 31, 2020 at 5:57:26 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Weldon, William C (CDC) <wiw4@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Dear Uwe and Kim,
Please see below for the locations for the first two lab locations.
Best,
Anita

---

**From:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
**Sent:** Friday, January 31, 2020 5:49 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Subject:** RE: Regulatory discretion - Need to confirm process and next steps

Here is the info:

AMERICAN OVERSIGHT

Illinois Dept of Public Health-Chicago Laboratory

Attn: Matt Charles
2121 West Taylor (2nd floor)
Chicago, IL 60612
Phone: 217-220-1739
matt.charles@illinois.gov

California Department of Public Health
Attn: Debra Wadford
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Phone: 510-685-2965

**Wendi Kuhnert-Tallman**
**phone - 404-639-3103**

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**Sent:** Friday, January 31, 2020 5:40 PM
**To:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sadove, Elizabeth (FDA/OC) <Elizabeth.Sadove@fda.hhs.gov>
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**Sent:** Friday, January 31, 2020 5:01 PM
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**Subject:** RE: Regulatory discretion - Need to confirm process and next steps
**Importance:** High

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AMERICAN OVERSIGHT

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Kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Thursday, January 30, 2020 6:57 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Regulatory discretion - Need to confirm process and next steps
**Importance:** High

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AMERICAN OVERSIGHT

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Best,
Anita
4044332667

+ Wendi who is now overseeing lab activities for the response.

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/25/2020 4:02:36 PM
**To**: Faison, Tremel (OS/ASPR/BARDA) [Tremel.Faison@hhs.gov]
**CC**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Gitterman, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4747486679444f24aa8d1086cca27390-SRG]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]
**Subject**: RE: 2019 nCoV

Tremyl,

No problem, we have worked under the impression you know about the interactions. Will make sure this happens going forward.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
**Sent:** Saturday, January 25, 2020 10:45 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Gitterman, Steven <Steven.Gitterman@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Subject:** 2019 nCoV

Hi Uwe,

I understand Micro has been in contact with Rosemary/Rodney's group regarding 2019 novel CoV? I hear there is a pre-EUA template?

Can I ask that please be kept in the loop with in any correspondence with BARDA? As the ASPR/FDA MOU point of contact I have to be able to give updates to senior leadership. I know Rodney and Rosemary have dealt with you directly in the past and I don't have a problem with that – I just need to be included too. I'm also going to make sure Rodney's group remembers this.

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Thanks and if you have any questions or concerns please let me know.

Have a good weekend,
Tremel

*Tremel A. Faison, MS, RAC, SCT(ASCP)*
Director (Acting)
Regulatory and Quality Affairs Division (RQA)
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Emergency Response and Preparedness (ASPR)
U.S. Department of Health and Human Services (HHS)
330 Independence Avenue, SW
Room G644
Washington, DC 20201

Phone: (b) (6)
Cell: (b) (6)
(b) (6)

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/2/2020 1:30:44 PM
**To**: Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: draft CDC EUA template

No, we are good, thanks, Uwe

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 1:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template

Should I review these documents or are they finalized?

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 02, 2020 1:19 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template

Agree,

The only other item I found: The standalone paragraph:

Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens from the same patient may be necessary to detect the virus.

Can now be deleted since the updated language with '(types and time points) ' is now added in the paragraph; "Negative results ……..

Otherweise, look really good.

Uwe

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 1:12 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara

AMERICAN OVERSIGHT

<Tamara.Feldblyum@fda.hhs.gov>
**Subject:** FW: draft CDC EUA template
**Importance:** High

Hi all,
The clean documents look good to go. Only the LoD study data is needed to be included in the documents.
Thanks,
Li

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 02, 2020 12:32 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Good morning all,

Thank you for reviewing the EUA template so quickly. We appreciate your feedback and have incorporated all of your suggested changes in the EUA template and the instructions for use. I've attached the tracked changes versions and clean versions of both.

We would like to send the documents, understanding that the LoD table will need to go into the EUA template and the instructions for use, for CDC clearance this afternoon. Is that acceptable to you? What other documents do you need from us?

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 9:34 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: draft CDC EUA template
**Importance:** High

Dear Julie,

Please find attached DMD's comments in the EUA template, looks good, we just need the LoD data. We inserted them in the clean version for ease of viewing. Once the LoD is finalized we recommend dropping the EUA template performance section into your instructions for use performance section.

We would also like to request the following limitation addition/change in the IFU:

New:

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- Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has only been established in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).

And maybe strengthen the negative results one by combining two of the current limitations with the addition in green:

- Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.

Julie, also when are you planning to send the complete package for CDC clearance – in parallel with our review or after we have reviewed and say it is good.

Let us know if have any questions.

Best regards
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 2, 2020 12:10 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>
**Subject:** draft CDC EUA template

Hi all,

Here is the latest version of the CDC EUA template. We believe that the only data set missing is the limit of detection study, which we will have for you tomorrow, likely in the afternoon. I've attached both a tracked changes version which captures all of our combined edits and a clean version from which we can work if you agree with all of our combined edits.

Please let us know if there are additional questions. We will be available all day tomorrow to discuss.

Thanks,
Julie

AMERICAN OVERSIGHT

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 5:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Dear Julie,

Please find attached the final redline (FYI) and clean Patient and HCP facts sheets for you to send forward for CDC clearance.
In addition, below is an outline of the main items we would expect to see in the EUA request package:

- CDC Cover Letter
- EUA Template
- Labeling:
  - Final Instructions for Use/Package Insert (let us know which you choose)
  - Final Product Information Sheet
  - Final Verification Requirements
  - Final Box and Vial Labels
- Fact Sheets:
  - HCP Fact Sheet
  - Patient Fact Sheet
- Appendix – include any line data and additional information (bioinformatic analysis) used to support the summary information in the EUA template

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Saturday, February 01, 2020 3:13 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Hi Kim,

Here are some edits and comments from our epidemiologists. Please let me know if they are acceptable or if we need to discuss.

Thanks,
Julie

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 4:16 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Goldberg, Brittany (FDA/CDRH) <Brittany.Goldberg@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Clean instruction for use and question regarding in silico analyses

Dear Julie,

Please find attached the HCP and Patient Fact Sheets, there were a number of changes resulting from the updated intended use and the additional internal review at FDA so I haven't didn't include a redline – but let me know if you need it I can send it along.

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 31, 2020 3:27 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** Clean instruction for use and question regarding in silico analyses
**Importance:** High

Hi all,

Attached is the clean instructions for use without the performance data. There is one screen shot that needs to be replaced.

We have another question regarding the presentation of the in silico analyses (also attached). We have discussed the approach, and we'd like your feedback on how you would like the data summarized. The data will be sent as an appendix with the submission along with the rest of our data.

We appreciate your help!
Thanks,
Julie

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/30/2020 1:29:34 PM
**To:** Humes, Rosemary (OS/ASPR/BARDA) [Rosemary.Humes@hhs.gov]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Scheduling 2019-nCoV Dx WG call

Rosemary, see available times below

Uwe

| | EST | x=avail |
|---|---|---|
| Friday, 1/31 | 10-11 | |
| | 11-12 | X |
| | 1-2 | X |
| | 3-4 | |
| Monday, 2/3 | 9-10 | |
| | 10-11 | |
| | 11-12 | |
| | 12-1 | |
| | 1-2 | |

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
**Sent:** Thursday, January 30, 2020 12:23 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Weldon, William C (CDC) <wiw4@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Beanan, Maureen J (NIH) (b) (6) @mail.nih.gov>; Marston, Hilary D (NIH) (b) (6) @nih.gov>; Munster, Vincent J (NIH) (b) (6) @nih.gov>; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Karem, Kevin L (CDC) <kdk6@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Lee, John S (OS) <John.Lee@hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** Scheduling 2019-nCoV Dx WG call

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Diagnostics Colleagues,
In case you haven't heard, an interagency Novel Coronavirus MCM Task Force has been established, there was a kick-off call for agency leads yesterday. Although informal workgroups have been busy, including this Dx group, I've been asked to convene a Dx WG for more formal coordination. The Task Force leads should be reaching out to give you more details, they may adjust the members on the group, but in the meantime I would like to have a call tomorrow or Monday if at all possible. The call would give us an opportunity to share agency efforts to support diagnostics for 2019-nCoV, outline key gaps and challenges to Dx development. I will send updated landscape slides later today.
**Please respond ASAP to let me know which times below work for you**. I'll send an invite based on time that works best for as many of you as possible.
Thanks very much for this and all the information you have been sharing in this response,
Rosemary

| | EST | x=avail |
|---|---|---|
| Friday, 1/31 | 10-11 | |
| | 11-12 | |
| | 1-2 | |
| | 3-4 | |
| Monday, 2/3 | 9-10 | |
| | 10-11 | |
| | 11-12 | |
| | 12-1 | |
| | 1-2 | |

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
BB: 202-695-6334

---

**From:** Humes, Rosemary (OS/ASPR/BARDA)
**Sent:** Saturday, January 25, 2020 1:11 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Weldon, William C. (CDC/DDID/NCIRD/DVD) <wiw4@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Beanan, Maureen (NIH/NIAID) [E] (b) (6) @mail.nih.gov>; Marston, Hilary (NIH/NIAID) [E] (b) (6) @nih.gov>; Munster, Vincent (NIH/NIAID) [E] (b) (6) @nih.gov>; Opdyke, Jason A CIV USARMY DOD JPEOCBD (US) <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>
**Cc:** Lee, John (OS/ASPR/BARDA) <John.Lee@hhs.gov>
**Subject:** Landscape slides for NSC - need your review

Coronavirus team,
BARDA and NIH have been asked to provide the interagency MCM slides for a meeting with the NSC. I have updated the Dx set, attached for your review. Only slides 3+4 will go forward to NSC, the others are

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informational to help us track what's going on. At the request of leadership, the published assays and reagents have been separated from Dx assays in development for reagent/kit distribution.
WHO removed the links to the assays from Charite, HKU and China CDC. The Charite and HKU groups, with PHE and others, just jointly published information on their assay in Eurosurveillance (https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.3.2000045)

Please reply:
Slides 3+4 - are these OK, is anything missing?
Other slides: any corrections or new info to add?

Many thanks for your continued support in meeting the expectations for information,
Rosemary

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
(b) (6)
BB: (b) (6)

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/23/2020 1:49:08 PM
**To**: Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) [gky2@cdc.gov]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Lindstrom, Stephen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ad1828a337c4d4f9aa30f8fa5cd6c4f-HHS-sql5-cd]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

We just lost you, will you call back?

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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Kim.Sapsford@fda.hhs.gov






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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

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- BLASTn analysis queries with the 2019-nCoV rRT-PCR assays primers and probes will be performed against public domain nucleotide sequences (more detail regarding parameters are included in the attached document). Database search parameters will follow a strategy to demonstrate the potential for cross-reactivity depending on the target of the design.

1. BLASTn analysis query excluding all coronavirus sequences.
1. BLASTn analysis query including coronaviruses, but excluding human SARS and bat SARS coronaviruses

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*
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Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) AND (b) (4) or AND/OR (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

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Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/30/2020 10:10:41 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) [jfv3@cdc.gov]
**Subject:** RE: Intended use wording

Happy to help.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Thursday, January 30, 2020 8:56 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Burke, Stephen A (CDC) <gky2@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Intended use wording

Thank you Uwe!
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 8:04 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Ross, Jennifer (FDA/OC) <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Intended use wording

Dear Julie,
We made one small update and deleted the word 'current' from the sentence: "*from individuals who meet* (b) (5) *CDC criteria for 2019-nCoV testing.*"

So, the final Intended Use FDA is comfortable with now reads as follow:

**Final Intended Use:**
The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from

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individuals who meet CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization

Please let me know if you have any questions.
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Wednesday, January 29, 2020 5:43 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Intended use wording
**Importance:** High

Hi Kim and Uwe,

We are hoping to have some agreement on the intended use as soon as possible. This is the language that I believe we have agreed upon. Can you please confirm?

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet current CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories

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designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization.

Thanks,
Julie

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI)
**Sent:** Wednesday, January 29, 2020 1:42 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** RE: Intended use wording

Yes – thank you!

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 1:32 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** RE: Intended use wording

Julie – should I still focus (b) (4)

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Wednesday, January 29, 2020 11:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Intended use wording

Hi Kim,

We agree with the proposed change below. Thank you for proposing it. Would you mind sending all of the intended use language so we can be sure we are using the correct version in our documents?

Thank you all again,
Julie

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 11:08 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** Intended use wording

Julie as discussed on the call:

Current:

(b) (4)

Potential:

(b) (4)

If in the future that were to change and we need and/or we could update the factsheets accordingly via amendment.

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*
Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/25/2020 8:37:29 AM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Got the invite, thanks

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** January 25, 2020 at 8:24:48 AM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Some additional comments attached –

I have set up a call for 2 pm to discuss – hopefully you got the invite – let me know if this time doesn't work and I can move around

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 10:23 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>

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**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Here some additional comments added to Li initial edits.

Signing off now too. Thanks for the quick review.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 9:59 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

My comments to the draft PI (without the performance data) are in the attached.
I am signing off now.
Li

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 8:36 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Great thanks for your quick review.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 8:33 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

I think the data (b) (5) [redacted]

In addition, a (b) (5) [redacted] still need to be conducted.

I will review the draft PI without the performance data and send you all my comments.

Li

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 24, 2020 7:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

I am forwarding our draft Package Insert minus performance data sections for a first look. We will forward the one-pager product information sheet once we have that draft.

I am also forwarding a list of clinical specimens that CDC has tested with the panel so far. (b) (5) [redacted]

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:29 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

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FDA agree with use of "Product Information Sheet" rather than Instructions for Use and do not have any additional comments on the box/vial labels.

Please make sure to submit the developed product information sheet as part of your labeling package with the EUA submission (should include Instructions for use, product information sheet, final box/vial labels) and make sure it includes instructions to the end user for obtaining the full Instructions for Use document.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 5:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

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Sorry with attachment!!

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

BLASTn analysis queries with the 2019-nCoV rRT-PCR assays primers and probes will be performed against public domain nucleotide sequences (more detail regarding parameters are included in the attached document). Database search parameters will follow a strategy to demonstrate the potential for cross-reactivity depending on the target of the design.

1. BLASTn analysis query excluding all coronavirus sequences.

1. BLASTn analysis query including coronaviruses, but excluding human SARS and bat SARS coronaviruses

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

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Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) AND (b) (4) or AND/OR (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

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Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
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gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
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gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases

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are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/25/2020 8:36:04 AM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Kim,
Thanks , 2PM works for me.
Have not seen the invite yet.
Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** January 25, 2020 at 8:24:48 AM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Some additional comments attached –

I have set up a call for 2 pm to discuss – hopefully you got the invite – let me know if this time doesn't work and I can move around

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 10:23 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Here some additional comments added to Li initial edits.

Signing off now too. Thanks for the quick review.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Ph: 301-796-5456
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 9:59 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

My comments to the draft PI (without the performance data) are in the attached.
I am signing off now.
Li

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 8:36 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Great thanks for your quick review.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 8:33 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

I think the data (b) (5) [redacted]

In addition, a(b) (5) [redacted] still need to be conducted.

I will review the draft PI without the performance data and send you all my comments.

Li

---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 24, 2020 7:07 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

I am forwarding our draft Package Insert minus performance data sections for a first look. We will forward the one-pager product information sheet once we have that draft.

I am also forwarding a list of clinical specimens that CDC has tested with the panel so far. (b) (5) [redacted]

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:29 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

AMERICAN OVERSIGHT

FDA agree with use of "Product Information Sheet" rather than Instructions for Use and do not have any additional comments on the box/vial labels.
Please make sure to submit the developed product information sheet as part of your labeling package with the EUA submission (should include Instructions for use, product information sheet, final box/vial labels) and make sure it includes instructions to the end user for obtaining the full Instructions for Use document.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 5:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH)

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<Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Sorry with attachment!!

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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FDA U.S. FOOD & DRUG ADMINISTRATION

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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Kim.Sapsford@fda.hhs.gov






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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

BLASTn analysis queries with the 2019-nCoV rRT-PCR assays primers and probes will be performed against public domain nucleotide sequences (more detail regarding parameters are included in the attached document). Database search parameters will follow a strategy to demonstrate the potential for cross-reactivity depending on the target of the design.

1. BLASTn analysis query excluding all coronavirus sequences.

1. BLASTn analysis query including coronaviruses, but excluding human SARS and bat SARS coronaviruses

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks so much for spending your time on a Saturday to help us out on this!

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Regards,
Steve

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

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Thank you for catching that.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) AND (b) (4) or AND/OR (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

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Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases

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are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/25/2020 3:54:21 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

(b) (5)

[redacted]

Uwe Scherf
See comment provided in Instructions for use document¶

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:51 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Uwe I don't see your edit

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:48 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Here with one additional note. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:44 PM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

See attached – Uwe do you have any additional edits – I can then quickly make a DMD version Li can send back in our follow up email

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:17 PM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Li, you so fast, it is hard to keep up ☺

I added my comment to Li's,

Tamara

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 3:08 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** FW: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

See my comments in the attached.
Li

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Saturday, January 25, 2020 2:59 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Burke, Stephen A (CDC) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

We have a draft of the product information sheet for your review. Please provide comments as soon as you can.

Thanks,
Julie

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:29 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

FDA agree with use of "Product Information Sheet" rather than Instructions for Use and do not have any additional comments on the box/vial labels.
Please make sure to submit the developed product information sheet as part of your labeling package with the EUA submission (should include Instructions for use, product information sheet, final box/vial labels) and make sure it includes instructions to the end user for obtaining the full Instructions for Use document.

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Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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---

**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 5:15 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Thanks for the additional review! I revised the box label to state that there would be a "Product information sheet" rather than Instructions for Use. Will this be acceptable?

Thank you!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:20 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Sorry with attachment!!

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Some very minor edits for consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Thursday, January 23, 2020 1:29 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim and Li,

We are able more information regarding catlog/part numbers on our vial labels and box labels. I think on a previous response from Kim you were satisfied with these labels. We'd like to confirm that before we start printing in our manufacturing process.

Thanks!

Talk to you in just a couple of minutes.

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear Steve,

Great thank you – we will review and discuss.
Please include Li Li (cc'd) on all communications going forward – he will be the Lead Reviewer on your submission
Is there a good tentative time for a follow-up call tomorrow that would work for CDC?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Wednesday, January 22, 2020 11:29 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Subject:** RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Hi Kim,

Based on our discussion yesterday, we've made edits to the current draft for your consideration. In addition we're including an example of the in silico cross-reactivity analysis approach and would appreciate your feedback. The overall strategy would be as follows:

BLASTn analysis queries with the 2019-nCoV rRT-PCR assays primers and probes will be performed against public domain nucleotide sequences (more detail regarding parameters are included in the attached document). Database search parameters will follow a strategy to demonstrate the potential for cross-reactivity depending on the target of the design.

1. BLASTn analysis query excluding all coronavirus sequences.
1. BLASTn analysis query including coronaviruses, but excluding human SARS and bat SARS coronaviruses

Perhaps we can have another call once you've reviewed so that we can discuss further.

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 19, 2020 5:21 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>;

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Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Subject:** EUA Template for CDC 2019-nCoV rRT-PCR - Draft

Dear All,

Please find attached the draft CDC EUA template – I have tried to fill out as much CDC information as possible for you - based on what you have provided me so far. I suggest that we plan to touch base early next week – please let me know if there are times/days when you are not fully booked – we can accommodate on our end – and I will set something up.

Let me know if you have any questions – I will be monitoring email.
Best regards
Kim

Also latest news report: http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 6:17 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks so much for spending your time on a Saturday to help us out on this!

Regards,
Steve

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 5:17:56 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>

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**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear All,

Please find attached some draft fact sheets for patients and HCP. In MERS-CoV we also had a contacts FS (for asymptomatic that had a contact risk) but didn't seem to apply to the 2019-nCoV at this time.

I also made some minor comments to the draft intended use in the attached.

Let me know if you have any questions

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 2:00 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I apologize for the delay, we would like to change to "AND" so that testing is only performed when both S&S and epi risk are met.

Thank you for catching that.

Regards,
Steve

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 1:15 PM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I have one question about the intended use:

Do you want (b) (4) AND (b) (4) or AND/OR (b) (4) Just checking as I work on the fact sheets. The intended use you sent said "and/or"

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Saturday, January 18, 2020 8:49 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks very much Kim! We'll look over your comments and get back to you with any questions.

Thanks again for your support!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*

AMERICAN OVERSIGHT

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, January 18, 2020 8:45 AM
**To:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Dear Steve, Steve, and Julie

I wanted to provide comments back on the evaluation you provided for your consideration – since you indicated you were going to be working on the validation this weekend. Please see the attached – let me know if you have any questions, what your thoughts are….I will be online all weekend.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Sent:** Friday, January 17, 2020 4:50 PM

AMERICAN OVERSIGHT

**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

I am forwarding two documents with the preliminary information spoken about this afternoon in regard to labels, proposed intended use, device description, and draft performance evaluation plan.

Thanks so much for the help!

Regards,
Steve

**Steve Burke, Ph.D., RAC**
*Program Manager*
*CDC Influenza Division (Battelle Contractor)*
Office: 404-639-4915
gky2@cdc.gov

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Friday, January 17, 2020 4:36 PM
**To:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Cc:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Burke, Stephen A. (CDC/DDID/NCIRD/ID) (CTR) <gky2@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Hi Kim,

To begin, we plan to use the Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software and the QIAGEN EZ1 DSP Virus Kit and Buffer AVL (for off-board lysis) using both manual extraction and the QIAGEN EZ1 Advanced XL (Nucleic Acid Purification System). If the situation escalates, we will add other automated nucleic acid extraction chemistries.

I'll be online this weekend as well so don't hesitate to reach out.

Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 4:29 PM

AMERICAN OVERSIGHT

**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

I know right - have a good weekend, if you need anything let me know - I will be monitoring email and working on documents.

It would be helpful to know what extraction methods and PCR instruments CDC will be claiming with the EUA.

Best regards
Kim

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Date:** January 17, 2020 at 4:20:43 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Thanks Kim – it's never boring, is it?

Happy weekend,
Julie

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 17, 2020 1:59 PM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Roth, Kristian (FDA/CDRH) <Kristian.Roth@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Update from Wuhan Municipal Health and Health Committee - 4 new cases added

Couple of reports we have been following:

- https://www.todayonline.com/singapore/wuhan-virus-suspected-cases-singapore-go-5-moh-warns-more-come
Take w/ grain of salt.

- http://outbreaknewstoday.com/novel-coronavirus-thailand-reports-2nd-confirmed-case-60660/
I guess there was a second Thai case

- Translated w/Google translate - http://wjw.wuhan.gov.cn/front/web/showDetail/2020011809064
At 04:00 on January 16, 2020, 3 patients were discharged from the hospital and no new deaths were reported. After comprehensive research and judgment on the clinical manifestations, epidemiological history, and laboratory test results of the national, provincial and municipal expert groups, 4 new cases of pneumonitis infected with new coronavirus have been added in our city. At present, the new cases have been arranged for transfer to Wuhan All cases were treated at Jinyintan Hospital. All the patients were in stable condition without critical illness. The time of onset of the cases was concentrated from January 5th to 8th. Related epidemiological investigations and search of close contacts were underway. In addition, Thailand and Japan each reported a case of pneumonia with a new coronavirus infection from Wuhan. Currently, Thai diagnosed cases are being hospitalized; Japanese diagnosed cases have been discharged. Close contacts in the country are conducting follow-up and medical observations. As of now, 45 cases of pneumonitis with new-type coronavirus infection have been reported in our city, 15 cases have been cured and discharged, 5 cases are being treated in severe cases, and 2 cases have died. A total of 763 close contacts have been tracked, 665 medical observations have been lifted, and 98 people are still receiving medical observations. Among the close contacts, no related cases were found.

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- Also Hong Kong protocol: Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (pdf)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/7/2020 7:50:41 PM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**Subject**: RE: 2019 nCoV DMD EUA MCM Hours_01-22-2020.xlsx

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Friday, February 7, 2020 5:41 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: 2019 nCoV DMD EUA MCM Hours_01-22-2020.xlsx

Li:

| |
|---|
| 1/1/20 - 2/1/20 = 46 |
| 2/2/20 - 2/8/20 = 23 |

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 07, 2020 5:02 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: 2019 nCoV DMD EUA MCM Hours_01-22-2020.xlsx

Kim, LI, and Tamara,

Could you please fill in the number of our you worked on nCoV for the following time periods:

| |
|---|
| 1/1/20 - 2/1/20 = 110 |
| 2/2/20 - 2/8/20 = 43.25 |

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/7/2020 7:44:12 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Call this morning at 9 AM

Yes, please set up the 11 and 3 PM call, I will call in into the 9 AM call. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, February 7, 2020 7:11 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Call this morning at 9 AM

Hi Uwe –

I won't be on that call this morning (might also miss the Ebola/Coronavirus), I'm going to Ali's school this morning for a poetry slam. So if you can call in that would be good. They are a bit disorganized at the moment – I can call into the 4 pm one. But I can call in at 11 am and 3 pm to chat with CDC if you want me to – do you want me to set up the calls.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 07, 2020 6:56 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Call this morning at 9 AM

Kim,

Just to check, I know you are planning to have time today for your home. Are you planning to call in at 9 AM this morning to the 2019 nCoV IMG Morning Shift Brief

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/10/2020 7:55:17 AM
**To**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]
**CC**: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]
**Subject**: RE: 2/10/20 6 AM update

Julia, sure I will. Uwe

---

**From:** Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 7:38 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** RE: 2/10/20 6 AM update

Please also cc Suzanne and Linda with the daily updates Jeff requested you send.
Thank you!

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 10, 2020 at 6:34:12 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/10/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/10/20 6 AM update

**Status of activities on diagnostics**:

- Issue with rapid verification and implementation of CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel in handful of public health labs:
  - CDC informed FDA yesterday afternoon that (b)(4) has been notified that some laboratories have observed performance issues during verification testing, particularly with the N3 part of the assay showing sporadic aberrant reactivity in the negative controls. CDC is aware of these reports and is investigating.
  - Conference call with CDC has been scheduled for today 2 PM to discuss the issue and any investigation so far.

**New roadblocks/challenges/delays:**

- Delay of verification and implementation of CDC's nCoV assay is some public health labs. DMD will determine specific numbers and any CDC investigations at conference call Monday at 2 PM.

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**Enclosed also the compiled activities over the weekend which have been previously communicated:**

**Status of activities on diagnostics previously reported for 2/8/20 @ 2/9/20**:

- A total of 41 IVD Developers have requested and received EUA review template, additional requests (2) are pending clarification about the device technology.
- Conference call with CDC: CDC intends to add (b)(5) automated extraction methods to their EUA ((b)(4) Roche MagNA Pure 24), to support larger number of State Public Health labs who are only using these instruments. DMD/CDC agreed on (b)(5) . CDC expects to submit amendment in next 2 weeks.
- On 2/6/20 CDC started shipping CDC's 2019-nCoV PCR assay (b)(5) public health labs that are strategically located in US and to other public health labs in states with confirmed cases.
- CDC via their IRR (International Reagent Resource) is accepting orders for CDC's 2019-nCoV tests from qualified laboratories.
  - This includes (b)(4) qualified U.S. laboratories [state & local public health labs and (b)(4) labs]
  - (b)(4) qualified international labs, such as the (b)(4) laboratories.
  - CDC test will not be available in U.S. hospitals or other primary care settings.
- (b) (5)

- Phone call scheduled with FDA/BARDA/CDC on Monday to address issues regarding timeline for virus inactivation and availability of (b)(5) for commercial developers.

- CDRH was contacted by small app developer who intends to create a nCoV screening app for lay users and physicians to identify individuals who may have been infected with the 2019 nCoV. The intended output under consideration is a risk status with recommendation for prevention education, **self-quarantine**, self-care, online medical consultation, or **if high risk recommendation for a laboratory or hospital visit**.
  - Delicate intended use from the public health perspective in an outbreak situation
  - DMD is following up on actions taken towards apps during the Zika outbreak
  - DMD will contact app developer to get further information and clarification on the ap

**New roadblocks/challenges/delays:**

- For commercial developers: (b)(5)
  - Issues will be addressed during FDA/BARDA/CDC call scheduled for Monday
  - (b)(5)

Uwe

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**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 5:39:08 PM
**To**: merey.can@dpa.com
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic

https://www.fda.gov/news-events/press-announcements/fda-takes-significant-step-coronavirus-response-efforts-issues-emergency-use-authorization-first

Hallo Can,

Hier FDAs press release ueber das novel corona virus (2019-nCoV). Uwe

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 2:02:57 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]
**Subject**: RE: Meeting Today on Coronavirus - DMD just send the CDC EUA package to OCET & OCC for final FDA clearance

Jeff,

DMD just send the CDC EUA package to OCET & OCC for final FDA clearance.

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 9:44 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** Meeting Today on Coronavirus

Uwe, ARC,

I have a meeting at 3 PM today on coronavirus. Can you each (Uwe and ARC) give me an update early this afternoon before the meeting on the status of the EUA and of possible shortages respectively? The Administration's focus is starting to turn to the latter so expect requests for frequent updates from several parties.

Thank you.

Jeff

**Jeffrey Shuren, MD, JD**
*Director*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Email: jeff.shuren@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/4/2020 8:38:18 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject**: RE: Review CDC EUA Package this morning

Thanks, great, we are considering this cleared by the division.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 8:29 AM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Review CDC EUA Package this morning

I had no edits Li – looks good

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 8:21 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Review CDC EUA Package this morning

The memo looks great. I added only a couple of minor formatting edits to Li's document.

Tamara

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 8:04 AM

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**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Review CDC EUA Package this morning

The redlined version of the converted EUA review template, the FDA EUA Review Memorandum, is attached for your review and concurrence. I will finalize the document once you give a go ahead.
Li

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 7:52 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Review CDC EUA Package this morning

Dear Li,

I don't think we have a title, so if you have something you have used in the past that would be great.

Please add this final example conclusion, feel free to edit at the end, and Sign

**Final Conclusions for Interactive Review -** (b)(5) [redacted]

Thanks very much Li

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 7:43 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Review CDC EUA Package this morning

What is the title of the lead memo? Do I sign it at the end?
Li

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 7:42 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Review CDC EUA Package this morning

Li – once you have reviewed the template can you convert it to your Lead memo – we send the lead memo up to OCET/OCC (mainly as an FYI).
Note the template is our document now and doesn't need to go back to CDC with any changes
Any changes to the labeling – we need their concurrence/revised version to send up to OCET/OCC

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Tuesday, February 04, 2020 7:28 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** Review CDC EUA Package this morning

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Hi all,

I will review the template, PI, Product Information Sheet, and verification requirements first.

Thanks,
Li

**Li Li**
Scientific Reviewer
DMD: Division of Microbiology Devices | OHT7: Office of In vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3116 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 762-6200 | Fax: (301) 847-8512
li.li2@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/5/2020 9:17:51 AM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: FW: nCoV EUA review request
**Attachments**: (1) EUA Review Template_NAT_Novel Coronavirus 1.19.2020NNM.doc; EUAcover_2020-02-05-10-06-55.pdf

Li,

This is the one that just came in. Uwe

**From:** Navin Nauth-Misir <navin.nauth-misir@novacyt.com>
**Sent:** Wednesday, February 5, 2020 5:12 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** nCoV EUA review request

Please find attached a copy of

cover letter and

EUA template completed as far as we are able at this stage,

Hard copies have been sent

I look forward to your feedback

Navin Nauth-Misir
Group RA QA Director
navin.nauth-misir@novacyt.com

Novacyt Group
www.novacyt.com

Mobile: (b)(6)

Unit 1, Watchmoor Point, Camberley, Surrey, GU15 3AD, UK

Disclaimer. The information contained in this communication from navin.nauth-misir@novacyt.com is confidential and may be legally privileged. It is intended solely for use by the authorised receiver. If you are not the authorised receiver you are hereby notified that any disclosure, copying, distribution or taking action in reliance of the contents of this information is strictly prohibited and may be unlawful.

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# EMERGENCY USE AUTHORIZATION (EUA)

## EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (2019-nCoV)

## GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow *[Text]* should be completed by the IVD developer (sponsor) as applicable to their specific test. Text in **bold** outlines the Food and Drug Administration (FDA) suggestions and clarifications for the sponsors' consideration when completing the required information in a specific section.

- This is a EUA interactive review template for Pre-EUA/EUA submissions concerning molecular-based single target tests for detection of 2019 Novel Coronavirus (2019-nCoV), Wuhan, China. If you are developing a multiplex molecular-based assay for the detection and differentiation of nucleic acids from a panel of microorganisms, please review Appendix A for FDA recommendations.

- This is a EUA interactive review template for Pre-EUA/EUA submissions and not a guidance document. The template is subject to change as we learn more about the 2019-nCoV disease and its risk-benefit profile. Recipients will receive notice and updated templates as they become available.

- This EUA interactive review template is an FDA internal document and any proprietary information provided within the template and during the interactive review process will remain confidential as it does in a regular FDA premarket submission.

- Feedback provided by FDA during the interactive review of your pre-EUA/EUA is subject to change as we learn more about the 2019-nCoV disease and the risk-benefit profile evolves to address unmet public health needs.

- Prior to a potential authorization FDA will require developers of molecular-based tests to assess traceability of their test to an FDA-recommended reference material panel if available at the time. Specific details about the traceability study and the FDA-recommended reference material panel will be provided by the Lead Reviewer assigned to the Pre-EUA submission once the analytical and clinical evaluation data has been reviewed and found to be acceptable.

- Please be reminded that tests for the detection of 2019-nCoV or 2019-nCoV infection must not be distributed and/or used for clinical diagnoses without premarket clearance, approval, or EUA by the FDA. Clinical samples for 2019-nCoV testing should be sent to the appropriate public health laboratories until the IVD device subject of this Pre-EUA submission has received authorization from the FDA.

- Clinical specimens may be required to support the EUA request. Furthermore, please note that applicable regulations for human subject protection do apply under the

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EUA. Please refer to the Clinical Evaluation section of this document for more details.

- If authorized, the EUA means that this 2019-nCoV IVD is temporarily authorized for use until the public health emergency is terminated or the EUA is revoked by the FDA.

    - FDA recommends that you consider registration and listing your EUA product once you have been issued an EUA. If this is problematic, please notify the Agency during your Pre-EUA.
    - The EUA is not a pathway to permanent marketing of your device. Therefore, we strongly recommend that you consider, in addition to an EUA, a traditional premarket submission for your IVD so that your device can still be legally marketed after termination of the emergency declaration. We recommend that you identify as soon as possible in the Pre-EUA review process any consideration of moving your product forward towards De Novo/510(k) clearance. If so some of our feedback to you may take such a long-term goal into consideration in order to prevent additional testing where it may not be needed. Therefore, please consider submitting a Pre-Submission to inquire what studies would be required for a premarket approval/ clearance of your 2019-nCoV IVD. Details on how to submit a Pre-Submission to the Agency are outlined in the FDA guidance document: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.* [ HYPERLINK "https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program" ]

## A. EXECUTIVE SUMMARY (as of 3rd February 2020)

Primer Design, a Novacyt Group company, is developing a molecular diagnostic assay for detection of the novel coronavirus 2019-nCoV originating in Wuhan, China. Primer Design are asking FDA to consider Emergency Use Authorization of this assay.

## B. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the 2019 nCoV virus to diagnostic laboratories for the *in vitro* qualitative detection of RNA from the 2019-nCoV in high quality nucleic acid extract from the following specimen types, e.g., nasopharyngeal/oropharyngeal swabs,from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated with 2019-nCoV infection) and CDC novel coronavirus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated) to aid in the diagnosis of 2019-nCoV infection.

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## C. MEASURAND

Specific nucleic acid sequences from the genome of the 2019-nCoV: RNA dependent DNA (b)(4)

## D. APPLICANT

Primer Design Ltd
Unit 1, Watchmoor Point, Camberley, Surrey, GU15 3AD, UK
[ HYPERLINK "https://eur02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fnovacyt.com%2F&data=02%7C01%7Ctanya.stuchinskaya%40novacyt.com%7C08e2d1222a2c47c731ed08d7a57532a7%7C7f86b855a6074882a2cf7ae773bd7869%7C0%7C0%7C637159795081843040&sdata=92om44HY0RDGKqx%2FlUyzI7DbKuXLJqxyq5zYQ5svocs%3D&reserved=0" ]

Contact:
Navin Nauth-Misir
Group RA QA Director
[ HYPERLINK "mailto:navin.nauth-misir@novacyt.com%20" ]
*Mobile:* (b)(6)

## E. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name – Primerdesign 2019- nCoV
Established Name - 2019- nCoV

## F. REGULATORY INFORMATION

***Approval/Clearance Status:***

The Primerdesign 2019- nCoV test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

***Product Code:***

[XXX – FDA will complete]

## G. PROPOSED INTENDED USE

***1) Intended Use:***

**The proposed IU will be finalized based on the data and recommendations from Public Health authorities at the time of authorization – example text is provided below for a qualitative molecular test that detects organism RNA but may be adapted according to the specific emergency situation addressed by the device.**

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NOVACYT
GROUP

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**3rd February 2020**

**ATTN:** Division Director: Dr. Uwe Scherf, OHT7-OIR/OPEQ/CDRH/FDA

**RE:** Request for Pre-Emergency Use Authorization (Pre-EUA) of the Primerdesign 2019-nCoV

**Dear Dr. Scherf,**

Primer Design Ltd is submitting a Pre-Emergency Use (Pre-EUA) for the Primerdesign 2019-nCoV so we can obtain feedback from FDA concerning the studies and/or testing outlined in our Pre-Emergency Use Authorization (Pre-EUA) submission package.

The Primerdesign 2109-nCoV is a qRT-PCR assay designed for the *in vitro* qualitative detection of RNA from the 2019-nCoV in high quality nucleic acid extract from respiratory specimens, e.g., nasopharyngeal/oropharyngeal swabs, from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated with 2019-nCoV infection) and CDC novel coronavirus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated) to aid in the diagnosis of 2019-nCoV infection.

Attached to this letter is the first draft of our device EUA Interactive Review Template for FDA review as a Pre-EUA. One hard copy of the signed EUA Cover Letter and one electronic copy are enclosed. Also, these documents have been sent to you via email.

In case you should have any questions regarding the information provided and/or need additional information/data from us please contact me immediately either via email navin.nauth-misir@novacyt.com or phone +44 (0)7590 689939.

Sincerely,

Navin Nauth-Misir

Group RA QA Director

navin.nauth-misir@novacyt.com

Novacyt S.A.
Unit 1, Watchmoor Point
Camberley, Surrey
GU15 3AD
www.novacyt.com

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/1/2020 4:39:36 PM
**To**: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Potential diagnostic EUA for coronavirus PR
**Attachments**: EUA20000x CDC HCP FS Draft_01312020.CMS.docx; EUA20000x CDC Patient FS Draft_01312020.no CMS comments.docx

Megan,

Thanks, attached the fact sheets to help drafting the press release.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 4:25 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Fwd: Potential diagnostic EUA for coronavirus PR

Is there a number where I can give you a call?

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 1, 2020 at 4:09:14 PM EST
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Stark, Angela <Angela.Stark@fda.hhs.gov>, Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

Megan,

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We just got word from CDC that they are possibly submitting their EUA package tonight or some time tomorrow. If the data look good the review division will be able to get the package towards FDA clearance the same day.

What information do you need to update and finalize the press release?

Sorry for this super short notice, everything is moving super-fast.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Scherf, Uwe
**Sent:** Friday, January 31, 2020 1:48 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

Megan,

Attached please find the intended use of the CDC assay. Could you please update the draft based on this information.

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel

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Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 9:27 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
**Subject:** Potential diagnostic EUA for coronavirus PR

Hi all – I've pulled together a very rough draft of a press release re: a potential EUA for a CDC diagnostic. Do you have an update on the timing? And is there any information on the kind of test it is that you can share so that I can start filling in some of the blanks or XXs in the attached draft? Thank you!

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/30/2020 7:13:16 PM
**To**: John Tamerius [jtamerius@quidel.com]
**Subject**: Re: request for quick call

What is your number

---

**From:** John Tamerius <jtamerius@quidel.com>
**Date:** January 30, 2020 at 7:12:28 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: request for quick call

Sure. Sorry so late

Sent from my iPhone

On Jan 30, 2020, at 4:10 PM, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov> wrote:

John, can I call you now?
Uwe

---

**From:** John Tamerius <jtamerius@quidel.com>
**Date:** January 30, 2020 at 6:39:18 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** request for quick call

Hi Uve. Hope all is well over there on the east coast.

I finally had a 3 minute call with my boss (Doug Bryant, CEO at Quidel) and he asked me to explore one thing with you about pursuing an EUA for the novel Coronavirus that emerged in China. Can you spare 5 minutes any time soon? I know you must be overwhelmed, if not with this, then 100 other things.

Best wishes. john

PS: If you prefer, I could call Dr. Kim Sapsford-Medinitz, but my boss asked me to call you! Forgive me for that. ☺

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please notify the sender immediately and delete the message completely from your computer system. Thank you.

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/28/2020 12:32:52 PM
**To**: Sally A Hojvat [(b) (6)]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: WHO EPI-WIN Update on 2019-NCoV - 27.01.2020 and questions about developing tests for the virus

Sally,

Yes, IVD companies should contact CDRH-EUA-Templates@fda.hhs.gov. to receive the review template. It is ready to go and describes the studies. If you talk to any company please emphasize that they should work with us on some of the details regarding LoD and clinical evaluation. Alternative options are considered (in discussion with FDA) depending on availability of materials at the time of validation studies.

The link leads directly to us, and we make the introduction form the Division level, with the review template and a submission letter template.

Government agencies are all working hard to make specimens or a panel available, but nothing concret has emerged yet.

Look forward to see you on Monday, actually would like to chat on the phone with you about the last session sometime later this week or over the weekend.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sally A Hojvat <(b) (6)>
**Sent:** Tuesday, January 28, 2020 10:10 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Sally A. Hojvat (b) (6)
**Subject:** Fwd: WHO EPI-WIN Update on 2019-NCoV - 27.01.2020 and questions about developing tests for the virus
**Importance:** High

Hello Uwe,

Attached is what WHO are distributing to update countries on the status of the 2019-NCoV outbreak.
Was asked to pass this information on to the appropriate individuals at FDA by my contacts at WHO.
You are probably getting this through other channels but sending it in case you are not.

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I am beginning to get enquiries from IVD developers who are planning to make tests for the 2019 -NCoV virus and, I see that CDC are distributing primers and probes for molecular tests and information on how to run their version of a test , but have not seen a Declaration of Emergency from HHS published yet.

However, it looks as though this may be in the works, as FDA's website (below) indicates an IVD company to contact CDRH-EUA-Templates@fda.hhs.gov.

Is that a correct assumption?

Is that link leading them to someone in DMD who will send a template for either a molecular or serological test or how are you getting info. out to developers and who should they contact?

Also the fact that this already seems widespread may mean that FDA/CDC/NIH are not planning to make specimens or a panel available.

Correct or not?

Best regards and see you on Monday,

Sally

"Being able to quickly and accurately diagnose patients infected with the novel coronavirus is an essential step in helping patients identify the need for care and mitigate the spread of the virus to additional individuals. Currently, there are no commercially available products that are authorized to detect novel coronavirus; however, the FDA is actively working to facilitate the development and availability of diagnostics that can detect this virus. The agency is working with public health partners to advance and share the reference materials necessary to facilitate diagnostic development.

The FDA is also requesting that diagnostic test sponsors interested in potential EUA for tests to detect 2019-nCoV contact CDRH-EUA-Templates@fda.hhs.gov for further information and templates."

Begin forwarded message:

**From:** Sadia Shakoor <sadia.shakoor@aku.edu>
**Subject: Fw: EPI-WIN Update on 2019-NCoV - 27.01.2020**
**Date:** January 28, 2020 at 4:33:07 AM EST
**To:** Undisclosed recipients:;

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/3/2020 11:04:24 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Mair, Michael (Michael.Mair@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Michael.Mair]
**CC**: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Caliguiri, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b585f5da7b2449cb5721a870d4db281-HHS-Laura.C]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Urgent - CDC EUA package received

**Importance**: High

Jeff, Denise, Anna, Tim, and Michael,

AMERICAN OVERSIGHT

CDC just submitted their EUA package to request authorization for their 2019-Novel Coronavirus (2019-nCoV) assay. DMD staff has reviewed most of the data package already and will finish the review of the outstanding data as expeditiously as possible. I want to provide a clear update on how long that process could take and next steps once we have completed our review.

(b)(5) [redacted] We have been closely coordinating with OMA and they already have drafted a press release so that we are ready to make an announcement if an EUA can be issued tomorrow.
I will keep this group updated.

Thank you all in advance for your patience and help.

Best,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/31/2020 4:54:06 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: CDC

Ellen,

Yes, I am working on this now. Uwe

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 4:10 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** CDC
**Importance:** High

Hi Uwe,

Would you please respond to Anita Patel's email from last night, copying all on that email and adding me to the cc line, with the OCC-cleared text below.

Thanks,
Ellen

FDA and CDC have been working interactively together on CDC's request for an Emergency Use Authorization (EUA) for its 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens. At this time, there is no *in vitro* diagnostic test approved, cleared or authorized for such use.

On January 30th, CDC notified FDA that it would like to distribute the test to certain laboratories so that they can use the test prior to issuance of an EUA. This would help to address the significant public health concerns raised by the infectious disease at this early stage, and may help to prevent the spread of the infectious disease by addressing the high testing demands currently being faced by CDC.

We understand that CDC would like to distribute the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit, and any components, to laboratories designated by CDC as qualified and, in the United States, such laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. We also understand that CDC will ask each of the state laboratories to send positive samples and (b) (5) negative samples to CDC for further validation testing.

Based on our understanding of the facts and the public health concerns at issue here – specifically, that there is currently no other test available to respond to this emergency and that CDC is actively pursuing EUA authorization – at this time, FDA does not intend to object to the distribution and use of this test as described above. We ask that you please send the name and address of the specific laboratory(ies) that will be performing testing to the FDA/CDRH MCM Team Lead, Kim Sapsford (Kim.Sapsford@fda.hhs.gov) and the Director of the Division of Microbiology Devices, Uwe Scherf (Uwe.Scherf@fda.hhs.gov).

AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/26/2020 11:52:42 AM
**To**: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Birnkrant, Debra B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e740904c9042a0b99c6ddc16550b08-BIRNKRANT]; Styrt, Barbara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=458d7290e25347c2801b8214b89d81fa-STYRTB]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: NSC talking points

Michael,

CDRH is also ok, with the current wording for diagnostics. Thanks for adding the extra point Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 11:48 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** RE: NSC talking points

Hi – I incorporated what I have received so far – made a few tweaks – let me know if u have anything additional.

From BARDA - (b) (5)

AMERICAN OVERSIGHT

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 11:31 AM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** RE: NSC talking points

Suggested edits from DMD

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 10:24 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** FW: NSC talking points

Hi. In prep for the NSC meeting on 2019-nCoV MCM development , whenever it is, BARDA send over some "basic talking points we can use going up the chain."

I took a stab at edits - would appreciate any edits you have. Thx - m

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 2/1/2020 4:27:41 PM
**To:** McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

(b) (6)

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 4:25 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Fwd: Potential diagnostic EUA for coronavirus PR

Is there a number where I can give you a call?

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 1, 2020 at 4:09:14 PM EST
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Stark, Angela <Angela.Stark@fda.hhs.gov>, Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

Megan,

We just got word from CDC that they are possibly submitting their EUA package tonight or some time tomorrow. If the data look good the review division will be able to get the package towards FDA clearance the same day.

What information do you need to update and finalize the press release?

Sorry for this super short notice, everything is moving super-fast.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Scherf, Uwe
**Sent:** Friday, January 31, 2020 1:48 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

Megan,

Attached please find the intended use of the CDC assay. Could you please update the draft based on this information.

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 9:27 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
**Subject:** Potential diagnostic EUA for coronavirus PR

Hi all – I've pulled together a very rough draft of a press release re: a potential EUA for a CDC diagnostic. Do you have an update on the timing? And is there any information on the kind of test it is that you can share so that I can start filling in some of the blanks or XXs in the attached draft? Thank you!

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/23/2020 3:53:10 PM
**To**: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Congrats to DMD Novel Coronavirus Team

Thanks, very much appreciate!

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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uwe.scherf@fda.hhs.gov

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---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 3:13 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Congrats to DMD Novel Coronavirus Team

It's true!

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 3:12 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Congrats to DMD Novel Coronavirus Team

Thank you for this…….

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

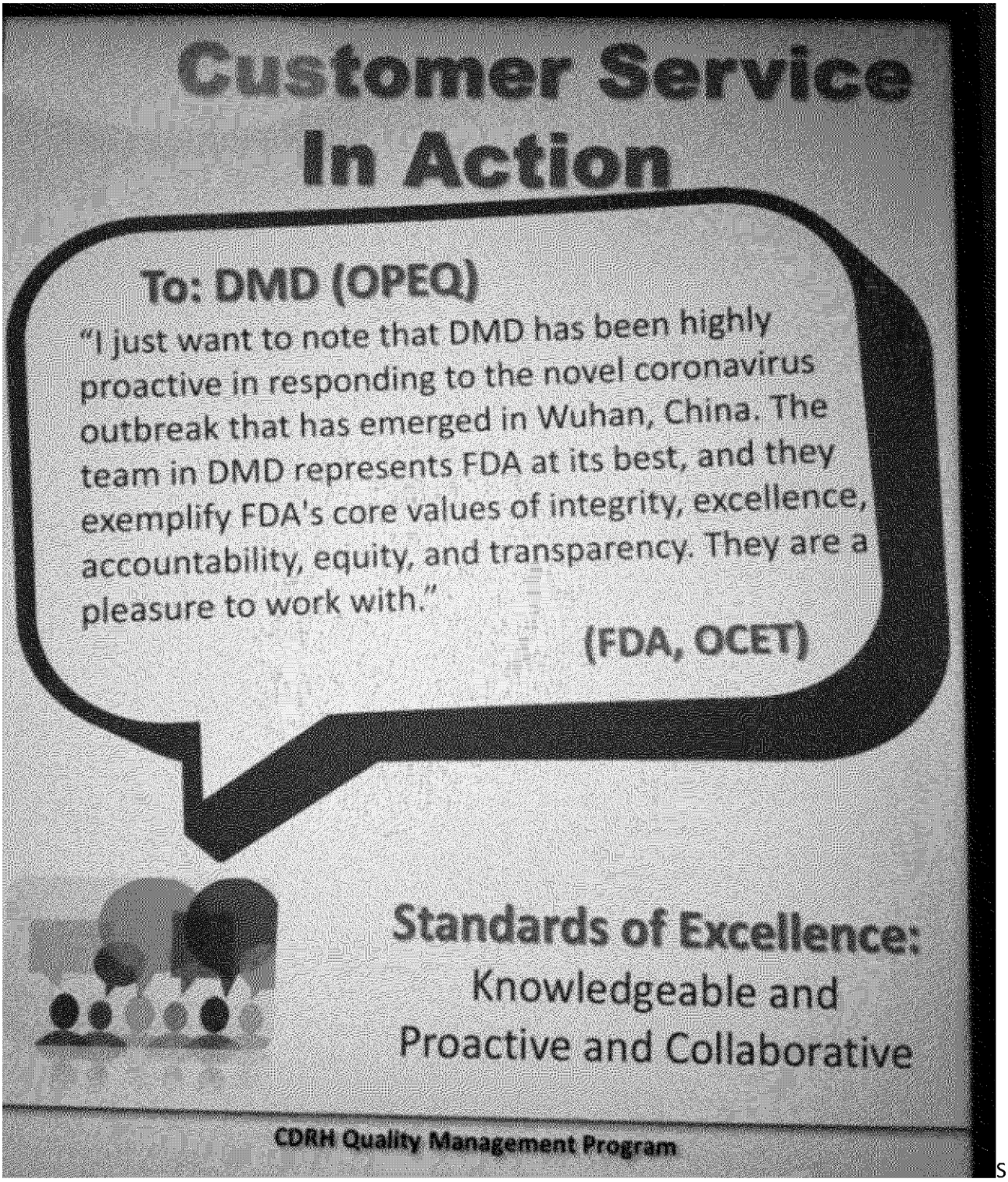
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U.S. FOOD & DRUG ADMINISTRATION

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**From:** Shea, Yvonne <Yvonne.Shea@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 1:19 PM
**To:** CDRH-OIR-IVD-DMD <CDRH-OIR-IVD-DMD@fda.hhs.gov>
**Subject:** Congrats to DMD Novel Coronavirus Team

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Shea, Yvonne <Yvonne.Shea@fda.hhs.gov>
**Subject:** Dmd

Sent from my Verizon, Samsung Galaxy smartphone

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/31/2020 4:47:18 PM
**To:** John Tamerius [jtamerius@quidel.com]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: Follow-up for EUA for nCoV

John,

Thanks you for the messages. I discussed the information you provided with my team. Based on what you described we encourage you to submit your data via the pre-EUA. To my knowledge you already received the template. Thank you for reaching out to us. WE also heard BEI might be the organization to contact to obtain virus.

Please let me know if you have any questions.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** John Tamerius <jtamerius@quidel.com>
**Sent:** Friday, January 31, 2020 3:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Follow-up for EUA for nCoV

Hi Uwe. I hope you got my email last night. I do have a bit of additional information:

(b) (4)

[redacted]

Best regards, John

---

**From:** John Tamerius
**Sent:** Thursday, January 30, 2020 5:22 PM

AMERICAN OVERSIGHT

**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Follow-up for EUA for nCoV

Hi again Uwe. Thank you so much for calling me last night and on such short notice. Here is information that I hope is helpful to you:

(b) (4)

Uwe, if I get more information tonight or tomorrow, I will send it to you. Please let me thank you again for your call to me earlier this evening.

Best regards, John

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/28/2020 12:11:41 PM
**To:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: 2019-nCov

Thanks, very helpful. Uwe

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 11:59 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: 2019-nCov

FYI, from Mary

---

**From:** Virginia Department of Health <vdh@public.govdelivery.com>
**Sent:** Tuesday, January 28, 2020 11:03 AM
**To:** Barcus, Mary <Mary.Barcus@fda.hhs.gov>
**Subject:** 2019-nCov

# *COMMONWEALTH of VIRGINIA*

## *Department of Health*

## 2019-nCoV

January 28, 2020

Dear Colleague,

The novel coronavirus (2019-nCoV) outbreak that began in Wuhan City, China continues to rapidly evolve. The Centers for Disease Control and Prevention (CDC) considers the immediate risk of 2019-nCoV infection to the American public to be low based on available information. On January 27, CDC raised the travel advisory for China to the highest level, Level 3 (Avoid Nonessential Travel). CDC recommends that travelers avoid all nonessential travel to China.

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Chinese health officials have reported more than two thousand infections with 2019-nCoV. Additional cases have been identified in an increasing number of countries. In the United States, five cases have been confirmed in four states (WA, IL, CA, AZ) as of January 27 at 5:00 PM. The number of confirmed cases will likely increase in the coming weeks.

On January 26, we announced three Patients Under Investigation (PUI) in the central (2) and northern (1) health planning regions of Virginia. A PUI is an individual who meets both clinical and epidemiologic criteria for 2019-nCoV. Two of the three PUIs have since tested negative and are not cases. As of January 27, there are no confirmed cases of 2019-nCoV in Virginia.

Symptoms have included fever, cough and shortness of breath. Based on what we know about other coronaviruses, symptoms may appear anywhere from two to 14 days after exposure. The severity has ranged from mild to severe, including some deaths. Based on preliminary information, older adults with underlying health conditions might be at increased risk of severe disease. Person-to-person spread of 2019-nCoV is occurring in China. It is unclear how easily or sustainably this virus is spreading between people. Investigations are ongoing to learn more and we expect clinical guidance to be revised. On January 17, 2020, CDC issued updated interim guidance to assist U.S. healthcare providers in the identification, evaluation, and reporting of a PUI for 2019-nCoV infection. Clinicians are advised to do the following:

1. Check the VDH Novel Coronavirus Webpage for the most up-to-date guidance.
2. Obtain a detailed travel history for patients with fever or acute respiratory illness.
3. If a patient meets the criteria of a PUI:

- Ask the patient to wear a surgical mask as soon as the PUI is identified.
- Evaluate the patient in a private room with the door closed, ideally in an airborne infection isolation room if available.
- Use standard, contact and airborne precautions, and eye protection (e.g., goggles or face shield).
- Immediately notify infection control personnel and your local health department.

The Virginia Department of Health will consult with CDC and Virginia's Division of Consolidated Laboratory Services (DCLS) about testing.

- Currently, 2019-nCoV testing is only available at CDC. Three specimen types (lower respiratory tract, upper respiratory tract, and serum specimens) are recommended for testing. If possible, more specimens (e.g., stool, urine) should be collected and stored until CDC determines if these should be tested.
- For biosafety reasons, virus isolation in cell culture or initial characterization of viral agents recovered in cultures of specimens from a PUI is not recommended.
- DCLS guidance regarding biosafety precautions, specimen collection and submission, and testing is available on the VDH Novel Coronavirus Webpage.

Emergency Medical Services (EMS) staff are advised to do the following:

1. Obtain a detailed travel history for patients with fever or acute respiratory illness.
2. EMS providers who believe a patient is a PUI should place a surgical mask on the patient as soon as possible. EMS providers should utilize standard precautions, contact precautions, airborne precautions, and use eye protection (e.g., goggles or a face shield) when treating and transporting the patient.
3. Transport of PUIs should be to the closest appropriate facility with an airborne infection isolation room, if possible. Hospitals should be notified before arrival that the patient is a PUI. After the transport is complete, decontaminate the ambulance work surfaces and equipment with an EPA-registered virucidal hospital disinfectant and follow the manufacturer's recommendations for use-dilution (i.e., concentration), contact time, and care in handling.

For more information on this evolving situation, please visit the VDH Novel Coronavirus Webpage and the CDC Novel Coronavirus 2019 website. These webpages will be updated as new information becomes available.

Sincerely,

M. Norman Oliver, MD, MA

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State Health Commissioner

A version of this letter is available on the VDH Resources for Health Care Professionals web page.

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VDH VIRGINIA DEPARTMENT OF HEALTH

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/24/2020 8:58:28 AM
**To**: Dowtin, Lesa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a58cf27088244caa863aa4f57a9b11ad-LXV]; Draper, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4b05cc2fa5f4ed3b3ffc6cf62039d06-Jennifer.Dr]; Colleli, Karen M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15e75ece7b6a4fe6ab09e06fa646798b-KMC]
**CC**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Montgomery, Daniel R [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6aa38c2edd0944d0b67f1b823985090a-DRM4]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]
**Subject**: RE: Request for overtime pay
**Attachments**: ucm030757_DMD_nCoV_AM.pdf

Lesa,

Thanks, attached the updated form for Anna Mielech. She is title 42 with a salary equivalent to a GS12/7 grade.

Thanks for your help.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 7:58 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Cc:** Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Colleli, Karen M <Karen.Colleli@fda.hhs.gov>; Draper, Jennifer <Jennifer.Draper@fda.hhs.gov>
**Subject:** FW: Request for overtime pay

Hi Bill,

Yes, Title 42 Appointees may earn OT since they do not receive Market Pay. However, it would depend on their current salary and that would determine the # of hours they could actually work.

Uwe,

AMERICAN OVERSIGHT

Please send your signed request to Jennifer Draper or Karen Colleli and they will verify the employee's eligibility.

Thanks

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:46 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Uwe,
I am not sure that we can authorize individuals under Title 42 for OT. I have removed Anna Mielech and authorized all others on the form attached. If we get the OK for Anna, we can complete another form or add her back.

Lesa and/or Daniel, can we authorize OT for Title 42?

Bill

**William H. Maisel, MD, MPH**
*Director, Office of Product Evaluation and Quality*
*CDRH Chief Medical Officer*

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-5550
william.maisel@fda.hhs.gov




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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:42 PM
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Dear Bill,

Attached please find the updated request form with the Grade and Step information. Only one individual Anna Mielech is a staff fellow under title 42 and she does not have this information.

Uwe

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**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov
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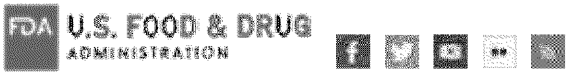
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**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:18 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Uwe,
I am supportive of OT pay and would be happy to authorize. Before I can sign the form, I need the grade/step information filled in as that information determines eligibility for OT pay (i.e. certain series/grades are not eligible for OT). Therefore, I can't formally authorize it until I know the grade of the individuals for whom you are requesting OT. Looping in Lesa/Daniel. Not sure who is in the best position to quickly provide that info (OPEQ operations or OIR).
Thanks
Bill

**William H. Maisel, MD, MPH**
*Director, Office of Product Evaluation and Quality*
*CDRH Chief Medical Officer*

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-5550
william.maisel@fda.hhs.gov




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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:04 PM
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** Request for overtime pay

AMERICAN OVERSIGHT

Dear Bill,

As you have seen from the DMD updates and the information in the press, the 2019-nCoV situation has been very challenging.

Our interactive review and teleconferences indicated that CDC will send CDRH a completed EUA review template any time soon. The staff has been fabulous and supporting the program 200%. I am anticipating CDC data to be reviewed over the weekend and a complete EUA review package next week. As soon as the emergency is declared we anticipate additional documents from commercial sponsors. This work is on top of the regular review work and I feel obliged to assure appropriate compensation for my staff. Attached please find the request form for overtime for your consideration.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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AMERICAN OVERSIGHT

# Overtime, Compensatory Time, and Holiday Pay Request and Authorization

*(Instructions for completing this form on reverse)*

2020-2531-CDRH

1. DATE: 01/23/2020

2. **TO:** *(Authorizing Official)*
a. NAME, TITLE, AND MAILING SYMBOL: William Maisel, MD, MPH, OPEQ Director, WA66-1678

3. **FROM:** *(Requesting Official)*
a. NAME, TITLE, AND MAILING SYMBOL: Uwe Scherf, PhD, Director Division of Microbiology Devices, OHT7/OPEQ WO66-3110
b. NO. OF PAGES FORWARDED: 2

| c. CHARGE OVERTIME TO | | d. TIME-KEEPER NO. | e. PAY PERIOD NO. *(No more than 4 PPs per form)* | f. INCLUSIVE DATES | |
|---|---|---|---|---|---|
| PAYROLL CAN | ADMIN CODE | | | FROM | TO |
| | | | | 01/23/2020 | 03/30/2020 |

4. **EMPLOYEES WORKING OVERTIME**

| a. NAME | b. GRADE/STEP | c. TIME-KEEPER* | d. NO. OF HOURS | | e. TYPE PAYMENT | | |
|---|---|---|---|---|---|---|---|
| | | | REQUESTED | WORKED | OT | COMP TIME | HOLIDAY |
| Anna Mielech | GS12/7 equiv | | 40 | | X | | |
| | | | | | | | |
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| | | | | | | | |
| *Complete for each different timekeeper. | | g. **TOTAL** | 40.00 | | | | |

5. **SPECIFIC DESCRIPTION OF TASK** *(Do not use general description, i.e., "typing," "filing")*
In timely support of the current outbreak of the 2019 novel coronavirus (nCoV) regarding pre-EUA and EUA submissions from government organizations like CDC, BARDA, and DoD to expeditiously authorize diagnostics tests for the detection of nCoV via the Emergency Use Authorization Autority.

6. **REASONS FOR NOT COMPLETING TASK DURING REGULAR HOURS**
The urgency of the 2019-nCoV outbreak requires constant instant responses to government stakeholders and IVD developers like CDC and commercial entities. This additional work is on top of the regular regulator review under MDUFA timelines and workload exceeds what staff can provide in 40 hours of their regular working hours.

7. **COMPLETED BY REQUESTING OFFICIAL** *(from box 3)*
a. DO YOU ANTICIPATE THE NEED FOR OVERTIME IN SUBSEQUENT PAY PERIODS FOR THIS TASK?
☒ Yes *(If "Yes," complete 7b.)* ☐ No
b. DESCRIBE STEPS TAKEN BY REQUESTOR TO REDUCE OR AVOID FURTHER OVERTIME
Review resources from other Branches of DMD will be used, however, specialized knowledge of the EUA process of the above listed individual might be required pending progression of the 2019-nCoV outbreak in the US.
SIGNATURE: Uwe Scherf -S Date: 2020.01.24 08:53:17 -05'00'

8. **COMPLETED BY APPROVING OFFICIAL**
REQUEST FOR OVERTIME
☐ Approved ☐ Disapproved
SIGNATURE
DATE

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# INSTRUCTIONS FOR COMPLETING FORM FDA 211

Overtime Work (within the provisions of Federal Personnel Manual Supplement 990-1) may be authorized only by officials to whom the necessary authority has been delegated (see FDA Staff Manual Guide 1430.5). Overtime or Holiday Pay will not be paid, nor compensatory time granted, without appropriate authorization. Requests should be initiated on Form FDA 211, "Overtime, Compensatory Time, and Holiday Pay Request and Authorization," and completed as follows:

| Item | Explanation |
|---|---|
| 1-3 | Self-explanatory, to be filled out by requesting official. A requesting official can be the employee, timekeeper, Administrative Officer, or supervisor. |
| 4 | If space is required for additional names of those working overtime, another Form FDA 211 should be filled out in its entirety. If more than one form is used for the same request, the forms should be clipped so that they are processed concurrently.<br><br>Only the "requested" side of the columns should be filled out by the requesting official in item 4d.<br><br>A check mark or "x" should be placed in the appropriate column of item 4e indicating the desired compensation. |
| 5-7 | Self-explanatory, to be filled out by requesting official. |
| 8 | To be filled out by authorizing official.<br><br>After evaluation (and adjustment if necessary), the authorizing official will sign to approve or disapprove the request. If disapproved, the request is returned to the requesting official. If approved, the request is returned to the requesting official who should then forward the document to the applicable timekeepers (and Budget Officer if required).<br><br>The timekeeper will enter hours worked in the appropriate column of item 4d. Hours worked are to be based on data which the employee provides on the bi-weekly time report and cannot exceed hours "requested." If hours worked exceed hours "requested," only the authorizing official may increase the "requested" amount and must initial the modification. |

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/31/2020 4:39:45 PM
**To:** John Tamerius [jtamerius@quidel.com]
**Subject:** RE: Follow-up for EUA for nCoV

John, can you please give me a call at 301-796-5456. Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** John Tamerius <jtamerius@quidel.com>
**Sent:** Friday, January 31, 2020 3:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Follow-up for EUA for nCoV

Hi Uwe. I hope you got my email last night. I do have a bit of additional information:

(b) (4)

[redacted]

Best regards, John

---

**From:** John Tamerius
**Sent:** Thursday, January 30, 2020 5:22 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Follow-up for EUA for nCoV

Hi again Uwe. Thank you so much for calling me last night and on such short notice. Here is information that I hope is helpful to you:

(b) (4)

[redacted]

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(b) (4)



Uwe, if I get more information tonight or tomorrow, I will send it to you. Please let me thank you again for your call to me earlier this evening.

Best regards, John

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/2/2020 8:54:39 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: My edits to the Clean template

No problem,

I will send the documents, thanks for getting this done so quickly. Enjoy the (b) (6) and some rest, you guys are great!

Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 8:53 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: My edits to the Clean template

Draft email to CDC – I need to leave for (b) (6) so please send when you are ready:

Dear Julie,

Please find attached DMD's comments in the EUA template, looks good, we just need the LoD data. We inserted them in the clean version for ease of viewing. Once the LoD is finalized we recommend dropping the EUA template performance section into your instructions for use performance section.

We would also like to request the following limitation addition/change in the IFU:

New:

- Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has only been established in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).

And maybe strengthen the negative results one by combining two of the current limitations with the addition in green:

- Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.

Let us know if have any questions
Best regards

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 02, 2020 8:45 AM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: My edits to the Clean template
**Importance:** High

When we send the template back to CDC, we will take a break.

So to get an final estimate: when it comes in with the LOD data, how much time will you need to review and sign off on the review template and the Instructions for use? I am asking it because if we need several hours and it comes in late in the evening we will wait until tomorrow to authorize.

Please give me an estimate how long you will need for final review?

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 8:40 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: My edits to the Clean template

Uwe,

What is the plan for the day? Should we keep checking e-mails all day or do we have a break until this afternoon?

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 02, 2020 8:39 AM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: My edits to the Clean template

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I have additional edits to the template, great job finding additional points. Uwe

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 8:28 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: My edits to the Clean template

I added a few minor edits to Li's document. The template is in good shape just needs the LoD data.

Tamara

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, February 02, 2020 7:56 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: My edits to the Clean template

My comments and edits were added to Kim's in the attached. Most edits were based on what we have already agreed upon for the PI.
Thanks,
Li

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 02, 2020 7:40 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** My edits to the Clean template

Dear Uwe, Tamara and Li,

My edits to the clean version – I updated some of the information that FDA was supposed to include. Otherwise it looks good to me, just need that LoD study ☺

I have to (b) (6) but otherwise will be available

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/26/2020 11:29:35 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: NSC talking points

Great thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 11:28 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: NSC talking points

Great I will send them back now.

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 11:25 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: NSC talking points

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Agree, how about his?

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 10:31 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: NSC talking points

Dear Uwe

Diagnostic part looks good – I had one comment to Michael for your consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 10:24 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Sadove, Elizabeth

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<Elizabeth.Sadove@fda.hhs.gov>
**Subject:** FW: NSC talking points

Hi. In prep for the NSC meeting on 2019-nCoV MCM development , whenever it is, BARDA send over some "basic talking points we can use going up the chain."

I took a stab at edits - would appreciate any edits you have. Thx - m

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/29/2020 6:54:48 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 1/29/20 6 AM update

Good morning Jeff, Elizabeth, Elle, Bill, Tim,

Enclosed the 1/29/20 6 AM update:

**Status of activities on diagnostics**:

- Additional IVD Developers, Abbott Diagnostics, Roche Molecular Diagnostics and BioMérieux, have requested and received EUA review template.
- Contacted companies with cleared respiratory panels that detect human coronaviruses to perform bioinformatic analysis against released 2019-nCoV genome sequences
  - Assess whether test predict cross-reactivity
- Received Feedback from BireFire/BioMérieux, they agreed to post Technical not of their webpage so we can link from FDA landing page directly to information

**New roadblocks/challenges/delays:**

- Need clarification on (b)(5) [redacted]
  - based on telecom on 1/28/20 3 PM, CDC has additional information available – pending data will assess whether addition testing is required. Without additional information conclusion is currently not possible.

**Summary of sponsors requested and received review template:**

- (b) (4) [redacted] (1/17/20)
- Inbios International (1/23/20)
- Quest Diagnostics (1/24/20)
- Quidel (1/25/20)
- Luminex (1/28/20)
- Qiagen (1/28/20)
- Abbott Diagnostics (1/28/20)
- Roche Molecular Diagnostics (1/28/20)

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- BioMérieux (1/28/20)

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**Sent**: 1/27/2020 9:47:32 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Draft EUA Letter for CDC 2019-nCoV test

Thanks, I will look at it now.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 9:26 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Draft EUA Letter for CDC 2019-nCoV test

Yes Jennifer think it would be good to discuss through with Uwe if he has time (maybe later morning to give him the opportunity to review), attached is the latest for discussion

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 6:53 PM

AMERICAN OVERSIGHT

**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Draft EUA Letter for CDC 2019-nCoV test

Hi – When I talked with Liz briefly at the end of the day, (b) (5)

(b) (5)

Should I set up a call in the morning?

Thanks!

Jennifer

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 5:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Draft EUA Letter for CDC 2019-nCoV test

So my only concern with this new conditions is...are (b) (5)

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 1:54 PM

**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Draft EUA Letter for CDC 2019-nCoV test

Suggested new language for L in the attached. I was looking at 21 CFR 314.70(c)(6).

(b) (5)

Thanks,

Jennifer

---

**From:** Ross, Jennifer
**Sent:** Sunday, January 26, 2020 3:19 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** Draft EUA Letter for CDC 2019-nCoV test

Hi Kim,

Since I'm back from leave, I'll handle clearing and obtaining signature on the EUA if it comes this week, consulting Liz along the way. I had two suggestions highlighted in green in the attached:

(b) (5)

Thanks!

Jennifer

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:27 AM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** FW: CDC expected to announce first US case of Wuhan coronavirus

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**From:** Sadove, Elizabeth
**Sent:** Wednesday, January 22, 2020 2:14 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: CDC expected to announce first US case of Wuhan coronavirus

I had a few minor proposed edits and comments. (b) (5) . I'll wait until you have a chance to review/respond to reconcile with HHS's drafts. Thanks!

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 6:20 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC expected to announce first US case of Wuhan coronavirus

Dear All,

Attached is the draft Letter of authorization for CDC – there are still a number of things that need to be updated as CDC haven't finalized the intended use and I don't have all the assay details yet……but it is a start. I based on the CDC H7N9 re-authorization letter and the most recent EUA (Chembio Ebola EUA).
Let me know if you have questions.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 5:46 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>

AMERICAN OVERSIGHT

**Cc:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Subject:** RE: CDC expected to announce first US case of Wuhan coronavirus

Sorry- will do Claire.

---

**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 5:45 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Subject:** RE: CDC expected to announce first US case of Wuhan coronavirus

Great - thanks all. Please include Claire too.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** January 21, 2020 at 5:41:05 PM EST
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: CDC expected to announce first US case of Wuhan coronavirus

Sounds good

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** January 21, 2020 at 5:39:55 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: CDC expected to announce first US case of Wuhan coronavirus

You're the best!

Marcy and I just received the determination/declaration language. I can reconcile the documents and input any questions… and then send back to you guys.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 5:39 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: CDC expected to announce first US case of Wuhan coronavirus

Ladies,
I have a draft LOA I worked on at the weekend - can send you later tonight when I am back online
Best regards
Kim

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** January 21, 2020 at 4:58:52 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: CDC expected to announce first US case of Wuhan coronavirus

AM OVERSIGHT

Jennifer is on leave this week, so I'll be covering OCET for this week.

Should I start to pull together a draft (b) (5)

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 1:43 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC expected to announce first US case of Wuhan coronavirus

Dear Michael,

We just go off a call with CDC – they are anticipating a full data pack for us to review later this week, early next week. We will keep you up to date with timing.

Let me know if you have any questions
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 1:34 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** CDC expected to announce first US case of Wuhan coronavirus

https://www.google.com/amp/s/amp.cnn.com/cnn/2020/01/21/health/wuhan-coronavirus-first-us-case-cdc-bn/index.html

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/31/2020 8:18:50 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: Rosemary's request

Perfect, thanks, Uwe

I will also let Jeff, Elizabeth and Ellen know that we received the 1st request. You'll see the email in a moment. Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 8:15 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Rosemary's request

Uwe – these are great, couple of minor edits/comments for your consideration in green
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov






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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:46 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Rosemary's request

Kim,

AMERICAN OVERSIGHT

I drafted some point for Rosemary which we can send tomorrow. Any additional points that come to your mind? I am fine with the goals.

Thanks, Uwe

**Subject:** USG Strategy needed for Diagnostics 2019-nCoV

CoV Dx Team,
I have been asked to coordinate the drafting of a USG strategy for CoV diagnostics, this will be used to brief up, including possibly to the NSC. Some of you will remember we had to do this for Zika in 2016. As expected , turn around is short, expectation is to have this ready early next week. Vaccine and Therapeutics groups are doing same, it is my understanding that everything will be vetted and approved through the official 2019-nCoV MCM Task Force that includes senior representative from every agency.

Using what we did for Zika as a template, I have started drafting, and will share draft later today, but wanted to give you a heads up so you can start working.
To speed things along, I ask:
1. Review the proposed goals below – are these acceptable – please suggest edits/revisions. Send your input back today - just at the WG level now, vetting with leadership will come later.
2. Please provide by ~~Monday morning~~ COB today a draft brief summary of what you are currently doing, and what you plan to do if funding is made available.

Current activities

- Developed pre-EUA Review template for nucleic acids available by request under CDRH-EUA-Templates@fda.hhs.gov
- Provided template to 19 IVD sponsors
- Interactive review of pre-EUA submitted by sponsors
- Proactive drafting of documents requires for EUA authorization (e.g., Letter of Authorization, Fact sheet for HCP & Patients)
- Requested cross-reactivity prediction assessment of sponsors with cleared devices with respiratory devices
- Establishing LOINC codes for 2019-nCoV molecular tests to advance outbreak surveillance through advanced data interoperability

Plan if funding is available

- Development of FDA reference material for traceability purposes
-

3. Please provide ~~Monday morning~~ COB today by a list of any key challenges (other than access to samples/viruses) that you think need to be highlighted.

- Development of reference material for traceability purposes
- Develop material for initial laboratory verification purposes

**Proposed goals:**
Leveraging individual federal agency roles and expertise, USG interagency collaborative efforts are underway to achieve the following 2019-nCov diagnostic strategic goals:

- Expand 2019-nCoV testing capacity by providing the CDC Real-Time RT-PCR Assay for Detection 2019-Novel Coronavirus under EUA to public health and DoD laboratories.
- Rapidly advance the development of specific and sensitive commercial molecular assays to detect 2019-nCoV in clinical samples for use in the U.S. under EUA, and outside the U.S.

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(b) (5)

- Identify, collect, produce, and distribute necessary development reagents and materials including viruses, antigens, clinical samples and reference panels for test validation.
- Define and communicate to developers the FDA regulatory pathways for development, approval or clearance, and emergency use of coronavirus assays.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/26/2020 11:25:08 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: NSC talking points
**Attachments**: Talking Points 1-26-2020.docx

Agree, how about his?

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 10:31 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: NSC talking points

Dear Uwe

Diagnostic part looks good – I had one comment to Michael for your consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 10:24 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** FW: NSC talking points

Hi. In prep for the NSC meeting on 2019-nCoV MCM development , whenever it is, BARDA send over some "basic talking points we can use going up the chain."

I took a stab at edits - would appreciate any edits you have. Thx - m

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Talking points:

(b) (5) Draft

[redacted]

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/30/2020 10:58:48 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2019-nCoV 1/31/20 6 AM update

Jeff, Elizabeth Ellen, Bill and Tim,

1/31/20 6 AM update

**Status of activities on diagnostics**:

- Interactive review with CDC continues - clinical data evaluation finalized - awaiting analytical and bioinformatics analysis
- Documents for authorization being sent to OCET/OCC for final review:
  - Letter of Authorization
  - Fact sheet for HCP and Patient
- FDA requested bioinformatic analysis by sponsors with cleared respiratory panels to assess prediction of cross-reactivity to 2019-nCoV. 2 out of 4 sponsors completed assessment, no cross-reactivity predicted.
- A total of 19 IVD Developers have requested and received EUA review template. **See list below**
- DMD participated on call with CDC and the American Clinical Laboratory Association (ACLA) - provided brief overview of how to obtain the FDA EUA template for 2019-nCoV.
- Dr. Brittany Goldberg, Senior Medical Officer in DMD volunteered to join delegation of experts to support WHO 2019-nCoV Team in China

**New roadblocks/challenges/delays:**

- None [previously outstanding issue on clinical study resolved]

**Summary of sponsors requested and received review template: TOTAL 19**

- (b) (4) (1/17/20)
- Inbios International (1/23/20)
- Quest Diagnostics (1/24/20)
- Quidel (1/25/20)
- Luminex (1/28/20)
- Qiagen (1/28/20)
- Abbott Diagnostics (1/28/20)
- Roche Molecular Diagnostics (1/28/20)

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- BioMérieux (1/28/20)
- Thermo Fisher Scientific (1/29/20)
- (b) (4) (1/29/20)
- Mayo Clinic AZ (1/2920)
- Roche Molecular Systems Inc. (apparently independent of Roche Molecular Dx) 1/29/29)
- (b) (4) (1/29/20)
- (b) (4) (1/30/20)
- (b) (4) (1/30/20)
- Rheonix Inc. (1/30/20)
- DiaSorin Molecular (1/30/20)
- Cue Health Inc (1/30/20)

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/28/2020 2:42:41 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: Exercise of Enforcement Discretion

**Importance**: High

Ellen,

Thanks this look great. Yes, we should send to OCET and I can do that now .

Do you have any comments on the proposed legal language?

(b) (5) Draft

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 2:17 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Exercise of Enforcement Discretion

Attached with just a few edits to point #1, as discussed. Also attaching a clean copy. Do we need to send it to OCET?

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 1:43 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Exercise of Enforcement Discretion

Ellen,

Attached please find my comments. The exercise of enforcement discretion will ONLY be for testing in certain labs before the EUA is authorized. The shipment and validation is covered under a new provision added by PAHPRA, and permits pre-positioning of MCMs without FDA approval when the product(s) is intended to be held (and not used) for emergency use (section 564B), allowing stakeholders to prepare for rapid deployment of MCMs during an emergency. Which is the case here. I made edits to capture the testing aspect in the attachment.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 1:25 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Exercise of Enforcement Discretion

Please see attached for my revised version for your consideration and fact check.

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 12:48 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Exercise of Enforcement Discretion

Ellen,

Below the language OCET is proposing for the enforcement discretion email. What do you think?

Uwe

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 12:37 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Exercise of Enforcement Discretion

FDA proposes the following process for CDC and FDA to confirm/memorialize FDA's exercise of enforcement discretion for CDC to send initial kits to a few identified state labs to detect the novel coronavirus (2019-nCoV):

(b) (5)

We might want to run this by Marcy and Claire as well to see if they have additional concerns or thoughts. I can send to them with an explanation of the conversation last Friday, and cc: you all. Thanks!!

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 11:09 AM

**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Exercise of Enforcement Discretion

Liz,

Can we develop a draft email with the exact wording how we convey the execution of enforcement discretion, I understand that Jeff want to have this language settle today.

Thanks, Uwe

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 11:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Exercise of Enforcement Discretion

Here is the proposed enforcement discretion process in case we receive initial indications that CDC needs to send out its kits. Thanks, Liz

---

FDA proposes the following process for CDC and FDA to confirm/memorialize FDA's exercise of enforcement discretion for CDC to send initial kits to a few identified state labs to detect the novel coronavirus (2019-nCoV):

(b) (5)

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 4:49 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Exercise of Enforcement Discretion

Liz,

No, the number of expected tests, which labs, and the agreement that (b) (5) are good conditions.

Thanks, Uwe

AMERICAN OVERSIGHT

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 4:26 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Exercise of Enforcement Discretion

Great. (b) (5)

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 3:13 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Exercise of Enforcement Discretion

Liz,

CDRH leadership is comfortable with the email approach and with the suggested route to send the email to MCM Team Lead (Kim) and I on the Division level will sent the email stating the exercise of Enforcement Discretion.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 2:11 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Exercise of Enforcement Discretion

Liz,

Thanks for taking the lead and pushing this forward. Your proposed strategy of email conformation will be effective way. I have reached out to CDRH leadership to assess their comfort on an email and the 'signature' level. I got the impression they want someone in senior leadership.

Will update as I get feedback. Uwe

AMERICAN OVERSIGHT

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 1:36 PM

**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Exercise of Enforcement Discretion

Hi- After the call with Julie, Anita, and Dan last Friday, Anita said she would send a summary of what was discussed. I still have not received a summary. But, I had said I would offer a process for which we could confirm/memorialize our exercise of enforcement discretion for the initial kits being sent to a few labs. I'd like to be ready with a response.

(b) (5)

(b) (5) Thanks, Liz

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/24/2020 1:59:46 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: OCET SITREP Update for 3pm

Thanks, this work. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 1:58 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** OCET SITREP Update for 3pm

Uwe – is below okay for the DMD OCET SITREP (items in red are to let the Commissioner know information is confidential) – due to OCET by 3 pm
Thanks
Kim

**DMD SITREP Jan 24, 2020**

- Additional IVD Developer has requested and received EUA review template [Inbios International]
- Interactive review with CDC continues – final box and vial labels were reviewed, and cross reactivity study designs finalized.
- BioFire/Biomerieux provided a technical note to customers informing them that their current cleared assays, that include detection of other coronavirus species, are not predicted, based on bioinformatic analysis, to cross-reactivity with the 2019-novel coronavirus, FDA plans to link to this information and encourage other manufactures of cleared respiratory multiplex tests to perform similar analysis and provide this information to customers [e.g., (b)(4), (b)(5) Inc].
- Initial call held with (b)(4), (b)(5)

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 1:37 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Daily 2 PM update

Jeff,

**Status of activities on diagnostics**:

- OCET and OCC support Center recommendation to exercise enforcement discretion to allow CDC to (b)(5) their test
- Additional IVD Developer has requested and received EUA review template [Inbios International]
- Updating FDA 2019-nCoV landing webpage to provide information on cleared respiratory devices on predicting cross-reactivity to 2019-nCoV. BioFire/Biomerieux provided technical note to customer, FDA plans to link to this information and encourage other manufactures of cleared respiratory tests to perform similar analysis and provide this information. [e.g., (b)(4), (b)(5) ]

**New roadblocks/challenges/delays:**

- Considerations for (b)(5) – initial phone call with (b) (4), (b) (5) and OCET at 3 PM today

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov

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AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/23/2020 5:47:18 PM
**To**: Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]
**CC**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Dowtin, Lesa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a58cf27088244caa863aa4f57a9b11ad-LXV]; Montgomery, Daniel R [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6aa38c2edd0944d0b67f1b823985090a-DRM4]
**Subject**: RE: Request for overtime pay

Thank you so much.

Uwe

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:46 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Uwe,
I am not sure that we can authorize individuals under Title 42 for OT. I have removed Anna Mielech and authorized all others on the form attached. If we get the OK for Anna, we can complete another form or add her back.

Lesa and/or Daniel, can we authorize OT for Title 42?

Bill

**William H. Maisel, MD, MPH**
*Director, Office of Product Evaluation and Quality*
*CDRH Chief Medical Officer*

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-5550
william.maisel@fda.hhs.gov

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:42 PM
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Dear Bill,

Attached please find the updated request form with the Grade and Step information. Only one individual Anna Mielech is a staff fellow under title 42 and she does not have this information.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:18 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Uwe,
I am supportive of OT pay and would be happy to authorize. Before I can sign the form, I need the grade/step information filled in as that information determines eligibility for OT pay (i.e. certain series/grades are not eligible for OT). Therefore, I can't formally authorize it until I know the grade of the individuals for whom you are requesting OT. Looping in Lesa/Daniel. Not sure who is in the best position to quickly provide that info (OPEQ operations or OIR).
Thanks
Bill

**William H. Maisel, MD, MPH**
*Director, Office of Product Evaluation and Quality*
*CDRH Chief Medical Officer*

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https://www.research.net/s/cdrhcustomerservice?ID=1000&S=E

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:04 PM
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** Request for overtime pay

Dear Bill,

As you have seen from the DMD updates and the information in the press, the 2019-nCoV situation has been very challenging.

Our interactive review and teleconferences indicated that CDC will send CDRH a completed EUA review template any time soon. The staff has been fabulous and supporting the program 200%. I am anticipating CDC data to be reviewed over the weekend and a complete EUA review package next week. As soon as the emergency is declared we anticipate additional documents from commercial sponsors. This work is on top of the regular review work and I feel obliged to assure appropriate compensation for my staff. Attached please find the request form for overtime for your consideration.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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CDRH | Food and Drug Administration
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***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/23/2020 12:17:19 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject:** RE: current working documents for CDC 2019-nCoV submission

Just for clarification - Work: (b) (6) I my office cell phone number. Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 12:14 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** RE: current working documents for CDC 2019-nCoV submission

Cell phones:
Work: (b) (6)
Personal: (b) (6)

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Kim.Sapsford@fda.hhs.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 8:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** current working documents for CDC 2019-nCoV submission

AMERICAN OVERSIGHT

All current working documents for CDC 2019-nCoV submission

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/30/2020 8:32:04 AM
**To:** Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**Subject:** RE: Pre-EUA IVD template request

Agree,

They should use the structure of the NAT template and send to up data they have. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 8:18 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** RE: Pre-EUA IVD template request

Agree, we should look at what they have to offer

Tamara

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 6:48 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Fwd: Pre-EUA IVD template request

My thought is to respond that we don't have a template at this time. But we could invite him to submit - maybe highlight we are somewhat concerned (b) (5)

---

**From:** John Tamerius <jtamerius@quidel.com>
**Date:** January 29, 2020 at 5:33:12 PM EST

AMERICAN OVERSIGHT

**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Pre-EUA IVD template request

Hi Kim. Does the FDA consider (b) (4)

---

**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Saturday, January 25, 2020 4:03 PM
**To:** John Tamerius <jtamerius@quidel.com>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Pre-EUA IVD template request

Dear John,

Thank you for your email. Please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of 2019-novel coronavirus (2019-nCoV). I suggest when you are ready, the first step is to populate this draft template with the information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center). The Pre-EUA review is an interactive process, so we will provide feedback after receiving and reviewing the information provided. The draft review template is a shared "work-in-progress" document which you will populate with information and data as obtained and which we will review and provide feedback to you.

I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of 2019-nCoV to FDA (it includes the address for the Document Control Center). Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under type of submission please check "other" and specify Pre-EUA.

One hard copy of the signed EUA Cover Letter and one electronic copy of you Pre-EUA submission package (including the EUA Review Template - MS word document) should be enclosed in your Pre-EUA submission to FDA, and we also request that you submit the information requested via electronic mail to myself Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;
- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please be reminded that ***in the U.S. a test*** for the detection of 2019-nCoV or to diagnoses 2019-nCoV infection must not be distributed and/or used for clinical diagnosis without premarket clearance, approval, or EUA by the FDA.
NOTE: The EUA Interactive Review Template from the FDA is considered an internal working document and must not be distributed outside of your organization.

Please let me know if you have any questions, we look forward to working with you,
Best regards,
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** John Tamerius <jtamerius@quidel.com>
**Sent:** Saturday, January 25, 2020 6:02 PM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Subject:** Pre-EUA IVD template request

To whom it may concern:

I am interested in exploring the current EUA program on behalf of Quidel Corporation, located in San Diego, California. (b) (4) [redacted] If you have drafted specific guidance for development of coronavirus-specific coronaviruses, could you provide that too?

(b) (4) [redacted]

Thank you in advance for this consideration.

Best regards, John

PS: (b) (4) [redacted]

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/29/2020 7:53:40 PM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: RE Intended Use

Got it, thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 7:52 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: RE Intended Use

You are correct Uwe just in the letter of authorization

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 7:51 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: RE Intended Use

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Kim,

I am sorry it looks like there is a slight difference of the listed Intended Use in versus in the in the normal document. Jennifer still has after

CDC criteria for 2019-nCoV testing, **pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3)**.

Just to be 100% sure, and I checked the other documents with just the intended use, this wording in green only in the authorization letter and not in the intended use? Correct?

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 6:44 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Fwd: RE Intended Use

Thoughts? I am fine with it

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Date:** January 29, 2020 at 5:33:15 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: RE Intended Use

Kim, -

(b) (5)

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(b) (5)

Thanks,

Jennifer

---

**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 5:19 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** January 29, 2020 at 3:15:21 PM EST
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

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**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 3:14 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

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Thanks!

**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 3:00 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

Great. Thank you for clarifying!

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 3:00 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 2:57 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

I can't, but defer to you all..

**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 2:47 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

Thanks! (b) (5)

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 2:29 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 2:26 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

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**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 2:24 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE Intended Use

My subject line may have been misleading, so as clarification, this is for the letter and all the other documents with the EUA would be consistent with the language in the letter.

---

**From:** Ross, Jennifer
**Sent:** Wednesday, January 29, 2020 2:22 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC HCP and Patient Fact Sheets

Hello,

Do you have any concerns with this proposed change (red part is new)? (b) (5) .

(b) (5)

Thanks,

Jennifer

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/26/2020 10:38:40 AM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** Re: NSC talking points

Thanks, will look at it in 20 min.

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** January 26, 2020 at 10:30:55 AM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: NSC talking points

Dear Uwe

Diagnostic part looks good – I had one comment to Michael for your consideration.

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 10:24 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** FW: NSC talking points

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Hi. In prep for the NSC meeting on 2019-nCoV MCM development , whenever it is, BARDA send over some "basic talking points we can use going up the chain."

I took a stab at edits - would appreciate any edits you have. Thx - m

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/29/2020 9:58:25 AM
**To**: Chaitram, Jasmine M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f23099b19f4dfab6048ca7c6bd202c-HHS-zoa6-cd]

**Subject**: Accepted: TTFED discussion of plan for end user verification of 2019 coronavirus EUA assay
**Location**: conference call

**Start**: 1/29/2020 10:00:00 AM
**End**: 1/29/2020 11:00:00 AM
**Show Time As**: Busy

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/25/2020 4:16:49 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** FW: Wuhan/touching base
**Attachments:** EUA Review Template_NAT_Novel Coronavirus 1.19.2020.doc; Draft cover letter for Sponsor 01212020.docx

Email to Quest.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Scherf, Uwe
**Sent:** Friday, January 24, 2020 7:11 PM
**To:** Wagner, Michael J <Michael.J.Wagner@questdiagnostics.com>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** RE: Wuhan/touching base

Dear Mike, good to hear from you.

We are accepting Pre-EUA submissions. Please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of 2019-novel coronavirus (2019-nCoV). As you have in the past, I suggest the first step is to populate this draft template with the information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center).

I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of 2019-nCoV to FDA. Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under type of submission please check "other" and specify Pre-EUA.

One hard copy of the signed EUA Cover Letter and one electronic copy of you Pre-EUA submission package (including the EUA Review Template - MS word document) should be enclosed in your Pre-EUA submission to FDA, and we also request that you submit the information requested via electronic mail to Kim Sapsford at Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

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- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;

- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please be reminded that ***in the U.S. a test*** for the detection of 2019-nCoV or to diagnoses 2019-nCoV infection must not be distributed and/or used for clinical diagnosis without premarket clearance, approval, or EUA by the FDA. NOTE: The EUA Interactive Review Template from the FDA is considered an internal working document and must not be distributed outside of your organization.

Please let me know if you have any questions as you look through the template, we look forward to working with you on your Pre-EUA submission.

Kind regards,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Wagner, Michael J <Michael.J.Wagner@questdiagnostics.com>
**Sent:** Friday, January 24, 2020 7:01 PM
**To:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Wuhan/touching base

Don – Thank you. Uwe and I go way back.

Uwe – Hopefully the outbreak will contain itself, but if it does not, we look forward to working with you and the team again.

Michael

Michael J. Wagner, Esq.
Quest Diagnostics Incorporated | Legal Department | 1311 Calle Batido | San Clemente, CA 92673 USA | **phone** +1 949.940.7360 | michael.j.wagner@questdiagnostics.com | www.questdiagnostics.com
Please think about resource conservation before you print this message

---

**From:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 3:19 PM
**To:** Wagner, Michael J <Michael.J.Wagner@questdiagnostics.com>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Wuhan/touching base

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CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Michael,
Thank you for reaching out. Please feel free to contact Uwe Scherf who heads up the Micro Division. He has put together a team of people that will be working on this issue and can provide assistance.
Sincerely yours,
Don

---

**From:** Wagner, Michael J <Michael.J.Wagner@questdiagnostics.com>
**Date:** January 24, 2020 at 5:10:19 PM EST
**To:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** Wuhan/touching base

Hi Don,

I suspect that if DHHS declares an emergency, then we likely working together again on an authorization for a lab testing service (and not a distributed kit). I thought it might be a good idea to reach out ahead of time and make contact.

I wanted to let you know that Quest Diagnostics is working with CDC (via ACLA I believe), that Quest is considering a Wuhan assay (I presume a PCR), and Quest is aware of the emergency use authorization process if Quest develops an assay and if an emergency is declared.

I saw that Alberto transitioned to other opportunities a couple of years ago. Could you let me know who is leading the Microbiology team now?

And if an emergency is declared, could you let me know who has been assigned as lead reviewer? I will then share with the team here at Quest.

Thank you.

Michael
Michael J. Wagner, Esq.
**Quest Diagnostics Incorporated** | Legal Department | 1311 Calle Batido | San Clemente, CA 92673 USA | **phone** +1 949.940.7360 | michael.j.wagner@questdiagnostics.com | www.questdiagnostics.com
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# EMERGENCY USE AUTHORIZATION (EUA)

## EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (2019-nCoV)

## GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow ***[Text]*** should be completed by the IVD developer (sponsor) as applicable to their specific test. Text in **bold** outlines the Food and Drug Administration (FDA) suggestions and clarifications for the sponsors' consideration when completing the required information in a specific section.

- This is a EUA interactive review template for Pre-EUA/EUA submissions concerning molecular-based single target tests for detection of 2019 Novel Coronavirus (2019-nCoV), Wuhan, China. If you are developing a multiplex molecular-based assay for the detection and differentiation of nucleic acids from a panel of microorganisms, please review Appendix A for FDA recommendations.

- This is a EUA interactive review template for Pre-EUA/EUA submissions and not a guidance document. The template is subject to change as we learn more about the 2019-nCoV disease and its risk-benefit profile. Recipients will receive notice and updated templates as they become available.

- This EUA interactive review template is an FDA internal document and any proprietary information provided within the template and during the interactive review process will remain confidential as it does in a regular FDA premarket submission.

- Feedback provided by FDA during the interactive review of your pre-EUA/EUA is subject to change as we learn more about the 2019-nCoV disease and the risk-benefit profile evolves to address unmet public health needs.

- Prior to a potential authorization FDA will require developers of molecular-based tests to assess traceability of their test to an FDA-recommended reference material panel if available at the time. Specific details about the traceability study and the FDA-recommended reference material panel will be provided by the Lead Reviewer assigned to the Pre-EUA submission once the analytical and clinical evaluation data has been reviewed and found to be acceptable.

- Please be reminded that tests for the detection of 2019-nCoV or 2019-nCoV infection must not be distributed and/or used for clinical diagnoses without premarket clearance, approval, or EUA by the FDA. Clinical samples for 2019-nCoV testing should be sent to the appropriate public health laboratories until the IVD device subject of this Pre-EUA submission has received authorization from the FDA.

- Clinical specimens may be required to support the EUA request. Furthermore, please note that applicable regulations for human subject protection do apply under the

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EUA. Please refer to the Clinical Evaluation section of this document for more details.

- If authorized, the EUA means that this 2019-nCoV IVD is temporarily authorized for use until the public health emergency is terminated or the EUA is revoked by the FDA.

    - FDA recommends that you consider registration and listing your EUA product once you have been issued an EUA. If this is problematic, please notify the Agency during your Pre-EUA.
    - The EUA is not a pathway to permanent marketing of your device. Therefore, we strongly recommend that you consider, in addition to an EUA, a traditional premarket submission for your IVD so that your device can still be legally marketed after termination of the emergency declaration. We recommend that you identify as soon as possible in the Pre-EUA review process any consideration of moving your product forward towards De Novo/510(k) clearance. If so some of our feedback to you may take such a long-term goal into consideration in order to prevent additional testing where it may not be needed. Therefore, please consider submitting a Pre-Submission to inquire what studies would be required for a premarket approval/ clearance of your 2019-nCoV IVD. Details on how to submit a Pre-Submission to the Agency are outlined in the FDA guidance document: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.* [ HYPERLINK "https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program" ]

## A. EXECUTIVE SUMMARY (as of X/XX/20XX)

## B. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the ***[test name]*** to ***[indicate labs, if applicable]*** for the *in vitro* qualitative detection of RNA from the 2019-nCoV in ***[add all claimed specimen types, e.g., nasopharyngeal/oropharyngeal swabs, sputa, BAL, stool, and serum, etc.]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated with 2019-nCoV infection) and CDC novel coronavirus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated) to aid in the diagnosis of 2019-nCoV infection.

## C. MEASURAND

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Specific nucleic acid sequences from the genome of the 2019-nCoV [***please specify the targeted gene(s) of the pathogen***].

## D. APPLICANT

***[Official name, address and contact information of applicant]***

## E. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name - ***[test name]***
Established Name - ***[test name]***

## F. REGULATORY INFORMATION

***Approval/Clearance Status:***
The ***[test name]*** test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

***Product Code:***
[XXX – FDA will complete]

## G. PROPOSED INTENDED USE

***1) Intended Use:***
**The proposed IU will be finalized based on the data and recommendations from Public Health authorities at the time of authorization – example text is provided below for a qualitative molecular test that detects organism RNA but may be adapted according to the specific emergency situation addressed by the device.**

[***Test name***] is a [***specify test technology such as, real-time RT-PCR test***] intended for the qualitative detection of nucleic acid from the 2019-nCoV in [***describe all the specimen types***] from individuals meeting CDC 2019-nCoV clinical criteria (e.g., clinical signs and symptoms associated with 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated). Testing is limited to [***laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories***].

Results are for the identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in [***name specimen type***] during the acute phase of infection. Positive results

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are indicative of active infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The ***[test name]*** is intended for use by **[*include intended user, e.g., trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures*]**. The ***[test name]*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

***2) Special Conditions for Use Statements:***

For prescription use only
For in vitro diagnostic use only

***3) Special Instrument Requirements:***

The ***[test name]*** test is to be used with the [***list all RT-PCR Instruments, software requirements, automated extraction instruments***].

## H. DEVICE DESCRIPTION AND TEST PRINCIPLE

**Example text has been added under each of the sub-headings below for a fluorescence based rRT-PCR test for detection of organism RNA. If a different test principle is used by the test for the detection of a specific analyte please modify the description accordingly to capture the salient points in each of the sub-headings below. Please note that for new investigative technologies FDA may request additional detailed information so we can adequately assess the risks and benefits associated with the device.**

***1) Product Overview/Test Principle:***

**Describe the technology of the test and how this technology works to identify the measurand, the instruments employed/required to perform the test from sample collection to result (include all claimed extraction and PCR detection instruments), and the specimen types for which you claim to have specific performance characteristics as described below. If applicable, list all primer and probe sets and briefly describe what they detect. Please include the nucleic acid sequences for all primers and probes used in the test. Please indicate if the test uses biotin-Streptavidin/avidin chemistry in any of the steps for coupling reagents. Please note that an alignment with available reference genomes for different strains of the target pathogen is requested as part of the inclusivity evaluation (Section N).**

The ***[test name]*** is a real-time reverse transcription polymerase chain reaction (rRT - PCR) test. The 2019-nCoV primer and probe set(s) is designed to detect RNA from

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the 2019-nCoV in ***[list all the specimens]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated).

2) ***Description of Test Steps:***

**List and describe in detail all the steps of the test sequentially from specimen collection to detection.**

Nucleic acids are isolated and purified from ***[specimens]*** using ***[please describe the method(s) of extraction (please specify the specimen input volume for extraction and/or test, the nucleic acid elution volume and whether isolation/purification is manual and/or automated)].*** The purified nucleic acid is reverse transcribed using ***[enzyme mix/kits – please specify the input volume of purified nucleic acid added to the rRT-PCR reaction mix]*** into cDNA which is then subsequently amplified in ***[please describe the instrument(s) and enzyme mix]***. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by ***[please describe the detection instrument(s)]***.

3) ***Control Material(s) to be Used with [test name]:***

**List all control materials (provided with the test kit and/or required but not provided with the test kit and describe what they are, how they are expected to work, where in the testing process they are used, and the frequency of use. If a control is commercially available, provide supplier's name and catalog number or other identifier; if your device relies on external controls that are manufactured by a third party please note that these controls should also be validated within your analytical and clinical studies described below in Section (N).**

Controls that will be provided with the test kit include:

a) A "no template" (negative) control is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***

b) A positive template control is needed to ***[describe need]*** and is used ***[describe use – please specify the concentration of the positive control relative to the LoD of your test (note that ideally the positive control concentration should be such that it is close to the LoD of your test) and also specify frequency of use]***

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c) An extraction control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use].*** **Please note that if the no template control and positive control, are taken through the entire sample processing procedure, including the extraction, then a separate extraction control is not required**.

d) An internal control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use]***.

Controls that are required but not provided with the test kit include ***[describe control – provide recommended sources of the control materials – either a separate control kit for purchase that you the applicant develops or a control material that can be purchased from a third party].*** This/these control(s) is/are needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***.

**Please note that any control recommended to be used with your device (provided with the kit or not) needs to be validated in the context of your analytical and clinical study (i.e., you will need to run these controls as part of your studies). In instances where control material is not readily available through 3rd party vendors (which is often the case at the beginning of an outbreak) FDA may request that you include suitable control material with your device. Please note that external control materials are considered particularly important in the context of EUA devices because often GMP requirements for the manufacture of the EUA device are waived in emergency situations and reagent stability studies are limited. Hence the external controls offer some assurance of EUA test performance in the hands of the end user.**

## I. INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. **Please describe if a Ct cutoff is used as part of your testing algorithm and/or if the end user is required to review fluorescent curves for weakly positive samples before final interpretation. Although not typical for molecular-based tests, if the test result involves the use of an algorithm/calculation, for example a ratio value, when determining the final patient test result, please include a detailed description and any additional calibration materials that may be required.**

1) ***[Test name] Controls – Positive, Negative and Internal***

**Describe in detail the expected results generated, including acceptance criteria, for all the controls described in detail in Section H above. Describe the measured values (if applicable) for valid and invalid controls and outline the recommended actions the laboratory should take in the event of an invalid control result.**

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2) ***Examination and Interpretation of Patient Specimen Results:***

**Describe when clinical specimen test results should be assessed and outline the criteria for test validity**. **Example text**: Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

**Clearly indicate how to interpret numeric test values (if applicable) as positive or negative for presence of the 2019-nCoV. Indicate if the end user is required to review fluorescent curves for weakly positive samples before final interpretation and how to identify indeterminate/inconclusive results (if they exist) results and how the user should resolve them, e.g. if repeat testing may be required.**

**When applicable, provide a table clearly describing the possible combinations of test result values for each primer/probe set, and how they should be combined into a final interpretation of the result for your test. If the test produces result that will be used as part of a CDC recommended testing algorithm, please indicate what follow-up testing/process should be conducted, if applicable.**

## J. PRODUCT MANUFACTURING

**Please note that if you are developing a test for use at a single site (i.e., a laboratory developed test LDT), some of the information requested in this section may not be applicable. Please contact FDA for additional guidance for an emergency use LDT.**

The ***[test name]*** has been validated using only the components referenced in this submission and shall not be changed without prior concurrence from the FDA.

*1)* ***Overview of Manufacturing and Distribution:***

The product will be manufactured at [***manufacturer's name and FDA registration number (if applicable) or laboratory name if an LDT***] by [***manufacturer name, or laboratory name if an LDT***] personnel consistent with practices for the production of **[*types of devices*]** based on [***type of quality system****]. Material manufactured by [***manufacturer's name, or laboratory name if an LDT***] may be bottled and kitted by [***packager name***] manufacturing facility.

***Under the Emergency Use Authorization (EUA) most of the 21 CFR 820 Quality System Regulation (QSR) requirements can be waived for the duration of the EUA. FDA expects that developers follow comparable practices as much as possible and may consider previous compliance history when determining whether or not to waive certain QSR requirements for a specific product. Please note adverse events, as per 21 CFR Part 803, have to be reported for authorized devices (see Section R).**

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The current manufacturing capabilities include the ability to manufacture approximately **[*please insert the approximate number of units/products that can currently be manufactured per week at the manufacturing facility*]** products per week, however in the event of a surge in demand this could be increased to **[*please insert the approximate maximum number of units/products that could potentially be manufactured per week at the manufacturing facility if there was a surge in demand*]** product per week within a **[*please specify in weeks/months the expected timeframe required to increase product production if required*]** timeframe.

The product will be distributed by **[*please describe the distribution plan for the product and list all current distributors*]**.

2) ***Components Included with the Test***

Components manufactured by [***manufacturer's name and FDA registration number (if applicable)***] and supplied with the test include:

**List all components and reagents provided for your test, including a description of the primers and probes, volumes, concentrations, quantities, buffer components, etc.**

3) ***Components Required But Not Included with the Test***

Components required but not included with the test:

**List all components and reagents not included with the test that must be supplied by the user to perform the test, with specific supplier names and catalog numbers or other identifiers for obtaining these components and reagents. Please include here all specific consumables that were validated for use with your device, that are not interchangeable with other products and that are needed to guarantee device performance as established in the EUA validation studies listed in Section N below.**

4) ***Testing Capabilities***

**Briefly describe current sample throughput capacity, total time required to perform the test (from clinical specimen collection, specimen transport to result), and number of tests that can be performed per instrument run and per day.**

5) ***Reagent Stability:***

**Briefly describe stability test plan for *[test name]* reagents and include any accelerated stability information if available. Please note that reagent stability studies do not need to be completed at the time of EUA issuance, however the study design should be agreed upon during interactive review and the stability studies started immediately following authorization, if not before. When designing your stability study, we have some general recommendations that are outlined in Appendix B, for your consideration.**

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## K. PERFORMANCE EVALUATION

**If you plan to claim multiple target analytes to aid in differential diagnosis or you plan to claim multiple RT-PCR instruments and/or extraction methods, please refer to Appendix A and C, respectively, more information. Please note that any omission of a requested study in this document should be documented and justified.**

### *1) Analytical Sensitivity:*

a) *Limit of Detection (LoD):* **You should determine the LoD of the device utilizing the entire test system from sample preparation to detection for each clinical matrix claimed. Please note that claims for additional anticoagulants, for blood specimens, can be supported by a matrix equivalency study as outlined in Section N, subsection 3 below. The LoD is determined using dilutions of live propagated and titered 2019-nCoV stocks (CFU/mL or PFU/mL) spiked into a relevant clinical matrix. If wild-type virus is not available at the time of your validation studies, please contact FDA to discuss a potential alternative. Please note that if available please also provide Genomic Equivalent Copies (GEC)/mL units for the stock solutions used and include an explanation on how they were determined. Please note that LoD studies should be performed with live organisms, as described above. If you plan to use inactivated organism in your LoD determination you should describe how the material was inactivated and perform a study to determine whether the inactivation process impacted the LoD of the device.**

**First a tentative LoD must be established through limiting dilutions of the prepared material with 3-5 replicate measurements. Please note for all the analytical studies described in Section N that require replicate testing, one replicate equates to one independent extraction and PCR detection. Once a tentative LoD is established, the LoD should be confirmed by preparing at least 20 additional replicates at the LoD concentration and demonstrating that the organism was detected with a minimum 95% positivity (19/20). If this confirmatory study achieves a positivity of 100%, then a lower concentration needs to be tested (with 20 replicates) until <100% positivity is obtained.**

**Please use the following format when submitting LoD information and data:**

LoD studies determine the lowest detectable concentration of 2019-nCoV at which approximately 95% of all (true positive) replicates test positive. The LoD was determined by limiting dilution studies using characterized samples.

**List/describe the following in this section:**

- **Titers and strains of the 2019-nCoV stocks used for the LoD study and describe how the organism stocks were prepared and how the titers were determined.**

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- **The dilution factor and number of serial dilutions of the characterized 2019-nCoV that were tested to determine the LoD for each primer and probe set.**
- **The nucleic acid extraction/purification method.**
- **The real time PCR instrument.**

Serial dilutions of the characterized 2019-nCoV were then tested in **[*number of replicates (i.e., recommend that sample is extracted independently three-five times and each extraction tested once)*]** replicates. The lowest concentration at which all [*number of replicates*] replicates were positive was treated as the tentative LoD for each test. The LoD of each test was then confirmed by testing [*number of replicates (at least 20 recommended)*] with concentrations at the tentative limit of detection. The final LoD of each test was determined to be the lowest concentration resulting in positive detection of [*number of positive replicates (at least 19 out of 20 replicates)*]. [*Include analysis of LoD results, indicating the final LoD for each test*]

**Tentative LoD: [*Please provide a summary of the data for each strain tested]* example table 2019-nCoV stocks is provided below:**

| 2019-nCoV Strain Tested | Stock 2019-nCoV Titer | Serial 10-Fold Dilution Factor | Concentration in Dilution Tested [Include Units] | Replicate 1 $C_t$ | Replicate 2 $C_t$ | Replicate 3 $C_t$ | Replicate 4 $C_t$ | Replicate 5 $C_t$ | Call Rate | Lowest Concentration with Uniform Positivity per Analyte | Limit of Detection (LoD) per Virus Strain |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Example: [analyte]* | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

b) FDA Sensitivity Evaluation: The analytical sensitivity of the test has to be further assessed by evaluating an FDA-recommended reference material using an FDA developed protocol if applicable and/or when available. Details will be provided during the Pre-EUA interactive review.

c) *Reactivity/Inclusivity:* Reactivity of the ***[test name]*** was evaluated for additional isolates of 2019-nCoV.

**Reactivity: *[test name]* example table below**

| 2019-nCoV Strain/Isolate | Source/Sample Type* | Concentration | Ct** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

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| | | | |
|---|---|---|---|
| | | | |

***Please list source of material used for wet testing and sample type tested (i.e., organism – live or inactivated, purified nucleic acid – whole genome etc.).**
**** If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**At a minimum, the strain used in your LoD evaluation should be listed here (multiple isolates of the same 2019-nCoV strain that was used for the LoD studies can also be included if available). If additional isolates are not available at the time of your validation studies, please discuss with FDA. Each isolate should be tested at or near the LoD (no more than 3x LOD) of the test, spiked into clinical matrix utilizing the entire test system, including extraction. If you plan to claim more than one type of clinical matrix, we recommend that you perform this study in the most challenging clinical matrix, testing a minimum of 3 replicates. In addition, the wet testing should be accompanied by extensive inclusivity *in silico* analysis of the test primer and probes with all known strains/isolates (past/present) of 2019-nCoV (including the strain/isolate used for wet testing).**

## 2) *Analytical Specificity:*

a) *Cross-Reactivity:* Cross-reactivity of the ***[test name]*** was evaluated using both *in silico* analysis and by testing whole organisms **[*pathogen*]** (concentration) or purified nucleic acid from other ***[describe organisms]*** (concentration/reaction).

**Cross-Reactivity: *[test name]* example table for wet tested organisms below**

| Virus/Bacteria/Parasite | Strain | Source/ Sample type | Concentration | Ct Values* |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

***If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**Cross-reactivity studies are preformed to demonstrate that the test does not react with related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen. The FDA Tables 1 and 2, below are intended to recommend simulate testing of patients having infections with organisms which cause similar symptoms to those observed at the onset of 2019-nCoV infection. The FDA Tables also include other organisms and strains which have significant genetic similarity and therefore a higher likelihood of cross-reacting with 2019-nCoV specific reagents. Also included in the FDA Tables are recommended unclaimed organisms/strains which are likely to be endemic to the currently affected area should be included in cross-reactivity testing since these organisms/strains will be an important aspect of the differential diagnosis of 2019-nCoV infection.**

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**FDA Table 1 Cross-Reactivity: List of Organisms to be wet-tested and analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens**

| Other high priority pathogens from the same genetic family | High priority organisms likely in the circulating area |
|---|---|
| Human coronavirus 229E | Adenovirus (e.g. C1 Ad. 71) |
| Human coronavirus OC43 | Human Metapneumovirus (hMPV) |
| Human coronavirus HKU1 | Parainfluenza virus 1-4 |
| Human coronavirus NL63 | Influenza A |
| SARS-coronavirus | Influenza B |
| MERS-coronavirus | Enterovirus (e.g. EV68) |
| | Respiratory syncytial virus |
| | Rhinovirus |
| | *Chlamydia pneumonia* |
| | *Haemophilus influenzae* |
| | *Legionella pneumophila* |
| | *Mycobacterium tuberculosis* |
| | *Streptococus pneumonia* |
| | *Streptococcus pyrogenes* |
| | *Bordetella pertussis* |
| | *Mycoplasma pneumoniae* |
| | *Pneumocystis jirovecii* (PJP) |
| | Pooled human nasal wash - *to represent diverse microbial flora in the human respiratory tract* |
| | |

**FDA Table 2 Cross-Reactivity: List of Organisms to be analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens:**

| Other high priority pathogens from the same genetic family | High priority organisms, including organisms commonly found in the clinical matrix |
|---|---|
| | Influenza C |
| | Parechovirus |
| | *Candida albicans* |
| | *Corynebacterium diphtheriae* |
| | *Legionella non-pneumophila* |
| | *Bacillus anthracosis* (Anthrax) |
| | *Moraxella cararrhalis* |
| | *Neisseria elongate and miningitidis* |
| | *Pseudomonas aeruginosa* |
| | *Staphylococcus epidermis* |
| | *Staphylococcus salivarius* |
| | *Leptospirosis* |

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| | |
|---|---|
| | *Chlamydia psittaci* |
| | *Coxiella burneti (Q-Fever)* |
| | *Streptococcus aureus* |
| | |

***In silico* analysis should be performed on all potentially cross-reactive organisms outlined in the FDA Tables 1 and 2 above. You should provide the result summary of the *in silico* blast analysis (tabular format) evaluating whether there is any significant amplification of non-target sequences that could either result is cross-reactivity or potentially interfere with the detectability of the actual target analyte. As such we are asking that you provide individual blast results (non-truncated alignments) for each of the primers and probes used in your device with potential cross-reacting organisms. Please provide for our review the percent sequence homology for each organism relative to the target analyte primers/probes in your test. Please use the example table below when presenting the results of *in silico* analysis in your submission:**

**Results of *In Silico* Analysis**

| Pathogen | Strain | GenBank Acc# | % Homology Test FP (i.e. 0-100%) | % Homology Test RP | % Homology Test Probe |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**The analysis should include multiple representative strains from GenBank for each organism. If *in silico* analysis reveals other potential cross-reactants (i.e., ≥80% homology between one of your primers or the probe to any of the sequences of listed potential cross reactants), you should carefully review the alignments and determine based on the positions of the homologous stretches and mismatches if additional cross-reactivity and/or interference (please refer to item b below – microbial interference studies) wet testing will be required to rule out cross-reactivity or interference of that organism that may affect the performance of your device. In these circumstances if wet-testing is omitted you should include an explanation as to why *in silico* generated data is not clinically relevant (irrelevant isolate, location/extent of match within primer/probe, etc.), or why the performance of your test would not be impacted.**

**Organisms in FDA Table 1 should be wet tested in addition to the *in silico* analysis. Omissions from wet-testing should be discussed with FDA and supported by a well-documented justification that includes a due diligence attempt to obtain the live or inactivated organisms (and/or purified nucleic acid – which is acceptable for cross reactivity evaluation for an EUA).**

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**The wet testing evaluation should reflect test specimens prepared at the highest clinically relevant level of organism (i.e., a minimum of $10^6$ CFU/ml or higher for bacteria and $10^5$ $TCID_{50}$/mL or PFU/ml or higher for viruses) and should be tested with a minimum of three replicates per organism test specimen. Test specimens can be prepared by spiking cultured isolates/inactivated organisms/ purified nucleic acids (whole genome) into negative clinical matrix and determining cross reactivity based on triplicate replicates. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix.**

**If you plan to claim non-blood or non-respiratory clinical specimen types for diagnostic use with your device, e.g., stool specimens, etc., please consult FDA for more information on additional organisms that may be recommended for cross-reactivity testing, common examples are provided below for stool specimens (FDA Table 3):**

**FDA Table 3: Organisms to be analyzed for non-blood clinical specimens:**

| **Stool** |
|---|
| *Escherichia coli* |
| *Lactobacillus* |
| *Bacillus* spp. |
| *Clostridium* Spp. |
| *Enterobacter* |
| *Enterococcus* |
| Fusobacterium |
| Bacteroidetes |
| Bifidobacterium |
| Ruminococcus |
| |

b) *Microbial Interference Studies:* **If *in silico* analysis reveals ≥ 80% homology between the cross-reactivity microorganisms and your test primers/ probe(s), we recommend that you either perform (1) a microbial interference study with 2019-nCoV and the microorganisms that your test primers/ probe(s) have homology to, (2) as an alternative to the microbial interference study, you may provide justification as to why (e.g., amount of primer(s)/ probe(s) included in your master mix) the performance of your test would not be impacted by the presence of a causative agent of a clinically significant co-infection, or (3) explain why the *in silico* results are clinically irrelevant. In the case of the microbial interference study, interference should be evaluated using samples spiked at a low 2019-nCoV concentration, at 3x LoD, and a high interferent level (either microorganisms or nucleic acids purified from them), to represent the worst-case scenario, with a minimum of 3 replicates. If you plan to claim more than**

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**one type of blood clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix. If the LoDs are similar in the blood clinical matrices the study should be performed in the most challenging matrix, i.e., whole blood. In addition, if you are claiming blood and non-blood clinical specimens you may be required to perform this study in more than one clinical matrix. If interference is observed at the level tested, an additional titration study should be performed to determine the highest microorganism interferent level the 2019-nCoV test can tolerate.**

**c)** *Endogenous Interference Substances Studies*: **The extent of testing for endogenous interference substances depends on the matrix that is claimed for the device as well as on the technology of the device, e.g., if a nucleic extraction procedure is performed prior to testing or not. For EUA we do not typically ask for interference studies for tests that use conventional PCR and/or well-established extraction methods prior to testing (e.g., Boom method and column-based extraction methods).**

**For extraction procedures that are new or for nucleic acid-based technologies that are different from conventional PCR (e.g., various isothermal methods), we expect testing of potential interferents. The impact of interfering substances should be evaluated over the expected clinical range of the potentially interfering substance. Potential sources of endogenous interference include, but are not limited to, the ones listed in the tables below. It is important to note that the evaluation of interference and the generation of false negative results should be done using samples containing the analyte at or near the LoD and should not exceed 3x LoD. You should test a minimum of 3 replicates per substance. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed between the different clinical matrices this may warrant this study being performed in more than one clinical matrix. Biotin interference poses a risk to laboratory tests that incorporate the free biotin-streptavidin capture method. Therefore, please review this safety communication [ HYPERLINK "https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication" ] and the following [ HYPERLINK "onenote:http://sharepoint.fda.gov/orgs/CDRH-IVD/Orgs/DMD/DMD%20OneNotes/Language/Analytical%20Studies/Interference.one" \l "DRAFT%20guidance%20-%20Testing%20for%20Biotin%20Interference%20in%20In%20Vitro%20Diagnostic%20Devices&section-id={39D67316-5AE2-4791-958F-9387D384D6FA}&page-id={9298F00C-7C39-43CB-9EBA-29E5BC08BB6E}&end" ] ([ HYPERLINK "http://sharepoint.fda.gov/orgs/CDRH-IVD/Orgs/DMD/_layouts/OneNote.aspx?id=%2Forgs%2FCDRH-IVD%2FOrgs%2FDMD%2FDMD%20OneNotes%2FLanguage&wd=target%28Analytical%20Studies%2FInterference.one%7C39D67316-5AE2-4791-958F-**

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**9387D384D6FA%2FDRAFT%20guidance%20-%20Testing%20for%20Biotin%20Interference%20in%20In%20Vitro%7C9298F00C-7C39-43CB-9EBA-29E5BC08BB6E%2F%29" ]) to determine if biotin interference testing may be warranted for your device. We also recommend you consult with FDA prior to initiating biotin interference testing, if applicable.**

**The tables below indicate the potentially interfering substances that may be found in blood and respiratory specimens. For other non-blood specimen types, such as stool, the list of substances could be expanded – please consult with FDA.**

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *positive* results:**

| Potential Interfering Substance | Concentration | Results (Detected X/3) |
|---|---|---|
| **Respiratory Specimens** | | |
| Mucin: bovine submaxillary gland, type I-S | | |
| Blood (human) | | |
| Nasal sprays or drops | | |
| Nasal corticosteroids | | |
| Nasal gel | | |
| FluMist | | |
| Homeopathic allergy relief medicine | | |
| Throat lozenges, oral anesthetic and analgesic | | |
| Anti-viral drugs | | |
| Antibiotic, nasal ointment | | |
| Antibacterial, systemic | | |
| **Blood Specimens** | | |
| Hemoglobin | 10 mg/mL* | |
| Bilirubin Conjugated | 0.4 mg/mL* | |
| Bilirubin Unconjugated | 0.4 mg/mL* | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | |
| Triglycerides | 15 mg/mL* | |
| Cholesterol | 4 mg/mL* | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | |
| Rheumatoid Factor | 2000 IU/mL* | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *negative* results:**

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| Potential Interfering Substance | Concentration* | Viral Strain Level (In multiples of LoD) | Results (Detected X/3) |
|---|---|---|---|
| **Respiratory Specimens** | | | |
| Mucin: bovine submaxillary gland, type I-S | | | |
| Blood (human) | | | |
| Nasal sprays or drops | | | |
| Nasal corticosteroids | | | |
| Nasal gel | | | |
| FluMist | | | |
| Homeopathic allergy relief medicine | | | |
| Throat lozenges, oral anesthetic and analgesic | | | |
| Anti-viral drugs | | | |
| Antibiotic, nasal ointment | | | |
| Antibacterial, systemic | | | |
| **Blood Specimens** | | | |
| Hemoglobin | 10 mg/mL* | | |
| Bilirubin Conjugated | 0.4 mg/mL* | | |
| Bilirubin Unconjugated | 0.4 mg/mL* | | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | | |
| Triglycerides | 15 mg/mL* | | |
| Cholesterol | 4 mg/mL* | | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | | |
| Rheumatoid Factor | 2000 IU/mL* | | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

### 3) *Matrix Equivalency (if applicable):*

**A matrix equivalency study may be used to support certain specimen type claims that were not evaluated during the clinical study (e.g., serum versus plasma, use of different anticoagulants, use of difference swab types or viral transport media, etc.). Please note that LoD and clinical specificity studies are required for all claimed matrices. The matrix in which the clinical studies are conducted is the comparator. All other matrices are to be shown to be equivalent to the comparator matrix. We request a minimum of 40 paired samples each obtained from individual persons; negative (10 samples), low positive (1.5-2xLoD, 20 samples), and moderate positive (5-10xLoD, 10 samples) samples should be tested. Positive samples are prepared by spiking paired negative clinical matrix with the same amount of target analyte. Please note that individual (and not pooled) samples should be used in this study.**

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4) ***Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method:***

**A comparative LoD study may be required to support use of a comparator method in your clinical evaluation that has not been validated with a specific specimen type. The comparative LoD study should be conducted testing the same dilution series using both, your test and the comparator you chose in parallel (to dilution endpoints for both tests), 3-5 replicates per dilution level are sufficient for this study.**

5) ***Specimen Stability and Fresh-frozen Testing:***

**A specimen stability study may be required to support specimen stability claims in the instructions for use outside of those typically outlined in CSLI standards. A fresh/frozen and/or freeze/thaw study may be required to support the use of frozen specimens if they are used as part of the clinical evaluation. Please consult with FDA concerning an appropriate study design prior to initiating any studies.**

6) ***Clinical Evaluation:***

**This section should describe the clinical study used to evaluate the performance of your test. Please note that the exact requirements for the clinical evaluation will be very dependent on, access to 2019-nCoV disease clinical specimens at the time of the studies and the nature of the emergency. Our general clinical study evaluation recommendations for respiratory and serum clinical specimens are outlined below. If you are interested in claiming additional specimen types, for example, stool, please contact FDA for current recommendations. Please note these clinical study recommendations may be subject to change as we continue to learn about the 2019-nCoV disease or as the risk benefit analysis changes.**

**The clinical performance in general should be evaluated for each unique claimed clinical specimen type - with the exception of claims that can be supported by a matrix equivalency study (outlined in Section 3 above). The performance characteristics should ideally be established using a clinical study with a limited number of prospective samples. If a prospective study is not feasible, an acceptable alternative would be to test retrospectively collected 2019-nCoV nucleic acid negative and positive specimens from patients, accompanied by some basic information such as, the specimen collection date, date of onset of symptoms (if present/known), tests used to identify 2019-nCoV nucleic acid positive specimens, etc. Depending on the nature of the disease, if no prospective or retrospective specimens are**

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**available at the time of your pre-EUA submission for the 2019-nCoV disease we may accept a fully contrived clinical evaluation. The clinical evaluation should be comprised of a minimum of 100 negative individually collected specimens and 50 individual positive specimens (prospective, retrospective and/or contrived). Use of pooled specimens are not acceptable for the clinical evaluation of your test. Please see FDA Table 5 for more details. Please note that if a fully contrived clinical study is used to support your Pre-EUA submission, additional clinical testing of a limited number of natural clinical positive specimens and potentially negative specimens from the endemic region, if available, may be required at the time when this Pre-EUA transitions to an EUA as a result of an Emergency declaration for 2019-nCoV disease.**

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## FDA Table 5: Clinical study Recommendations:

| Details | Study Including Prospective/ Retrospective Specimens | Fully Contrived Sample Study |
|---|---|---|
| Minimum Number of Positive Specimens | 50<br><br>The number of natural (prospective/retrospective) positive clinical specimens should be at least 25 (collected from symptomatic patients in the 2019-nCoV disease endemic region(s)) and, if necessary, may be supplemented with contrived samples to generate the total of 50 positive specimens. Contrived samples should be prepared as described in the fully contrived sample study column. | 50<br><br>The contrived positive samples should be made in individual negative clinical matrix collected from subjects from a non-endemic population (pooled matrix is not acceptable for the clinical evaluation). Please note that the negative clinical matrix used for spiking should be confirmed negative by your test device prior to spiking. Half of the contrived positive samples can be prepared by spiking the 2019-nCoV at LoD and the remaining contrived positive samples should cover the range of the test up to and not higher than 5 x LoD.<br><br>Negative respiratory specimens: Can be archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection.<br><br>Negative blood specimens: Can be collected from healthy subjects from non-endemic areas. |
| Minimum Number of Negative Specimens | 100<br><br>Note: In general, for EUA the 100 individual negative samples can be collected from; (1) archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection for respiratory specimens, and (2) healthy subjects from non-endemic areas for blood specimens, that are "expected 2019-nCoV disease negative". Note these negative specimens can be used to also prepare any contrived positive specimens used in support of the clinical evaluation of the test.<br><br>Please note this recommendation is dependent on the current outbreak situation and is subject to change as we learn more about the 2019-nCoV disease/outbreak. If the outbreak situation for 2019-nCoV disease is primarily outside of the continental U.S. (OUS) it may be beneficial to consider collecting negative specimens that represent 50% endemic and 50% non-endemic regions. If negative specimens are collected from the endemic region of the 2019-nCoV disease these should be tested with the same comparator chosen for the positive specimens (more details provided below). For non-endemic collected specimens you can compare to the expected "negative" result. | |
| Recommended Comparator Method | Positive: Positive percent agreement should be calculated in comparison to a EUA PCR test (please see the following website for the most recent list of FDA authorized 2019-nCoV | Positive: Compare to expected result.<br><br>Negative: See Minimum Number of Negative Specimens row |

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| | | |
|---|---|---|
| for percent agreement performance calculations | tests: [ HYPERLINK "https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm" ]. If no EUA test available at the time of your EUA submission, please consult with FDA about your choice of comparator method – which ideally should be a well validated PCR test with comparable sensitivity to your subject device. Please note that a well validated PCR test should include evaluation of the tests LoD, inclusivity, exclusivity, interference and any clinical testing.<br><br>Negative: See Minimum Number of Negative Specimens row | |
| Comparator Method Note 1 | Please note when using natural clinical specimens, the comparator method must be validated for the specimen type claimed – if not you should perform a Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method study, as explained above (Section 4), to support its use as a comparator method in your clinical study. | N/A |
| Comparator Method Note 2 | Any occurrences of false results should be investigated with an additional validated PCR test and/or targeted sequencing, and the results of the discordant analysis can be footnoted in your final performance table but cannot be used to change the final performance calculations. | |
| Natural Clinical Specimens IRB/Informed Consent Note | For clinical specimens collected to support the EUA request, please note that sample collection needs to adhere to all applicable rules of human subject protection; as such, sample collection needs IRB approval, which includes review of the informed consent forms. Samples need to be collected with informed consent. If leftover de-identified samples are used, FDA exercises enforcement discretion regarding the informed consent requirement if the specimen collection meets the criteria described in the FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable ([ HYPERLINK "http://www.fda.gov/cdrh/oivd/guidance/1588.pdf" ]).<br>**Note that IRB approval is still required even if leftover de-identified samples are used in your study.** | |
| Additional Studies Warning | N/A | If fully contrived samples were used in your Pre-EUA submission, additional testing of natural clinical specimens may be requested, if available, to support transition of the Pre-EUA to EUA as a result of an Emergency declaration. |
| Testing Approach Note 1 | Please note all clinical specimens (natural and contrived) should be evaluated in accordance with your proposed diagnostic algorithm, including retesting when appropriate. We understand the limited nature of natural specimens may preclude retesting. In instances were retesting is indicated but not performed, for the purposed of performance evaluation, initial results will be analyzed for performance and equivocal/indeterminate results count against your final performance. | |
| Testing Approach Note 2 | Specimens should be tested in a blinded fashion, e.g., positive and negative samples should be mixed and blinded to the end user, end user should also be blinded to the results of any comparator method testing. | |

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**When you describe your clinical study please indicate/include:**

- **How the specimens were generated/collect/sourced**
- **If the study was fully prospective, mix of prospective, retrospective and/or contrived or fully contrived**
- **The rationale for the concentrations/specimens selected (if using contrived or 3-party sourced specimens)**
- **The total number of specimens tested**
- **The specimen types (clinical matrix)**
- **A summary of the study results**

**In the case of real-time PCR tests, please provide the line data in an Excel file as part of the Pre-EUA submission for each specimen (please indicate for each specimen if it was prospective, retrospective or contrived and the clinical matrix it represents); the data should include the $C_T$ values (for the specimen and the controls) and call/result for your device and, in the case of the natural clinical specimens, the comparator method results should be included as well.**

## L. UNMET NEED ADDRESSED BY THE PRODUCT

**This section will be finalized by FDA based on the state of the emergency at the time of authorization and based on recommendations from Public Health authorities at that time. Example text is provided below but may be adapted according to the specific emergency situation that is addressed by the device and the need at the specific time of the outbreak.**

[Outline background of pathogen, disease and current outbreak]

[Outline details of the disease such as the following:

- likely sources of transmission
- likely symptoms – if any
- Prevalence of symptomatic disease (what fraction of infection results in symptomatic disease)]

Laboratories in the United States are in need of diagnostic tools for use in the 2019-nCoV emergency for rapid diagnosis of acute 2019-nCoV infection.

A public health emergency has been declared by the Secretary of Health and Human Services (HHS) on [Month Day, YEAR] justifying the authorization of emergency use of *in vitro* diagnostic tests for detection of 2019-nCoV and/or diagnosis of 2019-nCoV infection.

The ***[test name]*** can augment clinically important laboratory evidence for individuals with active infection. The 2019-nCoV nucleic acid is generally detectable in [name

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specimen type] during the acute phase of infection (approximately [7] days following onset of symptoms, if present) [and possibly for longer in other specimen types].

Under emergency use authorization (EUA), ***[applicant name]*** plans to distribute the test or accept sample for testing with the ***[test name]*** for the detection of nucleic acid from 2019-nCoV in clinical specimens collected from individuals meeting CDC's 2019-nCoV clinical and/or epidemiological criteria. This EUA request for the ***[test name]*** is intended to expand domestic readiness within the United States and its territories by expanding diagnostic testing capabilities for 2019-nCoV during public health emergency.

FDA consulted with subject matter experts within HHS on the public health needs for diagnostic devices to detect 2019-nCoV nucleic acid. It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for 2019-nCoV detection during the public health emergency.

## M. APPROVED/CLEARED ALTERNATIVE PRODUCTS

Currently no methods for the detection of the 2019-nCoV have been approved/ cleared by FDA.

## N. RISKS AND BENEFITS:

**The Risks and Benefits section should be updated according to your specific device, some example language is given below but should be tailored to the device and the disease.**

Risks

The ***[test name]*** has been designed to minimize the likelihood of false test results. However, should false results occur, they may present risks to patients:

- False positive result:
  - A false positive 2019-nCoV result could [***update based on the pathogen***].
  - A false positive result in the context of the current public health emergency could lead to misallocation of resources used for surveillance and prevention.
  - A false positive result could delay correct diagnosis and initiation of appropriate treatment for the actual cause of patient illness.
- False negative result:
  - Although a negative result does not rule out 2019-nCoV infection, a false negative has the potential to result in initiation of inappropriate treatment and a delay in correct diagnosis.
  - A false negative result can trigger a waste of health care resources, as additional evaluations are pursued in the effort to establish the true diagnosis.
  - A false negative results can contribute to further spread of the disease.

Benefits

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The primary benefit of distributing the ***[test name]*** for clinical use is that it provides a relatively fast diagnostic method for symptomatic patients, which enables faster intervention.

- True positive test results provide support for the diagnosis of a 2019-nCoV infection. The results can be used in conjunction with clinical and epidemiological information to guide patient management.
- Distribution of the factsheets can help healthcare professionals and the public learn more about 2019-nCoV disease and how to avoid acquiring it.

Risk Assessment

- Negative results may not preclude a 2019-nCoV infection. It is emphasized that the ***[test name]*** should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure must be considered pivotal to making patient management decisions. A negative test should not be interpreted as definitive, if other aspects of the patient's clinical presentation or recent epidemiologic exposures indicate such is likely, and diagnostic tests for other diseases are negative.
- False negative results due to failure of PCR are minimized by the presence of controls that monitor nucleic acid extraction and PCR efficiency.
- Risk of patient discomfort or harm during sample collection is minimal.

Risk-Benefit Assessment

The risks posed by use of the ***[test name]*** are mitigated by:

- Use of the ***[test name]*** in conjunction with other laboratory, epidemiological, and clinical evaluation tools
- Distribution of Healthcare Provider and Patient fact sheets.
- Post-market studies/reporting or conditions of Authorization.

Based on these factors, the potential benefits from the use of the ***[test name]*** are expected to outweigh the risks.

## O. FACT SHEET FOR HEALTHCARE PROVIDERS AND PATIENTS:

**Include proposed Fact Sheets for Patients and Healthcare Providers**

## P. INSTRUCTIONS FOR USE/ PROPOSED LABELING/PACKAGE INSERT:

**Include Instructions for Use, Box Labels, Vial Labels and any other proposed labeling.**

## Q. RECORD KEEPING AND REPORTING INFORMATION TO FDA:

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[***Manufacturer name***] will track adverse events and report to FDA under 21 CFR Part 803. A website is available to report on adverse events, and this website is referenced in the Fact Sheet for Health Care providers as well as through the [***Manufacturer name***] Product Support website: [***Include link to Website***]. Each report of an adverse event will be processed according to [***Manufacturer name]***'s Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the FDA as required. Through a process of inventory control, [***Manufacturer name]*** will also maintain records of device usage/purchase. [***Manufacturer name]*** will collect information on the performance of the test, and report to FDA any suspected occurrence of false positive or false negative results of which [***Manufacturer name]*** becomes aware. [***Manufacturer name]*** will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

## R. ADMINISTRATIVE INFORMATION:

**Interactive Review Log:** Please use the table below to document interactive review with FDA and include interactions initiated by either FDA or yourself

| **Date** | **Type of Interaction** (phone/ email/ formal submission-DCC) | **Brief Description** (e.g., questions asked/ feedback from FDA received / any word documents included) |
|---|---|---|
| [X] | [X] | [X] |
| | | |
| | | |

## S. FDA ADMINISTRATIVE INFORMATION:

**This section will be finalized by the FDA Lead Reviewer upon completion of the review process and documents the interactive review of this submission and any conclusions resulting from the interactive review.**

1) **Summary of Interactive Review – Lead Reviewer to use this section to highlight any major issues solved during interactive review.**
2) **Final Conclusions for Interactive Review -** It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for [pathogen] detection during the public health emergency. **Conclusion should include an outline the unique features of the device compared to currently issued EUA's under the declaration, if applicable.**
3) **Upon competition of this section the Lead Reviewer should also sign this document and save the file as the final Decision Memorandum.**

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## APPENDIX A – Multiplex Panels Under EUA:

An emergency declaration by the HHS Secretary is typically specific for a pathogen/disease (i.e., there is a publicly declared health emergency involving a particular etiologic agent). Therefore, the EUA pathway is only applicable for testing patients with signs/symptoms/risk of exposure for that single agent in a given emergency. FDA has occasionally allowed limited additional target pathogens to be claimed for EUA devices, but panel members must be relevant to the event/disease outbreak subject of the specific emergency declaration. When determining whether to issue an EUA for a multiplex panel FDA takes into consideration the utility of the test (multiplex pathogen detection as an aid in differential diagnosis), clearance/approval status of IVDs for the other panel members, whether the proposed Intended Use fits within the HHS emergency declaration and the how the multiplex panel would fit into current public health authority patient testing algorithm recommendations. We recommend you contact FDA for specific feedback if you plan to claim multiple target analytes as part of your EUA test. If it is determined that a multiplex test is beneficial to the emergency response, please note that analytical and clinical evaluations for each of the target analytes will be required.

## APPENDIX B – General Study Design Recommendations for Reagent Stability:

- For EUAs you may follow the current FDA recognized CLSI Standard EP25 – Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline when evaluating the suitability of stability study designs. If you are planning to pursue a De Novo/510(k) for your device we recommend discussing in more detail your stability design to facilitate potential use of the EUA data in your regular premarket submission.
- Please note that use of only the positive controls is not acceptable for reagent stability evaluation because controls are usually formulated at a moderate positive level. For all the stability evaluations in addition to your external positive and negative controls and the no-template control you should include for the EUA evaluation at least one sample, that should be prepared by spiking negative clinical matrix at an analyte concentration of 3-5xLoD.
- If you are claiming multiple blood clinical specimen types in which similar LoDs are determined, you should use the most challenging clinical matrix for this study.
- Please note we typically recommend your stability study design includes the evaluation of at least 5 replicates. You should also evaluate, if available, 3 different lots of reagents.
- You should design your study to provide data for a timeframe that is about 10% longer than the one to be claimed – for example; a claim of 18 months should be supported by stability data out to 20 months and a claim of 7 days should include stability data out to 8 days.
- FDA considers 15-30°C to represent room temperature conditions. Ideally you should evaluate stability at both 15°C and 30°C, however, for the purposes of the EUA evaluation at 30°C is acceptable as the worse-case scenario.
- Shelf-Life Stability- Unopened kit:
    - You should evaluate real-time kit stability studies with unopened kits stored at the claimed storage temperature for your test.

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  - Accelerated stability evaluations for unopened kits is acceptable for EUA submissions while the real-time studies are on-going. However, please note real-time stability data is required to support regular pre-market submissions and for the final claim of an EUA.
- Shipping Stability - Unopened kit: Study should evaluate the anticipated handling and shipping times and temperatures expected for unopened kits.
- In-use/Opened Kit Stability: Depending on your device your stability study design should also support in-use stability of the kit reagents once the kit has been opened, e.g., storage at 2-8 $^{o}$C for 7 days. This includes on board stability once reagents have been placed on the instrument (if applicable).
- Inverted stability (if applicable): Study should support inverted stability for of kits.
- Freeze-thaw Stability: If you recommend aliquoting the reagents to meet the end-users needs following the initial thaw this recommendation should be supported by a freeze-thaw stability study, including the specific number of allowed freeze-thaw cycles.
- FDA analysis recommendations for real time stability studies are as follows:
  - Baseline of the study (t=0 of stability study) should not exceed a month from bottling
  - Clear baselines should be described (e.g., a month from bottling) for each stability claim under each study
  - Claims should be determined based on regression analysis. Any %change (%shift) from time zero (baseline) should be calculated between the target claim and the zero-time as (Ttest-Tbaseline)/ Tbaseline*100 with 95%CI using the regression equation obtained from plotting the mean values. When formulating your acceptance criteria for evaluating the shift from baseline you should consider the reproducibility of your device. However, generally, that the shift at the target claim due to storage cannot exceed 10-15%. The target stability is the next to last tested point that was within +/- 10% of time zero.
  - Acceptance criterion may be different, depending on the test samples analyte concentration distribution in the intended use population and the risk, in other words, the impact of false results to public health.

**APPENDIX C – Claiming Multiple Instruments and/or Extraction Methods:**

If you wish to claim multiple instruments and/or extraction methods for use with your test, please review the study recommendations provided below and contact FDA for any additional feedback. Please note that these analytical and clinical evaluation recommendations are based on the assumption that the elution volumes from the extraction methods and PCR volumes on the different RT-PCR instruments are identical.

- Limit of Detection (LoD): Please note that these studies should be repeated for each clinical matrix claimed in the Intended Use. Pick one RT-PCR instrument and determine the tentative LoD (using 5 replicates in 10-fold dilution) followed by the confirmatory LoD (20 replicates spiked at tentative LoD) for each extraction method on the chosen instrument. Note: If you detect 20/20 replicates in your confirmatory LOD study you should test the next lower concentration, using a 3-fold dilution, until

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you achieve a hit rate of <20/20.

- If the different extraction methods yield the same LoD (≤3xLOD) on the RT-PCR instrument chosen for initial testing, pick one extraction method for further LoD determination on the remaining RT-PCR instruments and follow the recommendations below.
- If the extraction methods do not yield the same LoD on the chosen RT-PCR instrument, please choose the extraction method with the worst LoD for further comparison of the LoD on all RT-PCR instruments.

For all other RT-PCR instruments you should use the following adaptive LoD study design:

- Please perform a refined tentative LoD study with 5 replicates at 0.5x, 1x, and 1.5 to 2x LoD. If you detect 4/5 replicates as positive at all the tested levels, you need to include the next higher concentration (i.e., 3x LoD). If you obtain 5/5 replicates at 0.5x LoD, you need to test the next lower concentration (i.e., 0.25x LoD). You will test in this manner until you find the lowest concentration that gives you 5/5 positive results for the tested RT-PCR instrument. This concentration should be used for a confirmatory LoD study for the given RT-PCR instrument using 20 replicates.

Final reported LoD: Please list all RT-PCR instruments with their respective LoDs if different LoDs are obtained. LoDs are considered comparable if they are between 1-3xLoD. These studies should be repeated for each clinical matrix claimed in the Intended Use.

- Interference Substances Studies (if applicable): Pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Inclusivity Testing: For the inclusivity testing, pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Exclusivity Testing: For exclusivity, you can perform this study using any extraction/instrument combination.

- Clinical study: If equivalency of the RT-PCR instruments is shown in an LoD study that tests and confirms that the LoD is the same or very similar for all of the RT-PCR instruments (between 2-3xLoD), then you can pick one RT-PCR instrument for your clinical study provided that the RT-PCR instruments in question are known to FDA for other *in vitro* diagnostic devices. If you find that one or more RT-PCR instruments machines has/have a different LoD, you should pick the extraction method / RT-PCR instrument combination with the worst LoD.

Note, if there are differences in the extraction input volume, extraction elution volume

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and PCR input volume (extracted nucleic acid) then the LoD should be confirmed, for each.

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**[Date]**

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**ATTN:** Division Director: Dr. Uwe Scherf**,** OHT7-OIR/OPEQ/CDRH/FDA

**RE:** Request for Pre-Emergency Use Authorization (Pre-EUA) of the [*Name of the Assay*]

**Dear Dr. Scherf,**

[***Name of the Company***] is submitting a Pre-Emergency Use (Pre-EUA) for the [***Name of the Medical Device Product***] so we can obtain feedback from FDA concerning the studies and/or testing outlined in our Pre-Emergency Use Authorization (Pre-EUA) submission package.

The [***Name of the Medical Device Product***] is [***brief description of the device***] and [***intended use***].

Attached to this letter is the first draft of our device EUA Interactive Review Template for FDA review as a Pre-EUA. One hard copy of the signed EUA Cover Letter and one electronic copy are enclosed. Also, these documents have been sent to you via email.

In case you should have any questions regarding the information provided and/or need additional information/data from us please contact me immediately either via email [_____] or phone [_____].

Sincerely,

[***Name***]

[***Signature block***]

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/29/2020 9:57:41 AM
**To**: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]
**CC**: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]
**Subject**: RE: Potential diagnostic EUA for coronavirus PR

Megan,

Sorry, not update on timing, waiting still for analytical and clinical data, CDC has staffing issues.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 9:27 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
**Subject:** Potential diagnostic EUA for coronavirus PR

Hi all – I've pulled together a very rough draft of a press release re: a potential EUA for a CDC diagnostic. Do you have an update on the timing? And is there any information on the kind of test it is that you can share so that I can start filling in some of the blanks or XXs in the attached draft? Thank you!

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**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






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U.S. FOOD & DRUG ADMINISTRATION

Febuary XX, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
Atlanta, GA 30333

Dear Dr. Redfield:

(b) (5) Draft

[redacted]

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(b) (5) Draft

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(b) (5) Draft

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(b) (5) Draft

[redacted]

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/24/2020 8:17:36 AM
**To**: Dowtin, Lesa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a58cf27088244caa863aa4f57a9b11ad-LXV]
**CC**: Draper, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4b05cc2fa5f4ed3b3ffc6cf62039d06-Jennifer.Dr]
**Subject**: RE: Request for overtime pay

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 7:58 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Cc:** Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Colleli, Karen M <Karen.Colleli@fda.hhs.gov>; Draper, Jennifer <Jennifer.Draper@fda.hhs.gov>
**Subject:** FW: Request for overtime pay

Hi Bill,

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Please send your signed request to Jennifer Draper or Karen Colleli and they will verify the employee's eligibility.

Thanks

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:46 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

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AMERICAN OVERSIGHT

Lesa and/or Daniel, can we authorize OT for Title 42?

Bill

**William H. Maisel, MD, MPH**
*Director, Office of Product Evaluation and Quality*
*CDRH Chief Medical Officer*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 301-796-5550
william.maisel@fda.hhs.gov




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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:42 PM
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Dear Bill,

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Uwe

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*Director, Division of Microbiology Devices*

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AMERICAN OVERSIGHT

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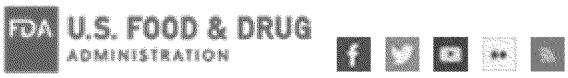
**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:18 PM

**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

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Thanks
Bill

**William H. Maisel, MD, MPH**
*Director, Office of Product Evaluation and Quality*
*CDRH Chief Medical Officer*

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Tel: 301-796-5550
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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 5:04 PM
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** Request for overtime pay

Dear Bill,

As you have seen from the DMD updates and the information in the press, the 2019-nCoV situation has been very challenging.

Our interactive review and teleconferences indicated that CDC will send CDRH a completed EUA review template any time soon. The staff has been fabulous and supporting the program 200%. I am anticipating CDC data to be reviewed over the weekend and a complete EUA review package next week. As soon as the emergency is declared we anticipate additional documents from commercial sponsors. This work is on top of the regular review work and I feel obliged to assure appropriate compensation for my staff. Attached please find the request form for overtime for your consideration.

Thanks, Uwe

AMERICAN OVERSIGHT

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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uwe.scherf@fda.hhs.gov

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AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/24/2020 11:24:58 AM
**To**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]
**Subject**: RE: Request for overtime pay

Thanks, Uwe

---

**From:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 10:31 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

I signed off on these. Just FYI – overtime requests can be handle at the office level so these do not need to go to Bill in the future.

**Donald St.Pierre**
*Deputy Director, New Product Evaluation*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 3414 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5454
Don.St.Pierre@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 9:18 AM
**To:** Colleli, Karen M <Karen.Colleli@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Draper, Jennifer <Jennifer.Draper@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Karen,

Thanks, attached the updated form, I included Anna to the names of the larger group.

Please let me know whether you need anything else.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Colleli, Karen M <Karen.Colleli@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 9:11 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Draper, Jennifer <Jennifer.Draper@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Subject:** RE: Request for overtime pay

Hi Uwe,

There should not be more than 4 pay periods included on each form. Please complete block 3.e to show PP 3, 4, 5, 6 and change block 3.f to show 01/24/2020 to 03/14/2020.

*Karen Colleli*
**Management Analyst**

**Operations Staff**
**Office of Product Evaluation and Quality**

**CDRH/Food and Drug Administration**
**White Oak, Bldg. 66, Rm. 1518 / 10903 New Hampshire Avenue / Silver Spring, MD 20993**
Ph: 301-796-5565 / Fax: 301-847-8120
Karen.Colleli@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1021&S=E

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 8:58 AM
**To:** Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Draper, Jennifer <Jennifer.Draper@fda.hhs.gov>; Colleli, Karen M <Karen.Colleli@fda.hhs.gov>
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**Subject:** RE: Request for overtime pay

Lesa,

Thanks, attached the updated form for Anna Mielech. She is title 42 with a salary equivalent to a GS12/7 grade.

Thanks for your help.

Uwe

AMERICAN OVERSIGHT

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Dowtin, Lesa <Lesa.Dowtin@fda.hhs.gov>; Montgomery, Daniel R <Daniel.Montgomery@fda.hhs.gov>
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**William H. Maisel, MD, MPH**
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AMERICAN OVERSIGHT

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**Subject:** RE: Request for overtime pay

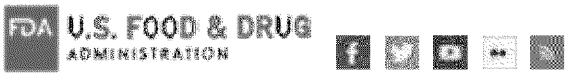
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*CDRH Chief Medical Officer*

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AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/24/2020 1:36:59 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Lloyd, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338a759166e74b13a5c9b385cde90eb9-Lindsay.Llo]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Daily 2 PM update

Jeff,

**Status of activities on diagnostics**:

- OCET and OCC support Center recommendation to exercise enforcement discretion to allow CDC to (b)(4), (b)(5) their test
- Additional IVD Developer has requested and received EUA review template [Inbios International]
- Updating FDA 2019-nCoV landing webpage to provide information on cleared respiratory devices on predicting cross-reactivity to 2019-nCoV. BioFire/Biomerieux provided technical note to customer, FDA plans to link to this information and encourage other manufactures of cleared respiratory tests to perform similar analysis and provide this information. [e.g., (b)(4), (b)(5)

**New roadblocks/challenges/delays:**

- Considerations for support (b)(5) – initial phone call with (b)(5) and OCET at 3 PM today

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/31/2020 7:07:40 PM
**To**: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
**Subject**: RE: Potential diagnostic EUA for coronavirus PR

Yes, sorry for the confusion.
Uwe

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Date:** January 31, 2020 at 1:54:40 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

Understood – also, there was no attachment – did you mean to say the information below or was there another document? Thank you!

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 1:52 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

Nothing concrete but we need to be prepared. Uwe

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 1:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

Yes – do you have an update on timing. Thanks!

**Megan McSeveney**
*Press Officer*
**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**

AMERICAN OVERSIGHT

Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 1:48 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

Megan,

Attached please find the intended use of the CDC assay. Could you please update the draft based on this information.

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 9:27 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
**Subject:** Potential diagnostic EUA for coronavirus PR

Hi all – I've pulled together a very rough draft of a press release re: a potential EUA for a CDC diagnostic. Do you have an update on the timing? And is there any information on the kind of test it is that you can share so that I can start filling in some of the blanks or XXs in the attached draft? Thank you!

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/28/2020 1:54:20 PM
**To**: Sally A Hojvat (b) (6)
**Subject**: RE: WHO EPI-WIN Update on 2019-NCoV - 27.01.2020 and questions about developing tests for the virus

Thank, will touch base. Uwe

**From:** Sally A Hojvat (b) (6)
**Sent:** Tuesday, January 28, 2020 1:51 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Sally A. Hojvat (b) (6)
**Subject:** Re: WHO EPI-WIN Update on 2019-NCoV - 27.01.2020 and questions about developing tests for the virus

Hi Uwe,

Thanks for the info . I will pass it on to anyone who asks me about developing a test for 2019-NCoV.

I am open tomorrow or Friday to talk about the last session on Monday.

Let me know what is best for you.

Best,

Sally

On Jan 28, 2020, at 12:32 PM, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov> wrote:

Sally,

Yes, IVD companies should contact CDRH-EUA-Templates@fda.hhs.gov. to receive the review template. It is ready to go and describes the studies. If you talk to any company please emphasize that they should work with us on some of the details regarding LoD and clinical evaluation. Alternative options are considered (in discussion with FDA) depending on availability of materials at the time of validation studies.

The link leads directly to us, and we make the introduction form the Division level, with the review template and a submission letter template.

Government agencies are all working hard to make specimens or a panel available, but nothing concret has emerged yet.

Look forward to see you on Monday, actually would like to chat on the phone with you about the last session sometime later this week or over the weekend.

Best, Uwe

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**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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---

**From:** Sally A Hojvat (b) (6) >
**Sent:** Tuesday, January 28, 2020 10:10 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Sally A. Hojvat (b) (6)
**Subject:** Fwd: WHO EPI-WIN Update on 2019-NCoV - 27.01.2020 and questions about developing tests for the virus
**Importance:** High

Hello Uwe,

Attached is what WHO are distributing to update countries on the status of the 2019-NCoV outbreak.
Was asked to pass this information on to the appropriate individuals at FDA by my contacts at WHO.
You are probably getting this through other channels but sending it in case you are not.

I am beginning to get enquiries from IVD developers who are planning to make tests for the 2019 -NCoV virus and, I see that CDC are distributing primers and probes for molecular tests and information on how to run their version of a test , but have not seen a Declaration of Emergency from HHS published yet.

However, it looks as though this may be in the works, as FDA's website (below) indicates an IVD company to contact CDRH-EUA-Templates@fda.hhs.gov.

Is that a correct assumption?

Is that link leading them to someone in DMD who will send a template for either a molecular or serological test or how are you getting info. out to developers and who should they contact?

Also the fact that this already seems widespread may mean that FDA/CDC/NIH are not planning to make specimens or a panel available.

Correct or not?

Best regards and see you on Monday,

Sally

"Being able to quickly and accurately diagnose patients infected with the novel coronavirus is an essential step in helping patients identify the need for care and mitigate the spread of the virus to additional individuals. Currently, there are no commercially

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available products that are authorized to detect novel coronavirus; however, the FDA is actively working to facilitate the development and availability of diagnostics that can detect this virus. The agency is working with public health partners to advance and share the reference materials necessary to facilitate diagnostic development.

The FDA is also requesting that diagnostic test sponsors interested in potential EUA for tests to detect 2019-nCoV contact CDRH-EUA-Templates@fda.hhs.gov for further information and templates."

Begin forwarded message:

**From:** Sadia Shakoor <sadia.shakoor@aku.edu>
**Subject: Fw: EPI-WIN Update on 2019-NCoV - 27.01.2020**
**Date:** January 28, 2020 at 4:33:07 AM EST
**To:** Undisclosed recipients:;

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Style Definition: TOC 1

# CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

For Emergency Use Only

## Instructions for Use

~~Package Insert~~

**Catalog # 2019-nCoVEUA-01~~01~~**
**1000 reactions**

For *In-vitro* Diagnostic (IVD) Use

Rx Only

Centers for Disease Control and Prevention
Division of Viral Diseases
1600 Clifton Rd NE
Atlanta GA 30329

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION



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(b) (5) Draft

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# CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

**For Emergency Use Only**

## Instructions for Use

**Catalog # 2019-nCoVEUA-01**
**1000 reactions**

For *In-vitro* Diagnostic (IVD) Use

Rx Only

Centers for Disease Control and Prevention
Division of Viral Diseases
1600 Clifton Rd NE
Atlanta GA 30329

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

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FDACDRH-p7-003502
MULTI-HHS-20-0522-B, 20-0523-A-003141

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/29/2020 7:36:01 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: RE Intended Use

I like it without the 'current' much better.

So the final intended use now is as follow. Please quality control one final time before I send it to Julie and Steve.

Thanks, Uwe

**Final Intended Use:**
The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 6:44 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** Fwd: RE Intended Use

Thoughts? I am fine with it

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Date:** January 29, 2020 at 5:33:15 PM EST
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: RE Intended Use

Kim, -

(b) (5)

Thanks,

Jennifer

---

**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 5:19 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>

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**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

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**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** January 29, 2020 at 3:15:21 PM EST
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

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**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 3:14 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

Thanks!

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**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 3:00 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

Great. Thank you for clarifying!

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 3:00 PM
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

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**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 2:57 PM

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**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

I can't, but defer to you all..

---

**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 2:47 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

Thanks! (b) (5)

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**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 2:29 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

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**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 2:26 PM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: RE Intended Use

(b) (5)

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**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 2:24 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE Intended Use

My subject line may have been misleading, so as clarification, this is for the letter and all the other documents with the EUA would be consistent with the language in the letter.

---

**From:** Ross, Jennifer
**Sent:** Wednesday, January 29, 2020 2:22 PM
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: CDC HCP and Patient Fact Sheets

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Hello,

Do you have any concerns with this proposed change (red part is new)? (b) (5)

(b) (5)

Thanks,

Jennifer

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/28/2020 1:52:04 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: 2019-nCoV: 1/28/20 2 PM update

**1/28/20 2 PM update**

**Status of activities on diagnostics**:

- Email confirm/memorialize CDRH's exercise of enforcement discretion:
  - Drafted and under review by CDRH & OCC
- Additional IVD Developers, Luminex and Qiagen, have requested and received EUA review template.
- Contacted companies with cleared respiratory panels that detect human coronaviruses to perform bioinformatic analysis against released 2019-nCoV genome sequences
  - Assess whether test predict cross-reactivity
  - Plan to provide information on FDA nCoV landing webpage
  - Companies contacted: (b)(4), (b)(5)

**New roadblocks/challenges/delays:**

- Need clarification on (b)(4), (b)(5) (b)(4), (b)(5) - Telecom scheduled to address issue 1/28/20 3 PM

Summary of sponsors requested and received review template:

- (b)(4), (b)(5) (1/17/20)
- Inbios International (1/23/20)
- Quest Diagnostics (1/24/20)
- Quidel (1/25/20)
- Luminex (1/28/20)
- Qiagen (1/28/20)

Please let me know if you have any questions.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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Ph: 301-796-5456
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/30/2020 7:48:20 AM
**To**: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**CC**: Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
**Subject**: RE: Question on EUA template requests FLAGGING for awareness/review - coronavirus - briefing points for Denise Hinton ahead of E&C subcommittee briefing tomorrow

Megan,

Yes we had 4:

- Altona Diagnostics (1/17/20)
- Inbios International (1/23/20)
- Quest Diagnostics (1/24/20)
- Quidel (1/25/20)

Uwe

---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 7:42 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
**Subject:** Question on EUA template requests FLAGGING for awareness/review - coronavirus - briefing points for Denise Hinton ahead of E&C subcommittee briefing tomorrow

Hi Uwe, thanks so much for all of your help. Can you remind me – did we have any requests for the template before the press release and webpage went live on January 27? Thank you! Megan

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov

AMERICAN OVERSIGHT

U.S. FOOD & DRUG ADMINISTRATION

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 10:38 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>
**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Subject:** RE: FLAGGING for awareness/review - coronavirus - briefing points for Denise Hinton ahead of E&C subcommittee briefing tomorrow

Megan,

Looks good from the diagnostics perspective, but could update the number of IVD developers who have requested the template. As of tonight it is 14.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 10:09 PM
**To:** McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>
**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Subject:** FLAGGING for awareness/review - coronavirus - briefing points for Denise Hinton ahead of E&C subcommittee briefing tomorrow

Good evening – flagging for your awareness and review (and apologies if I have missed anyone!) briefing points that have been developed with OCET, OL, and OMA input. As an fyi, many of the TP's were pulled from our website or cleared info from the past few days. **As the briefing is at 9:45 am tomorrow morning – we are asking to get back any comments to correct technical inaccuracies before 9 am tomorrow.** Apologies for the short turnaround and Many thanks!

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http://sharepoint.fda.gov/orgs/OC-OL/devices/Team%20Reference%20Library/20200130%20Hinton-EnC%20Memo.docx

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/27/2020 2:12:57 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
**Subject:** RE: blood test for nCoV?

Very interesting, looks like this virus is braking a lot of rules.

**Uwe**

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 1:49 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** FW: blood test for nCoV?

See below

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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---

**From:** Emily Turner (b) (6) @gatesfoundation.org>
**Sent:** Monday, January 27, 2020 1:26 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Conenello, Gina <Gina.Conenello@fda.hhs.gov>
**Subject:** blood test for nCoV?

Hi Gina, Kim,

Quick question – Scott Gottlieb's editorial today describes a diagnostic blood test for nCoV that 'relies on detecting parts of the virus' genome in the blood'. Is this a cell-free RNA assay? In my landscaping I haven't heard of anyone testing blood, just respiratory specimens.

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https://www.cnbc.com/2020/01/26/op-ed-we-need-to-prepare-for-us-outbreak-of-wuhan-coronavirus.html

Any info you can point me to would be much appreciated.

Thanks
Emily

**Emily Turner, PhD MScPH**
Program Officer
Global Health, Innovative Technology Solutions
Bill & Melinda Gates Foundation
V (b) (6)
E(b) (6) @gatesfoundation.org

Bill & Melinda Gates Foundation
www.gatesfoundation.org

AMERICAN OVERSIGHT

**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/26/2020 8:17:13 AM
**To:** Gitterman, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4747486679444f24aa8d1086cca27390-SRG]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: LOINC Coronavirus...

Steve,

The Indication for use is in it's final draft, see below. Based on this updated information, what would be the recommended LOINC code?

It is a NAT assay (b) (5) ?

Here the IU:
The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals meeting CDC 2019 novel coronavirus (2019-nCoV) clinical criteria (e.g., clinical signs and symptoms associated with 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated). Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Uwe

---

**From:** Gitterman, Steven <Steven.Gitterman@fda.hhs.gov>
**Sent:** Friday, January 24, 2020 11:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** LOINC Coronavirus...

Uwe, attached are two Coronavirus related files: an Excel spreadsheet with the complete records for all 118 Coronavirus entries in LOINC, and a PDF report which is a subset of each record that is likely easier to read. (I am aware that some fields are cutoff.) Even with no familiarity with LOINC, you can see it will be straightforward to find a few example records that should be exactly what's needed once the descriptive information is changed to fit the current outbreak virus. (Also attached is the LOINC manual and the Micro guide just FYI, but honestly I don't see why you'd want to get into the weeds for a one-time task, especially since we have Michael anyway. )

Be glad to go over this Monday. I'm sure we could work with CDC to develop exactly the LOINC records needed, or, even better (especially given the amount of FDA support), we can likely have a LOINC specialist with CDC on the phone and get this done pronto. (There is a form in a program called RELMA that makes the submission process very straightforward; I don't have it on my FDA computer [it needs installation] but Michael certainly does.)

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This could be a big win for SHIELD.

--

Best regards,

Steve

Steven Gitterman, M.D., Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
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Phone: 301-796-6694
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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/2/2020 8:31:14 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: TTFED suggested limitation

This works, let's go with that. Uwe

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 8:21 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: TTFED suggested limitation

What about:

- (b)(5) [redacted]

And maybe (b)(5) [redacted]

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 02, 2020 8:17 AM
**To:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: TTFED suggested limitation

Li made a good point.

We need (b)(5) [redacted]

Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 8:09 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: TTFED suggested limitation

See my comments below in blue

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 02, 2020 7:59 AM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: TTFED suggested limitation

Dear Uwe, Tamara and Li,

Can we include the following limitation in the PI:

- (b)(5) [redacted]

And maybe (b)(5) [redacted]

Best regards
Kim

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Saturday, February 01, 2020 6:55 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** RE: TTFED suggested limitation

I agree with Uwe. The current EUA covers (b)(5) (b) (5)

Tamara

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Saturday, February 01, 2020 6:33 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: TTFED suggested limitation

Kim,

This is very delicate wording and haven't had a chance to think this through. With current authorization CDC get a number of specimens types and can validate other going forward. We also have not worked out the support response for such a case.

So, no, we will not include that sentence into the current authorization.

Thanks, Uwe

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 6:25 PM

**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** TTFED suggested limitation

Dear Uwe, Tamara and Li,

During our TTFED discussion, we talked about including the following in the IFU – limitations section

(b)(5) [redacted]

requests should be submitted to FDA directly (CDRH-EUA-Reporting@fda.hhs.gov) and the test manufacturer.

It was to address (b)(5) [redacted].

What are your thoughts?

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
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Kim.Sapsford@fda.hhs.gov






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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/28/2020 10:49:39 AM
**To**: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]
**CC**: Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
**Subject**: RE: coronavirus diagnostics

Megan,

Unfortunately not yet. CDC has only send very limited data, the review division has a flow up call scheduled today with CDC to updated information. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 10:48 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** coronavirus diagnostics

Hi all – any update on the coronavirus potential EUA timing? Has CDC sent the data yet? Thanks!

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/30/2020 9:45:52 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** RE: 2019-nCoV 1/30/20 6 AM update

Thanks, 2 more tonight, quite impressive. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 9:23 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: 2019-nCoV 1/30/20 6 AM update

**Summary of sponsors requested and received review template:**

- Altona Diagnostics (1/17/20)
- Inbios International (1/23/20)
- Quest Diagnostics (1/24/20)
- Quidel (1/25/20)
- Luminex (1/28/20)
- Qiagen (1/28/20)
- Abbott Diagnostics (1/28/20)
- Roche Molecular Diagnostics (1/28/20)
- BioMérieux (1/28/20)
- Thermo Fisher Scientific (1/29/20)
- (b) (4)
- (b) (4)
- Roche Molecular Systems Inc. (apparently independent of Roche Molecular Dx) 1/29/29)
- Primer Design (1/29/20)
- (b) (4)
- (b) (4)
- Rheonix Inc. (1/30/20)
- DiaSorin Molecular (1/30/20)
- Cue Health Inc (1/30/20)

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New today in red

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 6:50 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** 2019-nCoV 1/30/20 6 AM update

Jeff, Elizabeth Ellen, Bill and Tim,

1/30/20 6 AM update

**Status of activities on diagnostics**:

- Update on use of PAHPRA provision under section 564B
  - OCET/OCC concluded that the (b) (5)

(b) (5)

  - CDRH/OCET/OCC are drafting email to communicate use of enforcement discretion to allow distribution and limited testing
- Interactive review with CDC continues
  - Intended use and Contact Fact Sheet were discussed
  - Outstanding clinical data received late yesterday
  - Indication for Use updated and finalized

(b) (4), (b) (5)

  - FDA landing webpage's link to sponsor's technical note in preparation

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- Additional IVD Developers, Thermo Fisher Scientific, (b) (4) Roche Molecular Systems Inc., Primer Design, have requested and received EUA review template. Now 14 total.
- Provided technical accuracies feedback on coronavirus briefing points for Denise Hinton ahead of E&C subcommittee briefing 1/30/20

**New roadblocks/challenges/delays:**

- Need clarification on negative clinical samples tested by CDC - data received late yesterday.

**Summary of sponsors requested and received review template:**

- Altona Diagnostics (1/17/20)
- Inbios International (1/23/20)
- Quest Diagnostics (1/24/20)
- Quidel (1/25/20)
- Luminex (1/28/20)
- Qiagen (1/28/20)
- Abbott Diagnostics (1/28/20)
- Roche Molecular Diagnostics (1/28/20)
- BioMérieux (1/28/20)
- Thermo Fisher Scientific (1/29/20)
- (b) (4)
- (b) (4)
- Roche Molecular Systems Inc. (apparently independent of Roche Molecular Dx) 1/29/29)
- Primer Design (1/29/20)

Please let me know if you have any questions.
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/30/2020 4:04:52 PM
**To:** Jarrell, Kristin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5f1019feb85c452d8f0c9a093fee748b-Kristin.Jar]
**CC:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** FW: coronavirus assistance

Dear Dr. Jarrell,

Thank you for your kind offer to help with the 2019-nCoV outbreak. As this moment the review division is still able to manage the activities, however, when additional applications are come in, and that can happen in the next 2 weeks, I would like to touch base with you again.

Kind regards,

Uwe Scherf

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Office of Product Evaluation and Quality

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uwe.scherf@fda.hhs.gov

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---

**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 3:45 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: coronavirus assistance

See below

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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---

**From:** Jarrell, Kristin <Kristin.Jarrell@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 2:35 PM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Subject:** coronavirus assistance

Hi there! I'm a DO3 RPM, but was curious if your department anticipates needing assistance in the next few months, given the concerns with 2019 nCoV.
Is there an opportunity for volunteers?

Kind regards,
**Kristin Jarrell, Pharm.D**
*Regulatory Project Manager*
**CDER || OND || ORO - OOD || DO3**
**U.S. Food and Drug Administration**
10903 New Hampshire Ave, Silver Spring, MD 20993 | USA
☎+1 301 796 0137 | : Kristin.jarrell@fda.hhs.gov






AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/23/2020 5:04:22 PM
**To**: Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]
**Subject**: Request for overtime pay
**Attachments**: ucm030757_DMD_nCoV.pdf

Dear Bill,

As you have seen from the DMD updates and the information in the press, the 2019-nCoV situation has been very challenging.

Our interactive review and teleconferences indicated that CDC will send CDRH a completed EUA review template any time soon. The staff has been fabulous and supporting the program 200%. I am anticipating CDC data to be reviewed over the weekend and a complete EUA review package next week. As soon as the emergency is declared we anticipate additional documents from commercial sponsors. This work is on top of the regular review work and I feel obliged to assure appropriate compensation for my staff. Attached please find the request form for overtime for your consideration.

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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uwe.scherf@fda.hhs.gov
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# Overtime, Compensatory Time, and Holiday Pay Request and Authorization

*(Instructions for completing this form on reverse)*

2020-2531-CDRH

1. DATE: 01/23/2020

2. **TO:** *(Authorizing Official)*
a. NAME, TITLE, AND MAILING SYMBOL: William Maisel, MD, MPH, OPEQ Director, WA66-1678

3. **FROM:** *(Requesting Official)*
a. NAME, TITLE, AND MAILING SYMBOL: Uwe Scherf, PhD, Director Division of Microbiology Devices, OHT7/OPEQ WO66-3110
b. NO. OF PAGES FORWARDED: 2

| c. CHARGE OVERTIME TO | | d. TIME-KEEPER NO. | e. PAY PERIOD NO. *(No more than 4 PPs per form)* | f. INCLUSIVE DATES | |
|---|---|---|---|---|---|
| PAYROLL CAN | ADMIN CODE | | | FROM | TO |
| | | | | 01/23/2020 | 03/30/2020 |

4. **EMPLOYEES WORKING OVERTIME**

| a. NAME | b. GRADE/STEP | c. TIME-KEEPER* | d. NO. OF HOURS | | e. TYPE PAYMENT | | |
|---|---|---|---|---|---|---|---|
| | | | REQUESTED | WORKED | OT | COMP TIME | HOLIDAY |
| Li, Li | | | 40 | | X | | |
| Anna Mielech | | | 40 | | X | | |
| Kim Sapsford | | | 40 | | X | | |
| Mayra Garcia | | | 40 | | X | | |
| Himani Bisht | | | 40 | | X | | |
| Stephanie Akselrod | | | 40 | | X | | |
| Silke Schlottmann | | | 40 | | X | | |
| Tamara Feldblyum | | | 40 | | X | | |
| | | | | | | | |
| | | | | | | | |
| *Complete for each different timekeeper. | | g. **TOTAL** | 320.00 | | | | |

5. **SPECIFIC DESCRIPTION OF TASK** *(Do not use general description, i.e., "typing," "filing")*
In timely support of the current outbreak of the 2019 novel coronavirus (nCoV) regarding pre-EUA and EUA submissions from government organizations like CDC, BARDA, and DoD to expeditiously authorize diagnostics tests for the detection of nCoV via the Emergency Use Authorization Autority.

6. **REASONS FOR NOT COMPLETING TASK DURING REGULAR HOURS**
The urgency of the 2019-nCoV outbreak requires constant instant responses to government stakeholders and IVD developers like CDC and commercial entities. This additional work is on top of the regular regulator review under MDUFA timelines and workload exceeds what staff can provide in 40 hours of their regular working hours.

7. **COMPLETED BY REQUESTING OFFICIAL** *(from box 3)*
a. DO YOU ANTICIPATE THE NEED FOR OVERTIME IN SUBSEQUENT PAY PERIODS FOR THIS TASK?
☒ Yes *(If "Yes," complete 7b.)* ☐ No
b. DESCRIBE STEPS TAKEN BY REQUESTOR TO REDUCE OR AVOID FURTHER OVERTIME
Review resources from other Branches of DMD will be used, however, specialized knowledge of the EUA process of the above listed individual might be required pending progression of the 2019-nCoV outbreak in the US.
SIGNATURE: Uwe Scherf -S Date: 2020.01.23 17:03:09 -05'00'

8. **COMPLETED BY APPROVING OFFICIAL**
REQUEST FOR OVERTIME
☐ Approved ☐ Disapproved
SIGNATURE | DATE

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# INSTRUCTIONS FOR COMPLETING FORM FDA 211

Overtime Work (within the provisions of Federal Personnel Manual Supplement 990-1) may be authorized only by officials to whom the necessary authority has been delegated (see FDA Staff Manual Guide 1430.5). Overtime or Holiday Pay will not be paid, nor compensatory time granted, without appropriate authorization. Requests should be initiated on Form FDA 211, "Overtime, Compensatory Time, and Holiday Pay Request and Authorization," and completed as follows:

| Item | Explanation |
|---|---|
| 1-3 | Self-explanatory, to be filled out by requesting official. A requesting official can be the employee, timekeeper, Administrative Officer, or supervisor. |
| 4 | If space is required for additional names of those working overtime, another Form FDA 211 should be filled out in its entirety. If more than one form is used for the same request, the forms should be clipped so that they are processed concurrently.<br><br>Only the "requested" side of the columns should be filled out by the requesting official in item 4d.<br><br>A check mark or "x" should be placed in the appropriate column of item 4e indicating the desired compensation. |
| 5-7 | Self-explanatory, to be filled out by requesting official. |
| 8 | To be filled out by authorizing official.<br><br>After evaluation (and adjustment if necessary), the authorizing official will sign to approve or disapprove the request. If disapproved, the request is returned to the requesting official. If approved, the request is returned to the requesting official who should then forward the document to the applicable timekeepers (and Budget Officer if required).<br><br>The timekeeper will enter hours worked in the appropriate column of item 4d. Hours worked are to be based on data which the employee provides on the bi-weekly time report and cannot exceed hours "requested." If hours worked exceed hours "requested," only the authorizing official may increase the "requested" amount and must initial the modification. |

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**From:** Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent:** 1/30/2020 9:45:26 PM
**To:** Tucker, Angela (b) (6) @roche.com]
**Subject:** RE: Request for EUA template for 2019-nCoV test development

Angela, thanks, and I my team appreciate your feedback, the same from our side here. Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

**From:** Tucker, Angela (b) (6) @roche.com>
**Sent:** Thursday, January 30, 2020 9:38 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Fwd: Request for EUA template for 2019-nCoV test development

Dear Uwe,

Just a courtesy note to you that are engaging. We look forward to working with your team.

All the best,
Angeal

Angela G. Tucker
Vice President, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588-2722

Phone: +1 925 730-8277
Cell: + (b) (6)
Fax: +1 925 225-0207
Email: (b) (6) @roche.com

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---------- Forwarded message ---------
From: **CDRH-EUA-Templates** <CDRH-EUA-Templates@fda.hhs.gov>
Date: Wed, Jan 29, 2020 at 7:05 PM
Subject: RE: Request for EUA template for 2019-nCoV test development
To: Tucker, Angela (b) (6) @roche.com>, CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Cc: Heinz Steneberg (b) (6) @roche.com>

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Dear Angela,

Thank you for your email. Please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of 2019-novel coronavirus (2019-nCoV). I suggest when you are ready, the first step is to populate this draft template with the information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center). The Pre-EUA review is an interactive process, so we will provide feedback after receiving and reviewing the information provided. The draft review template is a shared "work-in-progress" document which you will populate with information and data as obtained and which we will review and provide feedback to you.

I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of 2019-nCoV to FDA (it includes the address for the Document Control Center). Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under type of submission please check "other" and specify Pre-EUA.

One hard copy of the signed EUA Cover Letter and one electronic copy of you Pre-EUA submission package (including the EUA Review Template - MS word document) should be enclosed in your Pre-EUA submission to FDA, and we also request that you submit the information requested via electronic mail to myself Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;
- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please be reminded that ***in the U.S. a test*** for the detection of 2019-nCoV or to diagnoses 2019-nCoV infection must not be distributed and/or used for clinical diagnosis without premarket clearance, approval, or EUA by the FDA.

NOTE: The EUA Interactive Review Template from the FDA is considered an internal working document and must not be distributed outside of your organization.

Please let me know if you have any questions, we look forward to working with you,

Best regards,

Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch

Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)

Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993

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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov





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**From:** Tucker, Angela (b) (6) @roche.com>
**Sent:** Wednesday, January 29, 2020 11:08 AM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** Heinz Steneberg (b) (6) @roche.com>
**Subject:** Request for EUA template for 2019-nCoV test development

Hello there,

Please provide your current template for our review.

Thanks,

Angela G. Tucker
Vice President, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588-2722

Phone: +1 925 730-8277
Cell: + 1(b) (6)
Fax: +1 925 225-0207
Email: (b) (6) @roche.com

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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/2/2020 8:22:07 AM
**To**: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]
**Subject**: RE: Potential diagnostic EUA for coronavirus PR

Megan,

Timing update:

CDC could not provide the outstanding analytical data last. Their updated estimate now is this afternoon. Again, the DMD review team is standing by to review the package expeditiously when it arrives. Even when the data look good, not sure it can happen tonight, it looks good definitely tomorrow.

Best, Uwe

---

**From:** Scherf, Uwe
**Sent:** Saturday, February 1, 2020 4:09 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

Megan,

We just got word from CDC that they are possibly submitting their EUA package tonight or some time tomorrow. If the data look good the review division will be able to get the package towards FDA clearance the same day.

What information do you need to update and finalize the press release?

Sorry for this super short notice, everything is moving super-fast.

Best, Uwe

AMI OVERSIGHT

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Scherf, Uwe
**Sent:** Friday, January 31, 2020 1:48 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Potential diagnostic EUA for coronavirus PR

Megan,

Attached please find the intended use of the CDC assay. Could you please update the draft based on this information.

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 9:27 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>
**Subject:** Potential diagnostic EUA for coronavirus PR

Hi all – I've pulled together a very rough draft of a press release re: a potential EUA for a CDC diagnostic. Do you have an update on the timing? And is there any information on the kind of test it is that you can share so that I can start filling in some of the blanks or XXs in the attached draft? Thank you!

**Megan McSeveney**
*Press Officer*

**Office of Media Affairs**
**Office of External Affairs**
**U.S. Food and Drug Administration**
Tel: 240-402-4514/Cell:202-380-7748
Megan.McSeveney@fda.hhs.gov






AMERICAN OVERSIGHT

**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 1/26/2020 9:59:59 PM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: FDA CDC discussion on VALID.docx
**Attachments**: FDA CDC discussion on VALID.docx

**Importance**: High

Just finished my comments, sorry did not add them into Kim's version. I hope this helps.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 9:54 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: FDA CDC discussion on VALID.docx

Thanks, Kim

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 9:33 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: FDA CDC discussion on VALID.docx

Dear Elizabeth

Couple of comments/edits for your consideration.
Please let me know if you have any questions.

As we have done in the past the Emergency determination/declaration authorizing use of IVDs for the 2019-nCoV will be timed with the EUA request package for the first diagnostic (in this case as in the past this is CDC)

Best regards
Kim

AMERICAN OVERSIGHT

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
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---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, January 26, 2020 8:34 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: FDA CDC discussion on VALID.docx

Uwe and Kim,
I am terribly sorry to bother you at this time. (b) (5) [redacted] If you have a chance to review the first half page of the attached for accuracy, I would greatly appreciate it. Sorry to ask at this busy time; I know you are extremely busy doing far more important things.
Elizabeth

---

**From:** Hillebrenner, Elizabeth J
**Sent:** Sunday, January 26, 2020 8:29 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** FDA CDC discussion on VALID.docx

Jeff and Ellen,
Anticipating we will need a 1 pager on CDC and VALID this week, I have drafted a 1.5 pager for your review. I would appreciate your feedback.
Elizabeth

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**FDA and CDC Interactions on VALID**

(b) (5)



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(b) (5)



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**From**: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
**Sent**: 2/2/2020 8:17:07 AM
**To**: Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: TTFED suggested limitation

Li made a good point.

We need (b)(5) [redacted]

Uwe

---

**From:** Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Sent:** Sunday, February 2, 2020 8:09 AM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: TTFED suggested limitation

See my comments below in blue

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**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Sunday, February 02, 2020 7:59 AM
**To:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: TTFED suggested limitation

Dear Uwe, Tamara and Li,

Can we include the following limitation in the PI:

- (b)(5) [redacted]

And maybe (b)(5) [redacted]

AMERICAN OVERSIGHT

(b)(5)

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

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---

**From:** Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Sent:** Saturday, February 01, 2020 6:55 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** RE: TTFED suggested limitation

I agree with Uwe. The current EUA covers (b)(5)

(b) (5)

Tamara

---

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**Sent:** Saturday, February 01, 2020 6:33 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: TTFED suggested limitation

Kim,

This is very delicate wording and haven't had a chance to think this through. With current authorization CDC get a number of specimens types and can validate other going forward. We also have not worked out the support response for such a case.

So, no, we will not include that sentence into the current authorization.

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Thanks, Uwe

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Sent:** Saturday, February 1, 2020 6:25 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Subject:** TTFED suggested limitation

Dear Uwe, Tamara and Li,

During our TTFED discussion, we talked about including the following in the IFU – limitations section

(b)(5) [redacted] requests should be submitted to FDA directly (CDRH-EUA-Reporting@fda.hhs.gov) and the test manufacturer.

It was to address (b)(5) [redacted].

What are your thoughts?

Best regards
Kim

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**Sent**: 2/2/2020 8:09:23 AM
**To**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Feldblyum, Tamara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aee8d6986b34ba3b434a6ad94fb0755-TVF]; Li, Li (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b72e7bb9b3c24ac68610ad392366cf3e-LXL]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: TTFED suggested limitation

Kim,

This sound very good. Will need to reach out to Julie to determine whether they can live with that.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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AMERICAN OVERSIGHT

Best regards
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*MCM EUA Team Lead*

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**Subject:** RE: TTFED suggested limitation

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Tamara

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**Sent:** Saturday, February 01, 2020 6:33 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: TTFED suggested limitation

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**Subject:** TTFED suggested limitation

Dear Uwe, Tamara and Li,

During our TTFED discussion, we talked about including the following in the IFU – limitations section

(b)(5) [redacted] requests should be submitted to FDA directly (CDRH-EUA-Reporting@fda.hhs.gov) and the test manufacturer.

It was to address (b)(5) [redacted]

What are your thoughts?

Best regards
Kim

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*MCM EUA Team Lead*

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**Sent**: 1/23/2020 4:57:45 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Lias, Courtney H [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98a0fa6159ce418898b4b97381a76112-CDL]
**CC**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Feedback on (b) (5) - DMD - 2019-nCoV update

Dear Jeff, Bill, Tim and Courtney,

Feedback requested: (b) (5)

Please let me know whether you support this recommendation.

Also, in past emergencies, we worked directly with OCET on EUA package requests (draft documents) and cc CDRH as the final package moves up to OCET and the Commissioner. Please let me know, whether under the new OPEQ/CDRH structure this is still the approach we should take or whether OPEQ/CDRH wants to be involved in the review of the EUA request package. We would like to know so we can factor this into the review timelines. If so, please recommend individuals we should bring up to speed – given the time sensitive nature of these EUA requests.

General update: From the "AMA updates on Coronavirus" call that happened this morning, it appears based on the current case numbers that the mortality rate is about 2.5%. There are current 5 US airports that established screening. The travel alert was updated to a level 3 (highest rating).
CDC is testing 3 alert cases - individuals from the same family – test results are pending, 46 other individuals are also under investigation.

DARPA is involved to support the development of additional diagnostic platforms, but currently all specimens go to CDC for testing. There is consideration of sending sequencing out to LRN, however, CDC expect to have an assay ready to go in 2 weeks. A number of vaccines are in development based on MERS-CoV and SARS but there is a need for wild-type virus for the development of animal models. Funding is under discussion.

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In addition, we had a call CDC today to clarify data requirements to support their EUA request. CDC shares data constantly and anticipates a more complete data package for CDRH review very early next week. In other updates WHO have determined at this point that the Wuhan coronavirus is not yet a public health emergency of international concern.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

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Version 2
March 10, 2025

***Vaughn Index for FOIA Request No. 2020-2531***
***American Oversight v. HHS et. al., Case No. 1:20-cv-0947 (D.D.C.)***

| Doc. Start | Doc. End | Date of Redacted Doc. | Author(s) of Redacted Doc | Document Title | Exemption(s)** | Explanation |
|---|---|---|---|---|---|---|
| 0957 | 0961 | 02/04/2020 | Uwe Scherf | RE: White House Request-Due 0900 tomorrow (Wednesday) | (b)(4), (b)(6) | FDA-CVD-SCHERFU-00014646<br>Bates: 0958–0959<br>Personal Privacy Information: The redacted information contains the private email addresses of National Institutes of Health (NIH) employees.<br><br>Bates: 0959–0960<br>Personal Privacy Information: The redacted information contains a Department of Health and Human Services (HHS) employee's private phone numbers.<br><br>Bates: 0959–0960<br>Confidential Commercial Information: The redacted information in this email exchange contains confidential commercial information regarding the commercial development of diagnostics, vaccines, and therapeutics by specific companies.<br><br>Bates: 0960<br>Personal Privacy Information: The redacted information identifies the individuals that added content about broad-spectrum antivirals to the one-pager. |
| 0967 | 0969 | 01/31/2020 | Uwe Scherf | FW: DUE today: USG Strategy needed for Diagnostics 2019-nCoV | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014672<br>Bates: 0967<br>Personal Privacy Information: The redacted information contains the private email addresses of NIH employees.<br><br>Bates: 0968–0969<br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations |

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| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | regarding the Center for Devices and Radiological Health's current coronavirus diagnostic activities, proposed diagnostic strategy goals, potential plans for COVID-19 reference materials, and draft coronavirus diagnostics language for a United States Government strategy, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 0969<br>Personal Privacy Information: The redacted information contains an HHS employee's private phone numbers. |
| 0970 | 0972 | 01/31/2020 | Uwe Scherf | RE: DUE today: USG Strategy needed for Diagnostics 2019-nCoV | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014703<br>Bates: 0970<br>Personal Privacy Information: The redacted information contains private email addresses of NIH employees.<br><br>Bates: 0971–0972<br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations regarding the Center for Devices and Radiological Health's current coronavirus diagnostic activities, proposed diagnostic strategy goals, potential plans for COVID-19 reference materials, and draft coronavirus diagnostics language for a United States Government strategy, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 0972<br>Personal Privacy Information: The redacted information contains the private phone numbers of an HHS employee. |
| 0973 | 0987 | 01/26/2020 | Uwe Scherf | RE: EUA Template for CDC 2019- | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00014738<br>Bates: 0973–0977 |

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|---|---|---|---|---|---|---|
| | | | | nCoV rRT-PCR - Draft | | Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations regarding comments and edits to the Centers for Disease Control and Prevention's (CDC) draft intended use language, clinical performance data, as well as questions about the clinical specimens CDC tested for its Emergency Use Authorization (EUA) template, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 0983<br>Confidential Commercial Information: The redacted information contains confidential commercial information regarding nonfinal intended use language for the CDC's EUA template. |
| 0988 | 0991 | 01/31/2020 | Uwe Scherf | FW: Regulatory discretion – Need to confirm process and next steps | (b)(5) | FDA-CVD-SCHERFU00014739<br>Bates: 0990<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations related to the number of samples CDC planned to collect from state laboratories for further validation testing, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 0992 | 0995 | 02/01/2020 | Uwe Scherf | RE: NSC request nCoV MCM Task Force strategy | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014746<br>Bates: 0993<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding draft bullet points about coronavirus diagnostics for an interagency meeting related to COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive |

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| | | | | | | candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 0993–0995<br>Personal Privacy Information: The redacted information contains the private email addresses of National Institutes of Health (NIH) employees and the private phone numbers of an HHS employee. |
| 0996 | 1009 | 01/26/2020 | Uwe Scherf | RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00014747<br><br>Bates: 0997–0999<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the clinical specimen data the CDC used in its Emergency Use Authorization (EUA) template, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 1005<br>Confidential Commercial Information: The redacted information contains confidential commercial information regarding the CDC's nonfinal intended use language for its EUA template. |
| 1010 | 1021 | 1/24/2020 | Uwe Scherf | RE: EUA Template for CDC 2019-nCoV rRT PCR – Draft | (b)(4) | FDA-CVD-SCHERFU-00014769<br>Bates: 1017<br>Confidential Commercial Information: The redacted information contains confidential commercial information regarding the CDC's nonfinal intended use language for its EUA template. |
| 1028 | 1039 | 01/24/2020 | Uwe Scherf | RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft | (b)(4) | FDA-CVD-SCHERFU-00014789<br>Bates: 1035<br>Confidential Commercial Information: The redacted information contains confidential commercial information related to nonfinal intended use language for the CDC's EUA template. |
| 1046 | 1049 | 01/31/2020 | Uwe Scherf | RE: Regulatory discretion – | (b)(5) | FDA-CVD-SCHERFU-00014799<br>Bates: 1048 |

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| | | | | Need to confirm process and next steps | | Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations related to the number of samples the CDC planned to collect from state laboratories for further validation testing, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 1050 | 1056 | 01/26/2020 | Uwe Scherf | RE: Update from Wuhan Municipal Health and Health Committee – 4 new cases added | (b)(4) | FDA-CVD-SCHERFU-00014800<br>Bates: 1052<br>Confidential Commercial Information: The redacted information contains confidential commercial information related to nonfinal intended use language for the CDC's Emergency Use Authorization (EUA) template. |
| 1063 | 1067 | 01/25/2020 | Uwe Scherf | RE: Landscape slides for NSC – need your review | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014808<br>Bates: 1065–1067<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding draft language about Emergency Use Authorizations and clinical data collection for a Medical Countermeasures slide deck, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 1067<br>Personal Privacy Information: The redacted information contains the private email addresses of NIH employees and the private phone numbers of an HHS employee. |
| 1068 | 1076 | 01/22/2020 | Uwe Scherf | RE: EUA Template for CDC 2019- | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00014811<br>Bates: 1068<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations |

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| | | | | nCoV rRT-PCR - Draft | | regarding comments and potential questions from FDA personnel about the CDC's Emergency Use Authorization (EUA) template, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 1072<br>Confidential Commercial Information: The redacted information contains confidential commercial information related to nonfinal intended use language for the CDC's EUA template. |
| 1077 | 1080 | 1/30/2020 | Uwe Scherf | RE: Regulatory discretion – Need to confirm process and next steps | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014842<br>Bates: 1078–1079<br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations regarding how to address the Office of the Chief Counsel's (OCC) concerns about the application of existing statutory authority for Emergency Use Authorizations and FDA's review of clinical data in the CDC's EUA template, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 1078–1079<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion and advice from FDA's Office of the Chief Counsel (OCC) to the Centers for Devices and Radiological Health (CDRH) related to existing statutory authority and its effect on the scope of an EUA.<br><br>Bates: 1078<br>Personal Privacy Information: The redacted information contains the private telephone numbers of FDA employees. |

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| 1087 | 1090 | 01/25/2020 | Uwe Scherf | RE: Landscape slides for NSC – need your review | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014862<br>Bates: 1087–1090<br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations regarding draft language about Emergency Use Authorizations and materials and supplies needed for validation studies to include in the Medical Countermeasures landscape slide deck, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 1090<br>Personal Privacy Information: The redacted information contains the private email addresses of NIH employees and private phone numbers of an HHS employee. |
| 1091 | 1093 | 01/31/2020 | Uwe Scherf | RE: Regulatory discretion – Need to confirm process and next steps | (b)(5) | FDA-CVD-SCHERFU-00014870<br>Bates: 1092<br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations related to the number of samples CDC planned to collect from state laboratories for further validation testing, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 1094 | 1097 | 01/31/2020 | Uwe Scherf | RE: Regulatory discretion – Need to confirm process and next steps | (b)(5) | FDA-CVD-SCHERFU-00014874<br>Bates: 1096<br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations related to the number of samples that CDC planned to collect from state laboratories for further validation testing, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive |

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| | | | | | | candid and informed opinions and recommendations from its subject matter experts. |
| 1098 | 1099 | 01/25/2020 | Uwe Scherf | RE: 2019 nCoV | (b)(6) | FDA-CVD-SCHERFU-00014884<br>Bates: 1099<br>Personal Privacy Information: The redacted information contains the private phone numbers and email address of the-then Acting Director for the HHS, Office of the Assistant Secretary for Emergency Response and Preparedness, Biomedical Advanced Research and Development Authority, Regulatory and Quality Affairs Division. |
| 1106 | 1108 | 01/30/2020 | Uwe Scherf | RE: Scheduling 2019-nCoV Dx WG call | (b)(6) | FDA-CVD-SCHERFU-00014902<br>Bates: 1106–1107<br>Personal Privacy Information: The redacted information contains the private email addresses of NIH employees.<br><br>Bates: 1108<br>Personal Privacy Information: The redacted information contains an HHS employee's private telephone numbers. |
| 1109 | 1118 | 01/23/2020 | Uwe Scherf | RE: EUA Template for CDC 2019-nCoV rRT PCR – Draft | (b)(4) | FDA-CVD-SCHERFU-00014904<br>Bates: 1113<br>Confidential Commercial Information: The redacted information contains confidential commercial information regarding nonfinal intended use language for the CDC's EUA template. |
| 1119 | 1123 | 01/30/2020 | Uwe Scherf | RE: Intended use wording | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00014909<br>Bates: 1119<br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations regarding the CDC's draft intended use language for its Emergency Use Authorization (EUA) template and comments and edits from FDA personnel, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 1121–1122 |

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| | | | | | | Confidential Commercial Information: The redacted information contains confidential commercial information regarding the CDC's nonfinal intended use language for its EUA template. |
| 1124 | 1137 | 01/25/2020 | Uwe Scherf | RE: EUA Template for CDC 2019-nCoV rRT-PCR – Draft | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00014917<br>Bates: 1126<br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations related to questions and comments from FDA personnel about the clinical datasets, clinical specimens collected, and clinical studies included in the CDC's Emergency Use Authorization (EUA) template, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 1133<br>Confidential Commercial Information: The redacted information contains confidential commercial information regarding nonfinal intended use language for the CDC's EUA template. |
| 1138 | 1151 | 01/25/2020 | Uwe Scherf | RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00014937<br>Bates: 1140<br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations regarding the clinical specimen data and clinical studies the CDC included in its Emergency Use Authorization (EUA) template, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 1147<br>Confidential Commercial Information: The redacted information contains confidential commercial information regarding nonfinal intended use language for the CDC's EUA template. |

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CONFIDENTIAL SETTLEMENT COMMUNICATION PROTECTED BY FED. RULE OF EVIDENCE 408

Version 2
March 10, 2025

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| 1152 | 1165 | 01/25/2020 | Uwe Scherf | RE: EUA Template for CDC 2019-nCoV rRT-PCR - Draft | (b)(4), (b)(5) | FDA-CVD-SCHERFU-00014946<br>Bates: 1152<br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations related to suggested revisions and edits from FDA personnel about the nonfinal intended use language for the CDC's EUA template, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 1161<br>Confidential Commercial Information: The redacted information contains confidential commercial information regarding nonfinal intended use language for the CDC's EUA template. |

* Page prefix is FDACDRH-p7-AO-00
** Exemption codes refer to the sections of the Freedom of Information statue 5 U.S.C. § 552(b).

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***Vaughn Index (V2) for FOIA Request No. 2020-2531***
***American Oversight v. HHS et. al., Case No. 1:20-cv-0947 (D.D.C.)***

| Doc Start | Doc. End | Date of Redacted Doc | Author(s) of Redacted Doc | Document Title | Exemption(s)** | Explanation |
|---|---|---|---|---|---|---|
| 003020 | 003023 | 02/22/2020 | Uwe Scherf | RE: Draft CDC EUA Request for Sentinel Surveillance Activities | (b)(5) | FDA-CVD-SCHERFU-00013909<br>Bates: 3020, 3022<br><br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains non-final, pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) surveillance of community transmission of SARS-CoV-2 and draft notes from FDA personnel about these developing plans, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3022<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice to FDA's Centers for Devices and Radiological Health from the Office of the Chief Counsel (OCC) regarding the Centers for Disease Control and Prevention's (CDC) draft surveillance of community transmission of SARS-CoV-2 and notes from FDA personnel about these draft plans. |
| 003024 | 003025 | 02/18/2020 | Uwe Scherf | RE: Contract Manufacturer | (b)(5) | FDA-CVD-SCHERFU-00013913<br>Bates: 3025<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains FDA's draft response to the Centers for Disease Control and Prevention's (CDC) request related to the scope of the grant of Emergency Use Authorization (EUA) to the CDC for its test for SARS-CoV-2 and whether the EUA in existence at the time of this email exchange covered the production of CDC's tests by contract manufacturers, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would |

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| | | | | | | compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003026 | 003027 | 02/19/2020 | Uwe Scherf | Fwd: Update on EUA for CDC "surveillance" | (b)(6) | FDA-CVD-SCHERFU-00013921<br>Bates: 3026<br><br>Personal Privacy Information: The redacted information contains a Webex meeting number (access code) and password. |
| 003028 | 003033 | 02/19/2020 | Uwe Scherf | Guidance for Conducting Sentinel Surveillance to Detect Signals of Potential Community Transmission of 2019 novel coronavirus | (b)(5) | FDA-CVD-SCHERFU-00013921.0001 attachment to FDA-CVD-SCHERFU-00013921<br>Bates: 3028–3033<br><br>Deliberative Process Privilege: The redacted information in this email attachment contains pre-decisional, internal deliberations related to the Centers for Disease Control and Prevention's (CDC) draft plans for surveillance of community transmission of SARS-CoV-2 and notes from FDA personnel about these plans, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003034 | 003039 | 02/23/2020 | Uwe Scherf | RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities | (b)(5) | FDA-CVD-SCHERFU-00013950<br>Bates: 3035–3037<br><br>Deliberative Process Privilege: The redacted information in this email attachment contains discussions regarding draft language for a Centers for Disease Control and Prevention (CDC) Emergency Use Authorization (EUA) related to surveillance of community transmission of SARS-CoV-2 and notes from FDA personnel about proposed language, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3038 |

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| | | | | | | Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice to FDA's Centers for Devices and Radiological Health from the Office of the Chief Counsel (OCC) regarding the Centers for Disease Control and Prevention's (CDC) draft plans for surveillance of community transmission of SARS-CoV-2 and notes from FDA personnel about these plans. |
| 003040 | 003041 | 02/24/2020 | Uwe Scherf | FW: CoV Dx FDA/developer needs discussion | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00013961<br>Bates: 3040–3041<br><br>Personal Privacy Information: The redacted information contains the private email addresses of National Institutes of Health (NIH) personnel and a Webex meeting number (access code), password, and meeting link.<br><br>Bates: 3041<br>Deliberative Process Privilege: The redacted information in this email exchange contains a draft meeting agenda for a teleconference meeting with the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003042 | 003042 | 02/19/2020 | Uwe Scherf | RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx | (b)(5) | FDA-CVD-SCHERFU-00013967<br>Bates: 3042<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains discussion regarding draft language in an Emergency Use Authorization (EUA) letter of authorization and discussion about how to address concerns raised by FDA's Office of the Chief Counsel, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would |

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| | | | | | | compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003043 | 003043 | 2/24/2020 | Uwe Scherf | FW: Information request – WRCEVA SARS-CoV-2 genomic RNA product sheet | (b)(6) | FDA-CVD-SCHERFU-00013973<br>Bates: 3043<br><br>Personal Privacy Information: The redacted information contains the private email address of a National Institutes of Health (NIH) employee. |
| 003045 | 003046 | 2/19/2020 | Uwe Scherf | RE: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel: addition of ZEN probes | (b)(5) | FDA-CVD-SCHERFU-00013974<br>Bates: 3045–3046<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding draft language related to the Centers for Disease Control and Prevention's (CDC) 2019-nCoV Real-time RT-PCR Diagnostic Panel Emergency Use Authorization (EUA) application, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003047 | 003050 | 02/22/2020 | Uwe Scherf | RE: Coronavirus and MERS culturing | (b)(5) | FDA-CVD-SCHERFU-00013977<br>Bates: 3049<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the development of coronavirus diagnostic testing and MERS culturing, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003051 | 003052 | 02/19/2020 | Uwe Scherf | FW: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission | (b)(5) | FDA-CVD-SCHERFU-00013978<br>Bates: 3051–3052<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding |

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| | | | | | | draft language related to surveillance of community transmission of SARS-CoV-2 and notes from FDA personnel about these developing plans, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003053 | 003062 | 02/24/2020 | Uwe Scherf | FW: USG SSWG Updates – Current and scheduled availability of SARS-2 genomic RNA and scheduled availability of inactivated virus | (b)(6) | FDA-CVD-SCHERFU-00013979<br>Bates: 3053–3062<br><br>Personal Privacy Information: The redacted information contains the private email addresses of National Institutes of Health (NIH), Department of Health and Human Services (HHS), Federal Bureau of Investigation (FBI) and White House employees.<br><br>Bates: 3057, 3059, 3061–62<br>Personal Privacy Information: The redacted information also contains the private phone numbers of Department of Health and Human Services (HHS) employees.<br><br>Bates: 3062<br>Personal Privacy Information: The redacted information contains a meeting number (access code) and password. |
| 003063 | 003071 | 02/22/2020 | Uwe Scherf | RE: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014000<br>Bates: 3063, 3066–3071<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains non-final test results and deliberative discussions regarding the Centers for Disease Control and Prevention's (CDC) testing and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003072 | 003074 | 02/24/2020 | Uwe Scherf | FW: Information request | (b)(4), (b)(5), | FDA-CVD-SCHERFU-00014002<br>Bates: 3072–3073 |

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| | | | | | (b)(6) | Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the RNA the University of Texas Medical Branch (UTMB) was providing to companies that were developing diagnostic SARS-CoV-2 tests, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3072–3074<br>Personal Privacy Information: The redacted information contains National Institutes of Health (NIH) employee email addresses and the private phone number of a Department of Health and Human Services (HHS) employee.<br><br>Bates: 3073<br>Confidential Commercial Information: The redacted information identifies companies that made an Emergency Use Authorization (EUA) submission. |
| 003075 | 003082 | 02/21/2020 | Uwe Scherf | RE: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014006<br>Bates 3077–3082<br><br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains draft language and deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria, results, and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003086 | 003089 | 02/22/2020 | Uwe Scherf | RE: DRAFT CDC EUA Request for Sentinel Surveillance Activities | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014014<br>Bates: 3087, 3088 |

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| | | | | | | Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains draft language related to the Centers for Disease Control and Prevention (CDC) Emergency Use Authorization (EUA) for surveillance of community transmission of SARS-CoV-2 and notes from FDA personnel regarding these draft plans, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3088<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel (OCC) to the Center for Devices and Radiological Health (CDRH) regarding the Centers for Disease Control and Prevention's (CDC) Emergency Use Authorization (EUA) for surveillance of community transmission of SARS-CoV-2.<br><br>Bates: 3086<br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee. |
| 003090 | 003090 | 02/24/2020 | Uwe Scherf | FW: Information Request | (b)(4), (b)(6) | FDA-CVD-SCHERFU-00014016<br>Bates: 3090<br>Personal Privacy Information: The redacted information contains the private phone numbers of a Department of Health and Human Services (HHS) employee. The redacted information also contains the private email address for an NIH employee.<br><br>Bates: 3090<br>Confidential Commercial Information: The redacted information relates to companies that made Emergency Use Authorization (EUA) submissions. |
| 003091 | 003092 | 02/20/2020 | Uwe Scherf | RE: Draft Letter – EUA for CDC "surveillance" | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014031<br>Bates: 3091 |

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| | | | | | | Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding plans for draft language related to an Emergency Use Authorization (EUA) for the Centers for Disease Control and Prevention (CDC), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3092<br>Personal Privacy Information: The redacted information contains a Webex meeting number (access code) and password. |
| 003093 | 003095 | 02/17/2020 | Uwe Scherf | RE: BY noon tomorrow | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014034<br>Bates: 3093–3095<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding a timeline projection for the development of coronavirus diagnostics and potential costs related to the development, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3095<br>Personal Privacy Information: The redacted information contains the private phone numbers of a Department of Health and Human Services (HHS) employee. |
| 003096 | 003097 | 02//24/2020 | Uwe Scherf | FW: "Final" Dx development POC talking points and landscapes | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014036<br>Bates: 3096–3097<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding talking points related to the coronavirus diagnostics landscape, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's |

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| | | | | | | ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3096–3097<br>Personal Privacy Information: The redacted information contains the private email addresses of National Institutes of Health (NIH) and Department of Defense (DOD) employees. The redacted information also contains the private phone numbers of a Department of Health and Human Services (HHS) employee. |
| 003098 | 003104 | 02//24/2020 | Uwe Scherf | 2019-nCoV Diagnostics Landscape – POC 2-18-20.pptx | (b)(5) | FDA-CVD-SCHERFU-00014036.0001 attachment of FDA-CVD-SCHERFU-00014036<br>Bates: 3098–3104<br><br>Deliberative Process Privilege: The redacted information in this email attachment contains pre-decisional, internal deliberations regarding draft language for a slide deck related to COVID-19 diagnostics, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003105 | 003107 | 02//24/2020 | Uwe Scherf | Diagnostic for Coronavirus Timeline Projection v4 clean docx | (b)(5) | FDA-CVD-SCHERFU-00014036.0002<br>Bates: 3105–3107<br><br>Deliberative Process Privilege: The redacted information in this email attachment contains pre-decisional, internal deliberations regarding draft supplemental language for a slide deck related to COVID-19 diagnostics, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003108 | 003109 | 02/19/2020 | Uwe Scherf | RE: CDC 2019-nCoV Real-Time RT-PC Diagnostic Panel: addition of ZEN probes | (b)(5) | FDA-CVD-SCHERFU-00014044<br>Bates: 3108–3109<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations related to the |

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| | | | | | | Centers for Disease Control and Prevention (CDC) proposed addition of ZEN probes to its diagnostic panel, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003110 | 003112 | 02/19/2020 | Uwe Scherf | RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission | (b)(5) | FDA-CVD-SCHERFU-00014060<br>Bates: 3110–3111<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations related to the Centers for Disease Control and Prevention (CDC) surveillance of community transmission of SARS-CoV-2 and notes from FDA personnel regarding these draft plans, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003113 | 003119 | 02/17/2020 | Uwe Scherf | FW: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014064<br>Bates: 3113–3119<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria, results, and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003124 | 003128 | 02/21/2020 | Uwe Scherf | RE: Cut-off change-Number of public health labs that verified CDC panel for use | (b)(5) | FDA-CVD-SCHERFU-00014078<br>Bates: 3124–3125, 3127-3128<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control Prevention's (CDC) laboratory |

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| | | | | | | verification processes for public health labs including non-final information, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003129 | 003131 | 02/19/2020 | Uwe Scherf | RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission | (b)(5) | FDA-CVD-SCHERFU-00014081<br>Bates: 3130<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) surveillance of community transmission of SARS-CoV-2, and notes from FDA personnel related to these draft plans, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003132 | 003133 | 02/24/2020 | Uwe Scherf | RE: Intended Use | (b)(5) | FDA-CVD-SCHERFU-00014083<br>Bates: 3132–3133<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) draft intended use language statement, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003138 | 003141 | 02/17/2020 | Uwe Scherf | FW: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014103<br>Bates: 3138–3141<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria, results, and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal |

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| | | | | | | discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003142 | 003143 | 02/24/2020 | Uwe Scherf | FW: Intended Use | (b)(5) | FDA-CVD-SCHERFU-00014111<br>Bates: 3142–3143<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) draft intended use language statement, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003144 | 003153 | 02/19/2020 | Uwe Scherf | RE: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014123<br>Bates: 3146, 3148–3153<br><br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria and results, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003154 | 003161 | 02/21/2020 | Uwe Scherf | FW: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014124<br>Bates: 3156–3161<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria, results, and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 003169 | 003176 | 02/21/2020 | Uwe Scherf | FW: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014147<br>Bates: 3171–3176<br><br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria, results, and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003177 | 003185 | 02/17/2020 | Uwe Scherf | RE: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014156<br>Bates: 3177–3185<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria, results, and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003188 | 003193 | 02/18/2020 | Uwe Scherf | FW: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014183<br>Bates: 3188–3193<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria, results, and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003194 | 003202 | 02/18/2020 | Uwe Scherf | 2019-nCoVEUA-01 Lot 20-0121 | (b)(5) | FDA-CVD-SCHERFU-00014183.0001 attachment of FDA-CVD-SCHERFU-00014183 |

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| | | | | Heightened Water QC data for FDA_17Feb2020.pptx | | Bates: 3194–3202<br><br>Deliberative Process Privilege: The redacted information in this draft document contains pre-decisional, internal deliberations regarding draft language for a slide deck related to diagnostics quality control, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003203 | 003207 | 02/21/2020 | Uwe Scherf | RE: Cut-off change – Number of public health labs that verified CDC panel use | (b)(5) | FDA-CVD-SCHERFU-00014188<br>Bates: 3203–3204, 3206<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control Prevention's (CDC) laboratory verification processes for public health labs and preliminary testing data for notifications, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003208 | 003216 | 02/19/2020 | Uwe Scherf | RE: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014191<br>Bates: 3209, 3211–3216<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria, results, and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003217 | 003224 | 02/18/2020 | Uwe Scherf | FW: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014192<br>Bates: 3218–3223<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the |

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| | | | | | | Centers for Disease Control and Prevention (CDC) diagnostic testing criteria, results, and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003228 | 003229 | 02/18/2020 | Uwe Scherf | RE: For review by 11 am Tuesday: Dx development POC talking points and landscapes | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014194<br>Bates: 3228–3229<br><br>Deliberative Process Privilege: The redacted information in this email contains pre-decisional, internal deliberations discussions related to draft talking points for a slide deck regarding development of diagnostics, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3228–3229<br>Personal Privacy Information: The redacted information contains the private email addresses of National Institutes of Health (NIH) and Department of Defense (DOD) employees and the private phone numbers of a Department of Health and Human Services (HHS) employee. |
| 003230 | 003235 | 02/22/2020 | Uwe Scherf | RE: Cut-off change – Number of public health labs that verified CDC panel for use | (b)(5) | FDA-CVD-SCHERFU-00014197<br>Bates: 3231–3232, 3234–3235<br><br>Deliberative Process Privilege: The redacted information in this inter-agency email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) testing and laboratory verification processes for public health labs and preliminary testing notifications, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 003236 | 003242 | 02/18/2020 | Uwe Scherf | FW: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-SCHERFU-00014202<br>Bates: 3237–3242<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria, results, and laboratory verification processes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003243 | 003244 | 02/21/2020 | Uwe Scherf | RE: Information request – WRCEVA SARS-CoV-2 genomic RNA products sheet | (b)(4), (b)(6) | FDA-CVD-SCHERFU-00014206<br>Bates: 3243<br><br>Personal Privacy Information: The redacted information contains the private email addresses of National Institutes of Health (NIH) and Department of Health and Human Services (HHS) employees.<br><br>Bates: 3243<br>Confidential Commercial Information: The redacted information identifies companies that made Emergency Use Authorization (EUA) submissions.<br><br>Bates: 3244<br>Personal Privacy Information: The redacted information contains the private phone numbers of a Department of Health and Human Services (HHS) employee. |
| 003245 | 003246 | 02/19/2020 | Uwe Scherf | RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission | (b)(5) | FDA-CVD-SCHERFU-00014207<br>Bates: 3245–3246<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations with Centers for Disease Control and Prevention (CDC) regarding surveillance of community transmission of SARS-CoV-2 and notes from FDA personnel related to those draft plans, the release of which |

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| 003247 | 003251 | 02/22/2020 | Uwe Scherf | RE: Cut-off change – Number of public health labs that verified CDC panel use | (b)(5) | FDA-CVD-SCHERFU-00014213<br>Bates: 3247–3248, 3250–3251<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention (CDC) diagnostic testing criteria, results, and laboratory verification processes for public health laboratories, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003252 | 003254 | 02/15/2020 | Uwe Scherf | RE: Request for enforcement discretion | (b)(5) | FDA-CVD-SCHERFU-00014226<br>Bates: 3252<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) draft language for testing asymptomatic individuals for COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003255 | 003257 | 02/17/2020 | Uwe Scherf | RE: BY noon tomorrow | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014240<br>Bates: 3255–3256<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding diagnostic capacity, testing development, and utilization, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability |

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| | | | | | | to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 3257<br>Personal Privacy Information: The redacted information contains the private phone numbers of a Department of Health and Human Services (HHS) employee. |
| 003258 | 003261 | 02/24/2020 | Uwe Scherf | RE: For Data Population and Review by 1pm Monday | (b)(5) | FDA-CVD-SCHERFU-00014244<br>Bates: 3260<br><br>Deliberative Process Privilege: The redacted information in this agency email exchange contains pre-decisional, internal deliberations regarding data population review related to specific supply chain actions for coronavirus diagnostics, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003262 | 003263 | 02/20/2020 | Uwe Scherf | RE: CDC 2019-nCoV Real-Time RT-PC Diagnostic Panel: addition of ZEN probes | (b)(5) | FDA-CVD-SCHERFU-00014247<br>Bates: 3262–3263<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) addition of ZEN probes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 003264 | 003267 | 02/22/2020 | Uwe Scherf | RE: Coronavirus and MERS culturing | (b)(5), (b)(6) | FDA-CVD-SCHERFU-00014259<br>Bates: 3266<br><br>Deliberative Process Privilege: The redacted information in this agency email exchange contains pre-decisional, internal deliberations regarding the development of coronavirus diagnostic testing and MERS culturing, the release of which would cause foreseeable harm |

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* Page prefix is FDACDRH-p5-AO
** Exemption codes refer to the sections of the Freedom of Information statue 5 U.S.C. § 552(b).
*** Privilege asserted by the Executive Office of the President

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**CONFIDENTIAL SETTLEMENT COMMUNICATION PROTECTED BY FED. RULE OF EVIDENCE 408**

Vaughn Index Version 2.0
March 10, 2025

***Vaughn Index (V2) for FOIA Request No. 2020-2531***
***American Oversight v. HHS et. al., Case No. 1:20-cv-0947 (D.D.C.)***

| Doc. Start | Doc. End | Date of Redacted Doc | Author(s) of Redacted Doc | Document Title | Exemption(s)** | Explanation |
|---|---|---|---|---|---|---|
| 000001 | 000016 | 3/2/2020 | Timothy Stenzel, M.D., Ph.D. | Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency: Immediately in Effect Guidance | (b)(5) | FDA-CVD-STENZELT-00024875.0001<br>Attachment to FDA-CVD-STENZELT-00024875<br><br>Bates: 000006, 000008, 000016<br><br>Deliberative Process Privilege: The redacted information in this draft slide deck contains pre-decisional, internal deliberations about the inclusion and/or removal of certain language relating to FDA's guidance laboratory-based testing for COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000018 | 000019 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | FW: Seattle Flu Study-FDA discussion | (b)(6) | FDA-CVD-STENZELT-00024893<br>Bates: 000018-000019<br>Personal Privacy Information: The redacted information contains a Zoom meeting ID number and access codes for this meeting. |

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| 000020 | 000021 | 2/27/2020 | Timothy Stenzel, M.D., Ph.D. | RE: COVID-19 | (b)(4), (b)(6) | FDA-CVD-STENZELT-00024896<br>Bates: 000020-000021<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to the status of Quidel's test for COVID-19, including information pertaining to Quidel's receipt of viral RNA from third-party companies and a potential application for Emergency Use Authorization of this test. The release of this information would inform competitors about Quidel's operations, and the operations of the third-party companies mentioned in these records and would lead to predictable harm.<br><br>Bates: 000020-000021<br>Personal Privacy Information: The redacted information contains the private email address, phone number, and cell phone number of a Quidel employee. |
| 000022 | 000024 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: EUA Submission | (b)(4), (b)(6) | FDA-CVD-STENZELT-00024915<br>Bates: 000022-000024<br><br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to ThermoFisher's capacity to provide tests for COVID-19 after it receives Emergency Use Authorization and updates regarding ThermoFisher's efforts to prepare its submission for Pre-Emergency Use Authorization. The release of this information would inform competitors about ThermoFisher's operations and would lead to predictable harm. |

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| | | | | | | Bates: 000022-000024<br>Personal Privacy Information: The redacted information contains the private emails of ThermoFisher employees and the private telephone number and internal extension of a senior ThermoFisher employee. |
| 000025 | 000025 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | Accepted: Seattle Flu Study - FDA discussion | (b)(6) | FDA-CVD-STENZELT-00024922<br>Bates: 000025<br>Personal Privacy Information: The redacted information contains a Zoom meeting ID number. |
| 000026 | 000030 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: SEATTLE Flu Study Lab Result | (b)(6) | FDA-CVD-STENZELT-00024956<br><br>Bates: 000026, 000028-000030<br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee, the private phone numbers of two University of Washington employees, and a Zoom meeting ID number with access codes and call-in information. |
| 000031 | 000032 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | IDT | (b)(4), (b)(5) | FDA-CVD-STENZELT-00024957<br>Bates: 000031<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to IDT Technologies' test for COVID-19 works and the efficacy of this test. The redacted information also covers a third-party company implicated by this email exchange. The release of this information would inform competitors about IDT Technologies' operations and the operations of this third-party company and would lead to predictable harm.<br><br>Bates: 000031-000032 |

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| | | | | | | Deliberative Process Privilege: The redacted information in this email exchange between agency employees contains pre-decisional deliberations about draft language related to the authorization of IDT Technologies' COVID-19 tests, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000035 | 000035 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | Research lab is asking to do clinical testing for coronavirus and report results to patients | (b)(4), (b)(5) | FDA-CVD-STENZELT-00024969<br>Bates: 000035<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to a question from an entity about the use of third party's COVID-19 test kit for their own purposes. The release of this information would inform competitors about this entity's operations and lead to predictable harm.<br><br>Bates: 000035<br>Deliberative Process Privilege: The redacted information in this email exchange contains an internal discussion about the scope of a third-party's grant of Emergency Use Authorization for its COVID-19 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 000036 | 000037 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | Guidance on Minimum Criteria for LDTs | (b)(5) | FDA-CVD-STENZELT-00024972<br>Bates: 000036<br>Deliberative Process Privilege: The redacted information in this internal agency email exchange contains deliberations about guidance on FDA's minimum acceptable criteria to validate laboratory developed tests (LDTs) for COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000038 | 000041 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT) PCR Diagnostic Panel has been issue[d] emergency use authorization. | (b)(4) | FDA-CVD-STENZELT-00024976<br><br>Bates: 000039<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to the number of COVID-19 tests the NYSDOH Wadsworth Center can produce and the projected number of tests it will be able to produce in the future. The release of this information would inform competitors about the NYSDOH Wadsworth Center's operations and lead to predictable harm. |
| 000050 | 000052 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: NYS Wadsworth Center COVID-19 Test | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025042<br><br>Bates: 000050<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to quality control testing for COVID-19 tests being developed by two companies. The release of this information would inform these |

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| | | | | | | companies' competitors about their operations and would lead to predictable harm.<br><br>Bates: 000050<br>Deliberative Process Privilege: The redacted information in this internal agency email exchange contains a discussion about quality control testing of the COVID-19 tests being developed by two companies, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000053 | 000056 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | FW: Minimal Criteria for test validation | (b)(5) | FDA-CVD-STENZELT-00025049<br><br>Bates: 000053-000054, 000056<br>Deliberative Process Privilege: The redacted information in this email exchange contains draft FDA guidance on minimum acceptable criteria for the validation of COVID-19 tests, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000057 | 000058 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: IDT | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025079<br>Bates: 000057<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to applications submitted by two companies for Emergency Use Authorization of their COVID-19 tests. The release of this information would |

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| | | | | | | inform competitors about these companies' operations and would lead to predictable harm.<br><br>Bates:000057-000058<br>Deliberative Process Privilege: The redacted information in this email exchange between agency officials contains draft language relating to the agency's review of one company's application for Emergency Use Authorization for its COVID-19 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000062 | 000063 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: IDT Lot numbers | (b)(6) | FDA-CVD-STENZELT-00025115<br>Bates: 000062-000063<br>Personal Privacy Information: The redacted information contains the private email addresses and telephone numbers of University of Washington employees, and lot numbers for COVID-19 tests. |
| 000063 | 000063 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Lot Numbers | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025115<br>Bates: 000063<br>Personal Privacy Information: The redacted information contains the private email addresses and telephone numbers of University of Washington employees, and lot numbers of COVID-19 tests.<br><br>Bates: 000063<br>Confidential Commercial Information: The redacted information relates to lot numbers of a third party's COVID-19 tests. The release of this information would |

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| | | | | | | inform competitors about the third party's operations and would lead to predictable harm. |
| 000064 | 000065 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Minimal Criteria for test validation | (b)(5) | FDA-CVD-STENZELT-00025116Bates: 000064-000065<br>Deliberative Process Privilege: The redacted information in this email exchange between agency employees contains a discussion about the minimum acceptable criteria for the validation of COVID-19 tests, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000068 | 000069 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Minimal Criteria for test validation | (b)(5) | FDA-CVD-STENZELT-00025143<br>Bates: 000068-000069<br>Deliberative Process Privilege: The redacted information in this email exchange between agency employees contains a discussion about the minimum acceptable criteria for the validation of COVID-19 tests, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000070 | 000071 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Pre-EUA Request: Mayo Clinic SARS-CoV-2 Molecular Detection Assay | (b)(6) | FDA-CVD-STENZELT-00025183<br>Bates: 000070-000071<br>Personal Privacy Information: The redacted information contains the private email address, telephone number, and pager number of a Mayo Clinic employee. |
| 000072 | 000074 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: LGC- Seracare - COVID-19 Reference | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025203 |

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| | | | | Material - IVD Communications | | Bates: 000072-000074<br>Personal Privacy Information: The redacted information contains the private email addresses and private cell phone numbers of LGC Group employees.<br><br>Bates: 000073<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to a third-party company name. The release of this information would inform competitors about this company's operations and would lead to predictable harm. |
| 000075 | 000076 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | QC Testing of CDC 2019- nCoV rRT-PCR Primers Probes DRAFT.pdf | (b)(5) | FDA-CVD-STENZELT-00025219<br>Bates: 000075-000076<br>Deliberative Process Privilege: The redacted information in this email exchange between FDA and CDC contains a discussion about quality control testing for COVID-19 tests, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000077 | 000078 | 2/27/2020 | Timothy Stenzel, M.D., Ph.D. | RE: LGC Biosearch - RUO coronavirus Kit PO | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025230<br>Bates: 000077-000078<br>Personal Privacy Information: The redacted information contains the private email addresses and private cell phone numbers of LGC Group employees.<br><br>Bates: 000077-000078<br>Confidential Commercial Information: The redacted information contains confidential commercial |

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| | | | | | | information that relates to the number of COVID-19 test kits LCG Group can provide, and the timing associated with the provision of these test kits. The release of this information would inform competitors about LCG Group's operations and would lead to predictable harm. |
| 000082 | 000083 | 2/27/2020 | Timothy Stenzel, M.D., Ph.D. | RE: LGC - Seracare - COVID-19 Reference Material - IVD Communications | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025231<br><br>Bates: 000082<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to a third-party company name. The release of this information would inform competitors about this company's operations and would lead to predictable harm.<br><br>Bates: 000082-000083<br>Personal Privacy Information: The redacted information contains the private email addresses and private telephone and cell phone numbers of LGC Group employees. |
| 000088 | 000091 | 2/27/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Meeting with Dr. Tim Stenzel<br>FDA OIR | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025302<br><br>Bates: 000088-000090<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to ThermoFisher's COVID-19 test, including questions it asked FDA before submitting its application for Emergency Use Authorization of this test. The release of this information would inform competitors about ThermoFisher's operations and would lead to predictable harm. |

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| | | | | | | Bates: 000088-000090<br>Personal Privacy Information: The redacted information contains the private email addresses and private telephone numbers of ThermoFisher employees. The redacted information also contains a WebEx meeting number (access code) and password. |
| 000092 | 000095 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | Fwd: 2019-nCoV EUA Template | (b)(4), (b)(5), (b)(6) | FDA-CVD-STENZELT-00025360<br><br>Bates: 000092-000093<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to one company's ability to secure viral RNA from another company so it can validate its COVID-19 test. The release of this information would inform competitors about these company's operations and would lead to predictable harm.<br><br>Bates: 000092<br>Deliberative Process Privilege: The redacted information in this email exchange contains discussions about the prioritization of one company's access to viral RNA so the company can complete its evaluation of its COVID-19 tests, and the impact access to viral RNA might have on the agency's ability to grant Emergency Use Authorization in this instance, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| | | | | | | Bates: 000092-000093<br>Personal Privacy Information: The redacted information contains the private email addresses of company employees. |
| 000096 | 000098 | 2/27/2020 | Timothy Stenzel, M.D., Ph.D. | RE: (b)(4), (b)(5) | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025391<br><br>Bates: 000096- 000098<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to the shutdown of a manufacturing facility because multiple employees contracted COVID-19. The release of this information would inform competitors about this company's operations and would lead to predictable harm.<br><br>Bates: 000096- 000098<br>Deliberative Process Privilege: The redacted information in this email exchange contains a discussion between agency employees about the impact of shutting down a manufacturing facility because employees tested positive for COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000099 | 000100 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | RE: 2019 nCoV | (b)(6) | FDA-CVD-STENZELT-00025410<br>Bates: 000099<br>Personal Privacy Information: The redacted information contains private email address of a LabCorp employee and the private cell phone number of an FDA employee. |

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| 000101 | 000103 | 2/26/2020 | Timothy Stenzel, M.D., Ph.D. | RE: February 21st Meeting | (b)(6) | FDA-CVD-STENZELT-00025415<br><br>Bates: 000101- 000103<br>Personal Privacy Information: The redacted information contains the private email address, telephone and cell phone numbers, and internal extension of a ThermoFisher employee. |
| 000106 | 000114 | 2/26/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025436<br><br>Bates: 000109- 000114<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to the status of various companies' development of COVID-19 tests as of February 2020. The release of this information would inform competitors about these companies' operations and would lead to predictable harm.<br><br>Bates: 000109- 000114<br>Deliberative Process Privilege: The redacted information covers a draft presentation given by FDA to CDC to discuss the status of various companies' development of COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000120 | 000121 | 2/25/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Availability of CDC Designed Kits | (b)(5) | FDA-CVD-STENZELT-00025461<br>Bates: 000120-000121<br>Deliberative Process Privilege: The redacted information covers an email exchange between agency employees |

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| | | | | | | that discusses the availability and efficacy of COVID-19 test kits from two companies, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000122 | 000122 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | Attachment 00025462 | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025462.0001<br>Attachment to FDA-CVD-STENZELT-00025462<br>Bates: 000122<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to the status of various companies' Pre-Emergency Use Authorization applications for their COVID-19 tests as of February 2020. The release of this information would inform competitors about these companies' operations and would lead to predictable harm.<br><br>Bates: 000122<br>Deliberative Process Privilege: The redacted information contains a table included as an attachment to an email exchange between agency officials with information about various companies' COVID-19 tests, their Pre-Emergency Use Authorization applications, and the agency's prioritization of these applications, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 000123 | 000124 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | nCoV PEUA Assignments-Priority List.xlsx | (b)(5) | FDA-CVD-STENZELT-00025462<br>Bates: 000123-000124<br>Deliberative Process Privilege: The redacted information covers an email exchange between agency employees relating to various companies' development of COVID-19 tests and a discussion of licensing issues, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000127 | 000132 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | RE: 2019 nCoV | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025490<br><br>Bates: 000130- 000132<br>Deliberative Process Privilege: The redacted information contains a draft memorandum discussing interagency strategy recommendations from the MCM TF Diagnostic Working Group, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 000127- 000128<br>Personal Privacy Information: The redacted information contains the private email address and cell phone number of a LabCorp employee and the private phone number of an FDA employee. |
| 000135 | 000136 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | CDC Update to patient population | (b)(5) | FDA-CVD-STENZELT-00025506<br>Bates: 000135-000136 |

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| | | | | | | Deliberative Process Privilege: The redacted information in the email exchange covers internal agency discussions about CDC's request for FDA to grant Emergency Use Authorization for its test for a virus other than COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000138 | 000138 | 2/18/2020 | Timothy Stenzel, M.D., Ph.D. | Coronavirus and MERS Culturing | (b)(5) | FDA-CVD-STENZELT-00025521<br>Bates: 000138<br>Deliberative Process Privilege: The redacted information covers a question FDA asked to CDC regarding the use of CDC's assay in non-public health labs, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000139 | 000140 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Draft CDC EUA 2019-nCoV Letter of Authorization 2-24-20.doc | (b)(5) | FDA-CVD-STENZELT-00025524<br>Bates: 000139- 000140<br>Deliberative Process Privilege: The redacted information covers internal discussions about conditions CDC suggested FDA include in a grant of Emergency Use Authorization for COVID-19 tests, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000141 | 000142 | 2/25/2020 | Timothy Stenzel, M.D., Ph.D. | Availability of CDC Designed Kits | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025535<br>Bates: 000141 |

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| | | | | | | Confidential Commercial Information: The redacted information relates to the number of test kits IDT Technologies was able to provide as of the date of this email. The release of this information would inform competitors about IDT Technologies operations and would lead to predictable harm.<br><br>Bates: 000141<br>Deliberative Process Privilege: The redacted information includes a discussion between agency employees regarding the availability of CDC COVID-19 test kits and which entities FDA may distribute them to, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000152 | 000158 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | RE:2019 nCoV | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025595<br><br>Bates: 000152-000153, 000155-000156, 000158<br>Personal Privacy Information: The redacted information contains the private email addresses, telephone and cell phone numbers, and fax numbers of LabCorp and Roche employees. The redacted information also contains the private cell phone number of an FDA employee.<br><br>Bates: 000157<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to a discussion between FDA and Roche regarding Roche's research and development |

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| | | | | | | plans as it pertains to a particular product. The release of this information would inform competitors about Roche's operations and would lead to predictable harm. |
| 000162 | 000163 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | RE:2019 nCoV | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025608<br><br>Bates:000162<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to a third-party company name. The release of this information would inform competitors about this company's operations and would lead to predictable harm.<br><br>Bates:000162<br>Personal Privacy Information: The redacted information contains private email addresses and phone numbers of Roche employees. |
| 000166 | 000168 | 2/26/2020 | Timothy Stenzel, M.D., Ph.D. | RE: February 21st Meeting | (b)(6) | FDA-CVD-STENZELT-00025621<br><br>Bates: 000166-000168<br>Personal Privacy Information: The redacted information contains the private email addresses and phone numbers of ThermoFisher employees. |
| 000169 | 000171 | 2/25/2020 | Timothy Stenzel, M.D., Ph.D. | RE: IDT provides 2019-nCoV Kits that includes the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025635<br><br>Bates: 000169<br>Confidential Commercial Information: The redacted information contains confidential commercial information regarding questions about CDC and IDT Technologies' COVID-19 tests. The release of this information would inform competitors about CDC's and |

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| | | | | | | IDT Technologies' operations and would lead to predictable harm.<br><br>Bates: 000169-000171<br>Deliberative Process Privilege: The redacted information covers internal discussions between agency employees about CDC's and IDT Technologies' COVID-19 tests, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000175 | 000177 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | RE: 2/24/20 6 AM Update | (b)(5) | FDA-CVD-STENZELT-00025647<br><br>Bates: 000176-000177<br>Deliberative Process Privilege: The redacted information covers internal deliberations by agency employees relating to the testing of select patients for COVID-19 to determine its transmissibility and FDA's anticipation of new Pre-Emergency Use Authorization applications for COVID-19 tests, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000178 | 000180 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | RE: 2019 nCoV | (b)(6) | FDA-CVD-STENZELT-00025652<br><br>Bates: 000178, 000180<br>Personal Privacy Information: The redacted information contains private email addresses and phone numbers of |

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| | | | | | | Roche employees, and the private cell phone number of an FDA employee. |
| 000184 | 000187 | 2/20/2020 | Timothy Stenzel, M.D., Ph.D. | FW: Problems with CDC coronavirus test delay expanded US screening | (b)(4) | FDA-CVD-STENZELT-00025666<br><br>Bates: 000185<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to the Association of Public Health Laboratories' (APHL) count of the number of labs that have been able to verify use of CDC's COVID-19 test. The release of this information would inform competitors about APHL's operations and would lead to predictable harm. |
| 000188 | 000195 | 2/20/2020 | Timothy Stenzel, M.D., Ph.D. | Draft Letter for Dr. Redfield regarding an EUA | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025670.0001<br>Attachment of FDA-CVD-STENZELT-00025670<br><br>Bates: 000188-000195<br>Confidential Commercial Information: The redacted information in this draft letter contains confidential commercial information that relates to CDC's application for Emergency Use Authorization for its COVID-19 test. The release of this information would inform competitors about CDC's operations and would lead to predictable harm.<br><br>Bates: 000188-000195<br>Deliberative Process Privilege: The redacted information is a draft of the letter of authorization for CDC's COVID-19 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability |

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| | | | | | | to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000196 | 000196 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | Draft CDC EUA 2019-nCoV Letter of Authorization 2-24-20.doc | (b)(5) | FDA-CVD-STENZELT-00025670<br>Bates:000196<br>Deliberative Process Privilege: The redacted information covers an email exchange between agency employees that discusses the potential inclusion of certain conditions in FDA's grant of Emergency Use Authorization for CDC's COVID-19 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000199 | 000205 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | RE: RE: RE: 2019 nCoV | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025712<br><br>Bates: 000200<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to LabCorp's anticipated timeline for submitting its application for Pre-Emergency Use Authorization for its COVID-19 test. The release of this information would inform competitors about LabCorp's operations and would lead to predictable harm.<br><br>Bates: 000200-000203<br>Personal Privacy: The redacted information contains private email addresses and cell phone numbers of LabCorp employees and the private phone number of an FDA employee. |

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| 000215 | 000218 | 2/25/2020 | Timothy Stenzel, M.D., Ph.D. | RE: COVID-19 assays | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025749<br><br>Bates: 000215-000218<br>Confidential Commercial Information: The redacted information contains confidential commercial information related to Quidel's discussion with FDA regarding the development of their COVID-19 assays. The release of this information would inform competitors about Quidel's operations and would lead to predictable harm.<br><br>Bates: 000215-000216<br>Personal Privacy Information: The redacted information contains private email addresses and phone numbers of Quidel employees. |
| 000219 | 000221 | 2/25/2020 | Timothy Stenzel, M.D., Ph.D. | RE: 2019 nCoV | (b)(6) | FDA-CVD-STENZELT-00025788<br><br>Bates: 000219-000220<br>Personal Privacy Information: The redacted information contains the private email addresses, phone numbers, and cell phone numbers of ThermoFisher and FDA employees. |
| 000222 | 000223 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | RE: checking in on 2021 USCAP Timely USCAP Timely Topics lecture | (b)(6) | FDA-CVD-STENZELT-00025794<br>Bates: 000223<br>Personal Privacy Information: The redacted information contains University of Washington employee lodging information. |
| 000226 | 000226 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: SEATTLE Flu Study Lab Result | (b)(6) | FDA-CVD-STENZELT-00033548<br>Bates: 000226 |

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| | | | | | | Personal Privacy Information: The redacted information contains private email addresses of a public entity's employees. |
| 000227 | 000227 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: NYS Wadsworth Center COVID-19 Test | (b)(5) | FDA-CVD-STENZELT-00033549<br>Bates: 000227<br>Deliberative Process Privilege: The redacted information in this email exchange between agency employees contains internal deliberations about the right of the NYSDOH Wadsworth Center to reference data in CDC's Emergency Use Authorization application for its COVID-19 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000229 | 000229 | 2/29/2020 | Timothy Stenzel. M.D., Ph.D. | RE: NYS Wadsworth Center COVID-19 Test | (b)(5) | FDA-CVD-STENZELT-00033600<br>Bates: 000229<br>Deliberative Process Privilege: The redacted information covers a discussion between FDA employees about the need to obtain CDC's approval so other entities can begin referencing data in CDC's Emergency Use Authorization application for its COVID-19 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 000230 | 000230 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | Fwd: SEATTLE flu Study Lab Result | (b)(6) | FDA-CVD-STENZELT-00033607<br>Bates: 000230 |

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| | | | | | | Personal Privacy Information: The redacted information contains private email addresses of a public entity's employees. |
| 000232 | 000232 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | Fwd: 2019-nCov EUA Template | (b)(5), (b)(6) | FDA-CVD-STENZELT-00033680<br>Bates: 000232<br>Deliberative Process Privilege: The redacted information covers internal discussions about the availability of viral RNA for COVID-19 test developers, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 000232<br>Personal Privacy Information: The redacted information contains private email addresses of LabCorp employees. |
| 000234 | 000235 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | RE: 2019 nCoV | (b)(6) | FDA-CVD-STENZELT-00033775<br>Bates: 000234-000235<br>Personal Privacy Information: The redacted information contains the private email addresses of Roche employees. |
| 000236 | 000236 | 2/25/2020 | Timothy Stenzel, M.D., Ph.D. | Fwd: Co-Diagnostics SARS-CoV-2 Assay Garners CE Mark GenomeWeb | (b)(6) | FDA-CVD-STENZELT-00033828<br>Bates: 000236<br>Personal Privacy Information: The redacted information contains the private email address of an FDA employee. |
| 000237 | 000237 | 2/25/2020 | Timothy Stenzel, M.D., Ph.D. | Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-2 | (b)(5) | FDA-CVD-STENZELT-00033843<br>Bates: 000237<br>Deliberative Process Privilege: The redacted information relates to internal discussions between FDA employees |

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| | | | | published assays in individual tubes | | about the availability of COVID-19 test kits and whether, upon receipt, public health laboratories will be required to validate these test kits under existing Emergency Use Authorization conditions, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

* Page prefix is FDACDRH-AO.
** Exemption codes refer to the sections of the Freedom of Information statue 5 U.S.C. § 552(b).

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**From:** Shuren, Jeff
**To:** Shuren, Jeff
**Subject:** FW: Cut-off change - lot release testing criteria
**Date:** Sunday, March 1, 2020 11:56:31 AM

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 2:03 PM
**To:** Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Thanks you.

Uwe

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**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Tuesday, February 18, 2020 1:41 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

We are working to find answers to your questions below and will get back to you as soon as we have the information.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 3:53 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH)

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<Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thank you for this information. A couple of additional questions regarding (b) (5)

(b) (5)

Thanks,

Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 11:29 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
For clarification the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel consists of two separate boxes. Box #1 contains the primers and probes as described below:

**2019-nCoVEUA-01 Box #1: Primers and Probes**

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
|---|---|---|---|---|
| 2019-nCoV_N1 | RV202001 | 2019-nCoV_N1 Combined Primer/Probe Mix | 22.5 nmol | 1000 |

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| | | | | |
|---|---|---|---|---|
| 2019-nCoV_N2 | RV202002 | 2019-nCoV_N2 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N3 | RV202003 | 2019-nCoV_N3 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| RP | RV202004 | Human RNase P Forward Primer/Probe Mix | 22.5 nmol | 1000 |

Primer and probes from three individual boxes that were randomly selected after kit assembly were tested as presented in the powerpoint file provided earlier.

Also as requested, please find attached the QC testing process of primer/probe reagents at bulk and post-fill analysis.

We hope this helps to clarify the data presented and addresses your request.
Thank you very much.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

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**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)
**Sent:** Monday, February 17, 2020 10:07 AM
**To:** 'Scherf, Uwe' <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Uwe,
The samples tested represent 3 randomly selected kits at “final kit”. I hope this addresses your question.
We will send a meeting invitation shortly for 1pm if that time is still OK for your team.
Thank you very much.
Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 9:56 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

Thanks, please provide asap in writing (b) (5) [redacted]

Thanks,
Uwe

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Monday, February 17, 2020 9:15 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Below are the summary results of our heightened NTC QC testing for the distributed lot of N1, N2 and N3 reagents.

**2019-nCoVEUA-01 Lot 20-0121 Final Kit Heightened QC (NTC Reactions)**

| Marker | Frequency | Percentage | Average Ct | Range |
|---|---|---|---|---|
| (b) (5) [redacted] | | | | |

The attached powerpoint includes the detailed test results for your review.
We will provide a call-in number as soon as possible.
Thank you very much

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Steve

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**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 10:06 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Steve,

Thank you for the update, when will you send us the (b) (5) [redacted]

Regarding tomorrow's conference call, my team will be available at 1 or 2 PM tomorrow. Please let me know what will work better for you and your team. Please provide a call in number.

Thanks,
Uwe
-

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 9:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,
Thank you for your prompt response! We will attempt to address your questions, although we may need to consult further internally to get specific information on some of the questions.

Q1: Clarify how many total lots of EUA reagents are being distributed?
(b) (5) [redacted]

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Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5) [redacted]

Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately]. (b) (5) [redacted]

Please let us know if you have any additional questions.
Thank you very much!
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE Atlanta, GA 30333
Phone: 404-639-1587
**********

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 5:23 PM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Steve,

My team will meet soon to discuss your proposal.

I have the following preliminary questions [in red]. Please address them asap.

Per your email: (b) (5) [redacted]

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(b) (5) [Q1: Clarify how many total lots of EUA reagents are being distributed?] (b) (5) [redacted] [Q2: Clarify the rational why only N1 and N2 and not include N3. Provide data to justify exclusion of N3]. (b) (5) [redacted] [Q3: It is FDA's understanding that this specific lot is the only lot available for testing outside CDC headquarters and that new lots to be manufactured will not be available until March, clarify whether the proposed contingent measure will be applied immediately].

Thank you,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

-

---

**From:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Sent:** Sunday, February 16, 2020 4:29 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani <Himani.Bisht@fda.hhs.gov>; Mielech, Anna <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Dear Uwe,

(b) (5) [redacted]

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(b) (5)

(b) (5) N1 and N3 EUA assays to demonstrate the frequency and Ct range of false positive results.

If possible we would like to arrange a call with you sometime tomorrow to discuss this strategy and to learn how you would prefer to see this data summarized/presented. We are available from 9-11am or after 1pm if those times are available for you and your FDA colleagues.

Thank you very much for your consideration and support.
Steve

**********
Stephen Lindstrom, Ph.D.
Team Lead, Respiratory Viruses Diagnostic Laboratory
Respiratory Viruses Branch
Division of Viral Diseases, NCIRD
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-G04, Atlanta, GA 30333
Phone: 404-639-1587
**********

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 11:54 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E (FDA/CDRH) <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) (FDA/CDRH) <Li.Li2@fda.hhs.gov>; Bisht, Himani (FDA/CDRH) <Himani.Bisht@fda.hhs.gov>; Mielech, Anna (FDA/CDRH) <Anna.Mielech@fda.hhs.gov>; Feldblyum, Tamara (FDA/CDRH) <Tamara.Feldblyum@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change - lot release testing criteria

Hi Julie & Steve,

As a part of your efforts (b) (5) [redacted]

Thanks,
Uwe

**From:** Scherf, Uwe
**Sent:** Sunday, February 16, 2020 9:55 AM
**To:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
**Subject:** RE: Cut-off change

HI Julie,

Thanks for the update. Based on FDA's internal discussion this morning we have the following additional information request:

(b) (5) [redacted]

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(b) (5)



Thanks,
Uwe

---

**From:** Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Sent:** Sunday, February 16, 2020 8:05 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Lindstrom, Stephen (CDC) <sql5@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Cut-off change

Hi Uwe,

We will meet as a team to review data later this morning. We hope to get you something in writing as soon as possible.

There are laboratories that have not had any problems and are testing. We will need to work to find more detailed information for you.

Thanks,
Julie

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 16, 2020 7:40 AM
**To:** Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <sql5@cdc.gov>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>
**Subject:** Cut-off change
**Importance:** High

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Steve & Julie,

I know everyone is working very hard to finalize the proposal for cut-off change in for your assay. Do you have any update on when we could expect to receive the request and any data

On a second note, could you please clarify one issue for me: it is my understanding that (b) (5) [redacted] is that correct?

Thank you for your feedback.

Uwe

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| | |
|---|---|
| **From:** | Shuren, Jeff |
| **To:** | Shuren, Jeff |
| **Subject:** | Fwd: APHL Letter for FDA |
| **Date:** | Tuesday, February 25, 2020 4:43:16 AM |
| **Attachments:** | enforcement discretion request for COVID-19 for PHLs final.pdf |

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 24, 2020 at 8:34:10 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: APHL Letter for FDA

FYI

---

**From:** Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>
**Date:** February 24, 2020 at 8:20:42 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Fwd: APHL Letter for FDA

FYI

---

**From:** Becker, Scott | APHL <Scott.Becker@aphl.org>
**Sent:** Monday, February 24, 2020 11:22 AM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD); Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS)
**Subject:** APHL Letter for FDA

Dear Wendi and Ren:

I am writing to let you know that the APHL Board of Directors approved sending a letter urging the FDA Commissioner to consider enforcement discretion to allow governmental public health laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). In the letter we state that to the extent possible, public health laboratories could work together to:

- Utilize a standard protocol or use a limited set of protocols
- Purchase reagents including primers and probes from a common source
- Utilize a standard validation panel
- Recommend a minimum standard validation approach
- Enable confirmation at another PHL while cases remain sporadic. It is also possible to consider the use of LRN advanced labs to serve as a confirmatory lab if resources are available to do so.

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We recognize that not all PHL's will develop and implement an LDT. If PHL's decided against the use of an LDT for whatever reason, they could: 1) wait for the availability of the new CDC replacement kit, 2) coordinate with a PHL that has developed an LDT (this is not uncommon for PHLs to work together), or 3) use a commercially available assay once approved by FDA under an EUA.

We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request.

We will let you know the outcome of our communication with FDA, which is attached. The letter was sent to the FDA Commissioner, copy to his chief of staff; Dr. Redfield, copy to Dr. Jernigan.

Sincerely,

Scott Becker

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Scott Becker MS
Executive Director
Association of Public Health Laboratories
Silver Spring MD
240.485.2747

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**Scott J. Becker** (he/him)
Chief Executive Officer
**P** +1 240.485.2747 | **M** +1 301.526.5704
scott.becker@aphl.org | @scottjbecker

**Association of Public Health Laboratories**
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
www.aphl.org | APHL Blog
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APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

February 24, 2020

Stephen M. Hahn, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn,

On behalf of our nation's state and local public health laboratories (PHLs), we are writing to urge you to consider enforcement discretion to allow this select group of governmental laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request.

While we appreciate the many efforts underway at CDC to provide a diagnostic assay to our member labs under the Emergency Use Authorization (EUA), this has proven challenging and we find ourselves in a situation that requires a quicker local response. We are now many weeks into the response with still no diagnostic or surveillance test available outside of CDC for the vast majority of our member laboratories. While we understand that the EUA process is open to PHLs, we believe a more expeditious route is needed at this time.

To the extent possible, public health laboratories could work together to:

- Utilize a standard protocol or use a limited set of protocols
- Purchase reagents including primers and probes from a common source
- Utilize a standard validation panel
- Recommend a minimum standard validation approach
- Enable confirmation at another PHL while cases remain sporadic. It is also possible to consider the use of LRN advanced labs to serve as a confirmatory lab if resources are available to do so.

We recognize that not all PHL's will develop and implement an LDT. If PHL's decided against the use of an LDT for whatever reason, they could: 1) wait for the availability of the new CDC replacement kit, 2) coordinate with a PHL that has developed an LDT (this is not uncommon for PHLs to work together), or 3) use a commercially available assay once approved by FDA under an EUA.

We look forward to discussing this request with you and your staff as soon as possible. If you have questions, please contact Scott Becker at 301-526-5704 or via email at scott.becker@aphl.org.

Sincerely,

Grace Kubin

Scott J. Becker

Grace Kubin, Ph.D.
Director, Laboratory Services Section
Texas Department of State Health Services

Scott J. Becker, MS
Chief Executive Officer
Association of Public Health Laboratories

cc: Robert Redfield, MD, Director, Centers for Disease Control and Prevention

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# Senate HELP Bipartisan Staff Briefing on Supply Chain: Follow-up Questions

## Drugs

1. **How many FDA-registered drug manufacturing sites (including manufacturing sites that produce active pharmaceutical ingredients (API) and finished dosage form sites) are located in China? Of those, how many of those sites are located in Hubei Province?**

(b) (5)

2. **Of the 25 drug manufacturing sites in Hubei Province, how are finished dosage form manufacturing sites and how many manufacture API?**

(b) (5)

3. **Of those drug manufacturing sites registered with FDA, does FDA have information regarding the status of operation (ie, fully operational, less than fully operational, not operating) about each site? If so, please provide details.**

(b) (5)

4. **How many FDA-registered drug manufacturing sites in Hubei Province experienced some sort of closure related to the coronavirus outbreak?**

(b) (5)

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5. **Dr. Woodcock's October 2019 testimony notes that 13% as of August 2019 of the API manufacturers that supply the U.S. are located in China. What does FDA know about the status of these manufacturing sites? (on the 2/18 call, FDA indicated that China sourced 18% of the U.S. supply of API – please confirm which number is correct)**

(b) (5)

7. **What percent of the U.S. supply of API and finished dosage form drugs is manufactured domestically? Please provide what is known about the domestic manufacturing capacity for generics, small molecule, or biologics, if possible.**

(b) (5)

## Devices

8. **Of the 4,000 device manufacturing sites in China, how many are in Hubei Province? Does FDA have information regarding the status of operation (ie, fully operational, less than fully operational, not operating) about each site?**

(b) (5)

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(b) (5)

9. **On the 2/18 call, FDA indicated that the 4,000 device manufacturers included contract manufacturers, contract sterilizers, and finished product manufacturers – does this also include manufacturers of component parts for medical devices?**

(b) (5)

10. **What type of medical products do these manufacturing sites produce? What percentage is manufactured for the U.S. market (general percentage)?**

(b) (5)

11. **Of those device manufacturing sites registered with FDA, does FDA have information regarding the status of operation (ie, fully operational, less than fully operational, not operating) about each site? If so, please provide details.**

(b) (5)

12. **Have these manufacturing sites indicated whether they will experience delays in the manufacturing of devices or components of their devices? If so, does FDA have estimates regarding the level of delay/shortage (both for a whole device or a certain component of the device)?**

(b) (5)

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(b) (5)

[redacted]

**13. Is there any precedent for device shortages? If so, what is the typical approach for mitigating a device shortage?**

(b) (5)

[redacted]

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**14. Of the U.S. supply of medical devices and medical supplies, what percent is manufactured domestically? Please provide what is known about the domestic manufacturing capacity for medical devices such as masks and other PPE, needles, syringes, or other medical devices that may be needed for the domestic response to coronavirus, if possible.**

(b) (5)



**Drugs and Devices**

**15. Does China's FDA collect information about the status of drug or device manufacturing facilities? If so, does China share that information with the US government**

(b) (5)



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**From:** Shuren, Jeff
**To:** Shuren, Jeff
**Subject:** FW: COVID Congressional Engagement
**Date:** Tuesday, February 25, 2020 11:16:50 PM
**Attachments:** image019.png
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Senate HELP Bipar followup questions 2.24.20.pdf
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image034.jpg
image035.jpg
image036.jpg

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We also have been speaking with distributors, hospitals, hospitals associations, and industry trade associations, as well as working with HHS, CDC and other government bodies

(b) (5) [redacted]

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 25, 2020 at 10:45:50 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Mitchell, Diane <Diane.Mitchell@fda.hhs.gov>, Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>
**Subject:** FW: COVID Congressional Engagement

Jeff,

OL just sent additional intel and suggestions for tomorrow's briefing, below. As noted, all Senate HELP Health LAs will be invited. OL is asking that (b) (5) [redacted] I do concur with OL that you should be prepared for COVID-19 questions outside the Senate bipar list.

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I've also highlighted the point from staff below that they will appreciate context for the numbers.

Please note, (b) (5) [redacted]

(b) (5) [redacted]

Please do let me know if you have any questions or concerns on the overall plan for tomorrow, and if there is anything else you want to be sure we cover during tomorrow's 9 am prep.

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov





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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

---

**From:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 10:19 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

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Ken and Jennifer,

The committee staff is planning to invite all HELP LA's to the briefing, and we should expect additional questions in the drug and device space, outside of the QA doc to come up. Margaret did state that walking through the questions sounds good, and providing a general update would be nice for folks on the phone that haven't heard one from FDA. She also stated "In general, all the numbers you all shared, while they are very helpful, it would be also great to have in context – for example, where we have the number of facilities in China, do we also have the number of facilities globally? Recognizing there is a volume component there too."

We can discuss more at the prep, but regarding an update, (b) (5) [redacted]

(b) (5) [redacted]

These are just suggestions. There are a million TP's floating around, many of which you have generated, so we won't send any unless you request them.

Thanks,
Prakash

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:43 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>

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**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Same!

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

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jennifer.tomasello@fda.hhs.gov





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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

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**From:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:42 PM
**To:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Phone works for us.

---

**From:** Rath, Prakash (FDA)
**Sent:** Tuesday, February 25, 2020 4:41 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Thank you, and about to send.

For the briefing, we secured the EOC exec conference room, 32-1337, and center directors should have access from what I'm told. For the prep, it may be easier to do it by the phone, but please let us

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know otherwise.

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**From:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:40 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

I'm getting the 100% from JW, but if 9:00 – 9:30 still works lets lock it in and get out the invites.

Please also invite per her request:

Cindy Buhse (Lucinda)
Val Jenson; and
John Farley

---

**From:** Van Pool, Kendall
**Sent:** Tuesday, February 25, 2020 4:04 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Thanks so much.

We are still holding both windows so lock in and please send through the invite.

I'll check in on the prep time.

Can you include:

Janet Woodcock
Kendall Van Pool
Patrizia Cavazzoni (OPTIONAL if she can make it)

---

**From:** Tomasello, Jennifer
**Sent:** Tuesday, February 25, 2020 4:00 PM
**To:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Van Pool, Kendall

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<Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Prakash,

Thank you for confirming! Let me check on prep as we need to rearrange a couple things here. Will circle back.

Jennifer

**Jennifer Brown Tomasello, MPA**
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Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

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---

**From:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:57 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Hi all,

Just heard from HELP and 12-1 works for them. We'll find a room and send an invite shortly. Regarding a prep, I mentioned below that maybe we could look for times today, but it seems pretty late now.

Do you think Drs. Woodcock and Shuren would like/need a prep, and if so, could we use 15-30 min from 9-10 tomorrow? Please let us know.

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Thanks,
Prakash

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**From:** Rath, Prakash (FDA)
**Sent:** Tuesday, February 25, 2020 8:47 AM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

We inquired about these times and will circle back once we hear from the committee. Please 'hold' for now. If you feel it's necessary (and time permits), we can look for a quick prep time this afternoon.

Thanks,
Prakash

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 5:52 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

No worries and thank you! OL – please see if one of those two windows will work for staff.

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

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jennifer.tomasello@fda.hhs.gov

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*service you have received:*
***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

---

**From:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 4:59 PM
**To:** Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** FW: COVID Congressional Engagement

These windows will work for JW on Wednesday. Sorry for the back and forth on this!

Ken

---

**From:** Thomas, Ashley
**Sent:** Monday, February 24, 2020 4:57 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

9-10 am and 12-1 pm will work.

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FDA U.S. FOOD & DRUG ADMINISTRATION

Febuary 4, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Dear Dr. Redfield:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.[1]

On Feburary 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the 2019-nCoV. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) subject to the terms of any authorization issued under Section 564(a) of the Act.[2]

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (as described in the scope Section of this letter (Section II)) in individuals who

[1] For ease of reference, this letter will refer to "qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests" as "authorized laboratories."

[2] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. Feburary 4, 2020.

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meet CDC criteria for 2019-nCoV testing for the presumptive detection of 2019-nCoV by authorized laboratories, subject to the terms of this authorization.

**I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in individuals who meet CDC criteria for 2019-nCoV testing meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The 2019-nCoV can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel may be effective in diagnosing 2019-nCoV infection, and that the known and potential benefits of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, when used for diagnosing 2019-nCoV infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel for diagnosing 2019-nCoV infection.[3]

**II. Scope of Authorization**

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel by authorized laboratories for the presumptive detection of 2019-nCoV in individuals who meet CDC criteria for 2019-nCoV testing.

**The Authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel**

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is for the presumptive detection of 2019-nCoV RNA in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate), and other authorized specimens collected from individuals who meet CDC criteria for 2019-nCoV testing. The testing procedure consists of nucleic acid extraction and purification from the human specimen using authorized extraction methods/instruments followed by real time RT-PCR, where the RNA is reverse transcribed into cDNA and then amplified using the primer sets and detected using specific probes. The real time reverse transcriptase (RT)-PCR is performed on the FDA cleared Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS 1.4 software, or other authorized instruments or software.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel includes the following materials or other authorized materials:

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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- 2019-nCoV_N1, 2019-nCoV_N2 and 2019-nCoV_N3 vials containing primers and probes that target the nucleocapsid (N) gene and are designed for both universal detection of SARS-like coronavirus as well as specific detection of the 2019-nCoV
- RP vial containing the internal control primers and probes that target the Human RNase P gene
- nCoVPC vial containing the 2019-nCoV positive control used in the assay

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel also requires the use of additional authorized materials and authorized ancillary reagents that are not included with the test but are commonly used in clinical laboratories and are described in the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel requires the following control materials, or other authorized control materials; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use:

- Human Specimen Control (HSC): A human cell culture preparation used as an extraction control and positive control for the RNase P primer and probe set that is extracted and tested concurrently with each specimen extraction run.
- Positive Control for 2019-nCoV (nCoVPC): Run with each batch of specimens. Monitors for failures of rRT-PCR reagents and reaction conditions.
- No Template Control (NTC): Nuclease-free water included in each run. Monitors for reagent and system contamination.
- RNase P (RP) control in clinical samples: The RP primer and probe set is included in each run to test for human RNase P, which controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

The above described CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, when labeled consistently with the labeling authorized by FDA, entitled "CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), which may be revised by CDC in consultation with, and with concurrence of, the Division of Microbiology Devices (DMD)/Office of Health Technology 7 Office of In Vitro Diagnostics and Radiological Health (OHT7-OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The above-described CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized to be accompanied by the following information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

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- Fact Sheet for Patients: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel when used for the presumptive detection of 2019-nCoV and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel may be effective in the presumptive detection of 2019-nCoV, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, when used for detection of the 2019-nCoV in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel described above is authorized to detect 2019-nCoV in individuals who meet CDC criteria for 2019-nCoV testing.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

**III. Waiver of Certain Requirements**

I am waiving the following requirements for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the

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intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12)

**IV. Conditions of Authorization**

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

**Centers for Disease Control and Prevention (CDC)**

A. CDC will notify DMD/OHT7-OIR/OPEQ/CDRH in advance of any changes to the CDC criteria for 2019-nCoV testing.

B. CDC will make available the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with the authorized labeling only to authorized laboratories. CDC may request changes to the authorized labeling. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

C. CDC will provide to authorized laboratories the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers and the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Patients. CDC may request changes to the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers and the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Patients. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

D. CDC will make available on its website the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers and the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Patients.

E. CDC will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, authorized labeling and authorized Fact Sheets.

F. CDC will ensure that the authorized laboratories using the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

G. Through a process of inventory control, CDC will maintain records of test usage.

H. CDC will collect information on the performance of the test. CDC will report to FDA any suspected occurrence of false positive and false negative results and significant

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deviations from the established performance characteristics of the test of which CDC becomes aware.

I. CDC is authorized to make available additional information relating to the emergency use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel that is consistent with, and does not exceed, the terms of this letter of authorization.

J. CDC may request new Fact Sheets to accompany the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, if appropriate, and may request changes to such Fact Sheets. Such requests will be made by CDC in consultation with, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

K. CDC may request the addition of other instruments and associated software for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

L. CDC may request the addition of other extraction methods for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. CDC may request the addition of other specimen types for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. CDC may request the addition and/or substitution of other control materials for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. CDC may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. CDC will evaluate the analytical limit of detection and assess traceability[4] of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, CDC will update its labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. CDC will track adverse events and report to FDA under 21 CFR Part 803.

[4] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

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**Authorized Laboratories**

R. Authorized laboratories will include with reports of the results of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

S. Authorized laboratories will perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel as outlined in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use. Deviations from the authorized procedures, including the authorized RT-PCR instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel are not permitted.

T. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

U. Authorized laboratories will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and CDC (respvirus@cdc.gov) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

V. All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

**CDC and Authorized Laboratories**

W. CDC and authorized laboratories will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

**Conditions Related to Advertising and Promotion**

X. All advertising and promotional descriptive printed matter relating to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

Y. All advertising and promotional descriptive printed matter relating to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;

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- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from 2019-nCoV, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of 2019-nCoV under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel may represent or suggest that this test is safe or effective for the detection of 2019-nCoV.

The emergency use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection and/or diagnosis of 2019-nCoV is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Denise M. Hinton

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

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# FACT SHEET FOR HEALTHCARE PROVIDERS

**CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel** **February 4, 2020**

**2019 Novel Coronavirus (2019-nCoV)**

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Centers for Disease Control and Prevention (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Testing is to be conducted on specimens from people who meet CDC criteria for 2019-nCoV testing, available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section). The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel should be ordered only to presumptively detect 2019-nCoV infection. If outside the U.S., testing should follow appropriate public health authority consultation and/or guidance for the diagnosis and reporting of 2019-nCoV infection. All information and guidance, including for 2019-nCoV laboratory testing, may change as more data is gathered on this virus. Please check the CDC's 2019 Novel Coronavirus, webpage (see links provided in "Where can I go for updates and more information" section) regularly for the most current information.

**All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel**

**What are the symptoms of 2019-nCoV?**
Most patients with confirmed 2019-nCoV infection have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with 2019-nCoV infection. Based on what is known about MERS-CoV and SARS-CoV, signs and symptoms may appear any time from 2 to 14 days after exposure to 2019-nCoV virus. The median incubation period is unknown at this time.

Public health officials have identified cases of 2019-nCoV infection in the United States, which may pose risks for public health. To date most reported cases of 2019-nCoV infection outside of China have been directly or indirectly linked through residence in or travel to Wuhan City, China. There also are reports of human to human transmission through close contact with an individual confirmed to be ill with 2019-nCoV in countries outside China. Please check the CDC webpage for the most up to date information.

**This test is to be performed only using respiratory specimens collected from individuals who meet CDC criteria for 2019-nCoV testing.**

**What do I need to know about 2019-nCoV testing?**
Current information on 2019-nCoV infection for healthcare providers, including case definitions and infection control, is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel can be used to test upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, bronchoalveolar lavage, sputum, lower respiratory tract aspirate, nasopharyngeal wash/aspirate or nasal aspirate).
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel should be ordered for the presumptive detection of 2019-nCoV in individuals who meet CDC criteria for 2019-nCoV testing.
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized for use in qualified laboratories designated by CDC and in the U.S., certified under CLIA to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions following CDC *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007).*

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with 2019-nCoV as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with*

**Report Adverse events,** including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

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# FACT SHEET FOR HEALTHCARE PROVIDERS

**CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel** **February 4, 2020**

**2019 Novel Coronavirus (2019-nCoV)**

*2019 Novel Coronavirus (2019-nCoV)*. These specimens are only shipped for analysis to laboratories designated by CDC as qualified for analysis. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV)* (see links provided in "Where can I go for updates and more information" section).

**What does it mean if the specimen tests positive for 2019-nCoV?**
A positive test result for 2019-nCoV indicates that RNA from 2019-nCoV was detected, and the patient is presumptively infected with 2019-nCoV and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially 2019-nCoV infected patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

**What does it mean if the specimen tests negative for 2019-nCoV?**
A negative test result for this test means that 2019-nCoV RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out 2019-nCoV infection and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of 2019-nCoV infection.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with 2019-nCoV infection. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that 2019-nCoV infection is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If 2019-nCoV infection is still suspected based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities.

Risks to a patient of a false negative include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of 2019-nCoV within the community, or other unintended adverse events.

**What is an EUA?**
The United States (U.S.) FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of in vitro diagnostics (IVDs) under EUA for the detection and/or diagnosis of 2019-nCoV.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. However, based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of 2019-nCoV.

The EUA for this test is in effect for the duration of the 2019-nCoV emergency, unless terminated or revoked (after which the test may no longer be used). An FDA approved or cleared IVD should be used instead of an IVD under EUA, when applicable and available.

**Report Adverse events,** including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

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# FACT SHEET FOR HEALTHCARE PROVIDERS

**CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel** **February 4, 2020**

**2019 Novel Coronavirus (2019-nCoV)**

## Where can I go for updates and more information?

### CDC webpages:

**General:** https://www.cdc.gov/nCoV
**Healthcare Professionals:** https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
**Information for Laboratories:** https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
**Laboratory Biosafety:** https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
**Isolation Precautions in Healthcare Settings:** https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html#a4
**Specimen Collection:** https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html

### FDA webpages:

**General:** www.fda.gov/novelcoronavirus
**EUAs:**(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

### Manufacturer: CDC

CDC Emergency Operations Center (EOC)
1600 Clifton Road
Atlanta, Georgia, USA, 30329
Phone: **CDC EOC (770-488-7100)**

**Report Adverse events,** including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

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# FACT SHEET FOR PATIENTS

**CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel** **February 4, 2020**

**2019 Novel Coronavirus (2019-nCoV)**

You are being given this Fact Sheet because your sample(s) were tested for the 2019 novel coronavirus (2019-nCoV) using the Centers for Disease Control and Prevention (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Testing was done because you meet CDC criteria for 2019-nCoV testing.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of 2019-nCoV infection. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on 2019-nCoV please visit the CDC 2019 Novel Coronavirus webpage:**
- **https://www.cdc.gov/nCoV**

**What is 2019-nCoV Infection?**
2019-nCoV infection is caused by the 2019-nCoV. The 2019-nCoV infection can cause mild to severe respiratory illness in humans and was recently idenitifed in Wuhan, China. Limited information is available to characterize the spectrum of clinical illness associated with 2019-nCoV. 2019-nCoV likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, sneezing, difficulty breathing, etc.).

**What is the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel?**
The test is designed to detect 2019-nCoV in respiratory specimens, for example nasal or oral swabs.

**Why was my sample tested?**
Your sample(s) were tested because your healthcare provider believes you may have been exposed to 2019-nCoV based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and because:

- You live in or have recently traveled to a place where transmission of 2019-nCoV is known to occur, and/or
- Because you have been in close contact with an individual suspected of or confirmed to have 2019-nCoV infection.

The sample(s) collected from you were tested to help find out whether you may be infected with 2019-nCoV.

**What are the known and potential risks and benefits of the test?**
Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Risk that the test result is incorrect (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of 2019-nCoV to your family and others in your community.

**What does it mean if I have a positive 2019-nCoV test result?**
If you have a positive test result, it is very likely that you are infected with 2019-nCoV. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false

**Where can I go for updates and more information?** The most up-to-date information on 2019-nCoV is available at the CDC General webpage: **https://www.cdc.gov/nCoV**. In addition, please also contact your healthcare provider with any questions/concerns.

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# FACT SHEET FOR PATIENTS

**CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel** **February 4, 2020**

**2019 Novel Coronavirus (2019-nCoV)**

positive result). However, your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, such as symptoms, possible exposures, and geographic location of places you have recently traveled.

**What does it mean if I have a negative test result?**
A negative test result means that 2019-nCoV was not found in your sample. For 2019-nCoV, a negative test result for a sample collected while a person has symptoms usually means that 2019-nCoV did not cause your recent illness.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with 2019-nCoV infection, meaning you could possibly still have an infection with 2019-nCoV even though the test is negative. Therefore, while a negative test most likely means you do not have 2019-nCoV infection, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

**Is this test FDA-approved or cleared?**
No. This test is not yet approved or cleared by the United States (U.S.) FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of in vitro diagnostics under EUA for the detection and/or diagnosis of 2019-nCoV. This EUA will remain in effect (meaning this test can be used) for the duration of the 2019-nCoV emergency, unless it is terminated or revoked by FDA (after which the test may no longer be used).

**Where can I go for updates and more information?** The most up-to-date information on 2019-nCoV is available at the CDC General webpage: **https://www.cdc.gov/nCoV**. In addition, please also contact your healthcare provider with any questions/concerns.

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# CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

**For Emergency Use Only**

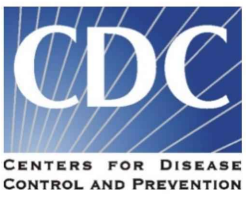
## Instructions for Use

**Catalog # 2019-nCoVEUA-01**
**1000 reactions**

For *In-vitro* Diagnostic (IVD) Use

Rx Only

Centers for Disease Control and Prevention
Division of Viral Diseases
1600 Clifton Rd NE
Atlanta GA 30329




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FDACDRH-p3-AO-002628
FDA-CVD-SHURENJ-00020120107 MULTI-HHS-20-0522-B, 20-0523-A-003317

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FDACDRH-p3-AO—002629

FDA-CVD-SHURENJ-00020127 MULTI-HHS-20-0522-B, 20-0523-A-003318

## Intended Use

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization.

## Summary and Explanation

An outbreak of pneumonia of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019. Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis 2019-nCoV and is based on widely used nucleic acid amplification technology. The product contains oligonucleotide primers and dual-labeled hydrolysis probes (TaqMan®) and control material used in rRT-PCR for the *in vitro* qualitative detection of 2019-nCoV RNA in respiratory specimens.

The term "qualified laboratories" refers to laboratories in which all users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC will limit the distribution of this device to laboratories whose users have successfully completed a training course provided by CDC instructors or designees.

## Principles of the Procedure

The oligonucleotide primers and probes for detection of 2019-nCoV were selected from regions of the virus nucleocapsid (N) gene. The panel is designed for both universal detection of SARS-like coronaviruses (one primer/probe set) as well as specific detection of the 2019-nCoV (two primer/probe sets). An additional primer/probe set to detect the human RNase P gene (RP) in control samples and clinical specimens is also included in the panel.

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RNA isolated and purified from upper and lower respiratory specimens is reverse transcribed to cDNA and subsequently amplified in the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS version 1.4 software. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software.

Detection of viral RNA not only aids in the diagnosis of illness but also provides epidemiological and surveillance information.

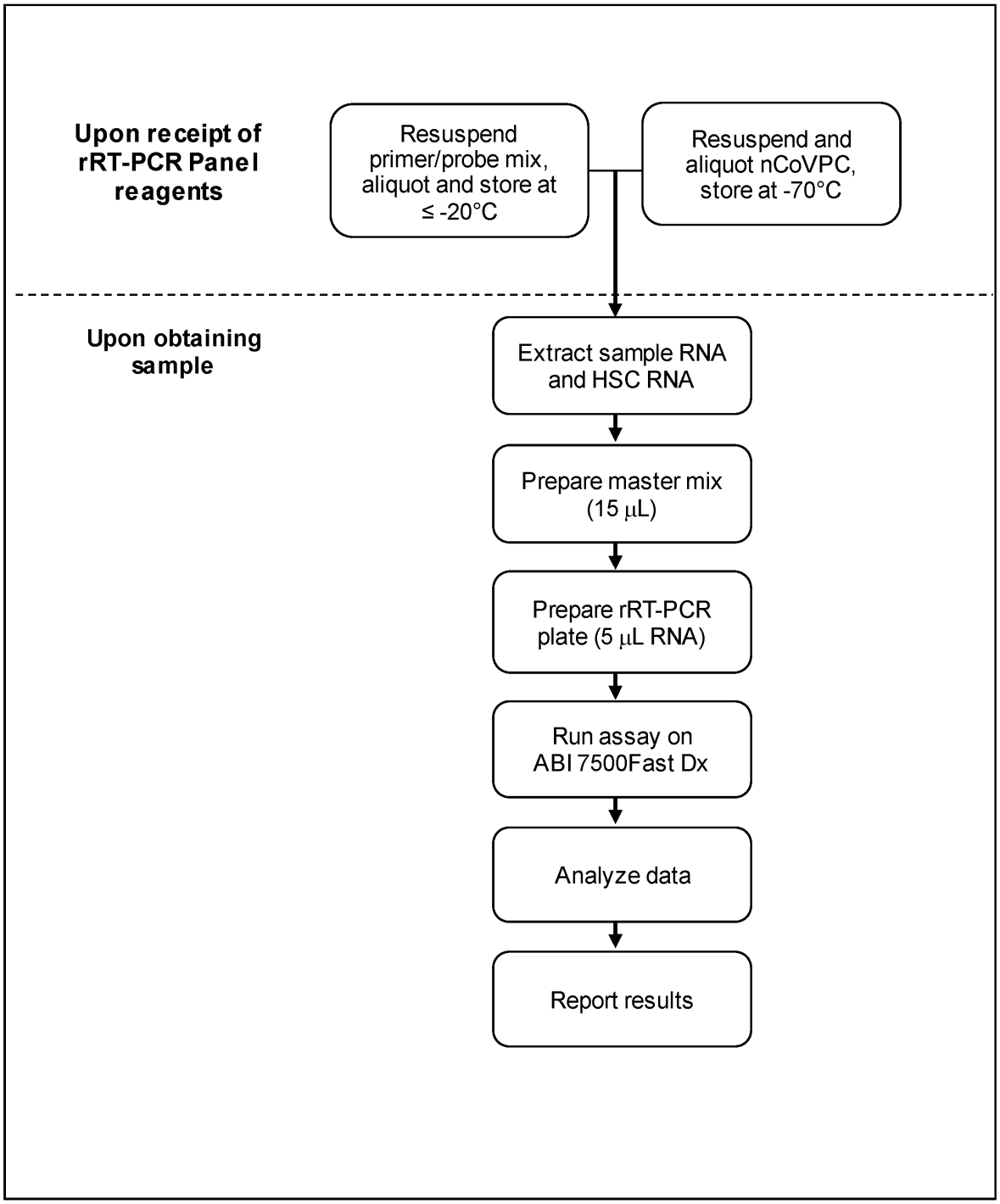
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FDA-CVD-SHURENJ-00020120 MULTI-HHS-20-0522-B, 20-0523-A-003320

## Summary of Preparation and Testing Process




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## Materials Required (Provided)

### 2019-nCoVEUA-01 Box #1: Primers and Probes

| *Reagent Label* | *Part #* | *Description* | *Quantity / Tube* | *Reactions / Tube* |
|---|---|---|---|---|
| 2019-nCoV_N1 | RV202001 | 2019-nCoV_N1 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N2 | RV202002 | 2019-nCoV_N2 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| 2019-nCoV_N3 | RV202003 | 2019-nCoV_N3 Combined Primer/Probe Mix | 22.5 nmol | 1000 |
| RP | RV202004 | Human RNase P Forward Primer/Probe Mix | 22.5 nmol | 1000 |

### Box #2: Positive Control

| *Reagent Label* | *Part #* | *Description* | *Quantity* | *Notes* |
|---|---|---|---|---|
| nCoVPC | RV202005 | 2019-nCoV Positive Control (nCoVPC)<br>For use as a positive control with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel procedure. The nCoVPC contains noninfectious positive control materials supplied in a dried state and must be resuspended before use. nCoVPC consists of *in vitro* transcribed RNA. nCoVPC will yield a positive result with each assay in the 2019-nCoV Real-Time RT-PCR Diagnostic Panel including RP. | 4 tubes | Provides (800) 5 µL test reactions |

## Materials Required (But Not Provided)

### Human Specimen Control (HSC)

| Description | Quantity | CDC Catalog No. |
|---|---|---|
| Manufactured by CDC. For use as an RNA extraction procedural control to demonstrate successful recovery of RNA as well as extraction reagent integrity. The HSC consists of noninfectious (beta-Propiolactone treated) cultured human cell materials supplied as a liquid suspended in 0.01 M PBS at pH 7.2-7.4. | 10 vials x 500uL | KT0189 |

### rRT-PCR Enzyme Mastermix Options

| Reagent | Quantity | Catalog No. |
|---|---|---|
| TaqPath™ 1-Step RT-qPCR Master Mix, CG (ThermoFisher) | 1000 reactions | A15299 |
| | 2000 reactions | A15300 |

### RNA Extraction Options

| Instrument/Manufacturer | Extraction Kit | Catalog No. |
|---|---|---|
| QIAGEN | QIAmp DSP Viral RNA Mini Kit | 50 extractions: 61904 |
| QIAGEN EZ1 Advanced XL | EZ1 DSP Virus Kit | 48 extractions: (62724)<br>Buffer AVL (19073) |

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| Instrument/Manufacturer | Extraction Kit | Catalog No. |
|---|---|---|
| | | EZ1 Advanced XL DSP Virus Card (9018703) |

## Equipment and Consumables Required (But Not Provided)

- Vortex mixer
- Microcentrifuge
- Micropipettes (2 or 10 µL, 200 µL and 1000 µL)
- Multichannel micropipettes (5-50 µl)
- Racks for 1.5 mL microcentrifuge tubes
- 2 x 96-well -20°C cold blocks
- 7500 Fast Dx Real-Time PCR Systems with SDS 1.4 software (Applied Biosystems; catalog #446985 or #4406984)
- Extraction systems (instruments): QIAGEN EZ1 Advanced XL
- Molecular grade water, nuclease-free
- 10% bleach (1:10 dilution of commercial 5.25-6.0% hypochlorite bleach)
- DNA*Zap*™ (Ambion, cat. #AM9890) or equivalent
- RNAse AwayTM (Fisher Scientific; cat. #21-236-21) or equivalent
- Disposable powder-free gloves and surgical gowns
- Aerosol barrier pipette tips
- 1.5 mL microcentrifuge tubes (DNase/RNase free)
- 0.2 mL PCR reaction plates (Applied Biosystems; catalog #4346906 or #4366932)
- MicroAmp Optical 8-cap Strips (Applied Biosystems; catalog #4323032)

## Warnings and Precautions

- For *in vitro* diagnostic use (IVD).
- For emergency use only.
- Follow standard precautions. All patient specimens and positive controls should be considered potentially infectious and handled accordingly.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCoV https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html.
- Specimen processing should be performed in accordance with national biological safety regulations.
- If infection with 2019-nCoV is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions.
- Performance characteristics have been determined with human upper respiratory specimens and lower respiratory tract specimens from human patients with signs and symptoms of respiratory infection.

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- Perform all manipulations of live virus samples within a Class II (or higher) biological safety cabinet (BSC).
- Use personal protective equipment such as (but not limited to) gloves, eye protection, and lab coats when handling kit reagents while performing this assay and handling materials including samples, reagents, pipettes, and other equipment and reagents.
- Amplification technologies such as PCR are sensitive to accidental introduction of PCR product from previous amplifications reactions. Incorrect results could occur if either the clinical specimen or the real-time reagents used in the amplification step become contaminated by accidental introduction of amplification product (amplicon). Workflow in the laboratory should proceed in a unidirectional manner.
    - Maintain separate areas for assay setup and handling of nucleic acids.
    - Always check the expiration date prior to use. Do not use expired reagent. Do not substitute or mix reagent from different kit lots or from other manufacturers.
    - Change aerosol barrier pipette tips between all manual liquid transfers.
    - During preparation of samples, compliance with good laboratory techniques is essential to minimize the risk of cross-contamination between samples, and the inadvertent introduction of nucleases into samples during and after the extraction procedure. Proper aseptic technique should always be used when working with nucleic acids.
    - Maintain separate, dedicated equipment (e.g., pipettes, microcentrifuges) and supplies (e.g., microcentrifuge tubes, pipette tips) for assay setup and handling of extracted nucleic acids.
    - Wear a clean lab coat and powder-free disposable gloves (not previously worn) when setting up assays.
    - Change gloves between samples and whenever contamination is suspected.
    - Keep reagent and reaction tubes capped or covered as much as possible.
    - Primers, probes (including aliquots), and enzyme master mix must be thawed and maintained on cold block at all times during preparation and use.
    - Work surfaces, pipettes, and centrifuges should be cleaned and decontaminated with cleaning products such as 10% bleach, "DNA*Zap*™" or "RNase AWAY®" to minimize risk of nucleic acid contamination. Residual bleach should be removed using 70% ethanol.
- RNA should be maintained on cold block or on ice during preparation and use to ensure stability.
- Dispose of unused kit reagents and human specimens according to local, state, and federal regulations.

## Reagent Storage, Handling, and Stability

- Store all dried primers and probes and the positive control, nCoVPC, at 2-8°C until re-hydrated for use. Store liquid HSC control materials at ≤ -20°C.
- Always check the expiration date prior to use. Do not use expired reagents.
- Protect fluorogenic probes from light.
- Primers, probes (including aliquots), and enzyme master mix must be thawed and kept on a cold block at all times during preparation and use.
- Do not refreeze probes.
- Controls and aliquots of controls must be thawed and kept on ice at all times during preparation and use.

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## Specimen Collection, Handling, and Storage

Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Training in specimen collection is highly recommended due to the importance of specimen quality. CLSI MM13-A may be referenced as an appropriate resource.

- Collecting the Specimen
  - Refer to Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV) https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
  - Follow specimen collection devices manufacturer instructions for proper collection methods.
  - Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron®, and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media. NP and OP specimens should be kept in separate vials.
- Transporting Specimens
  - Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens. Store specimens at 2-8°C and ship overnight to CDC on ice pack. If a specimen is frozen at -70°C or lower, ship overnight to CDC on dry ice.
- Storing Specimens
  - Specimens can be stored at 2-8°C for up to 72 hours after collection.
  - If a delay in extraction is expected, store specimens at -70°C or lower.
  - Extracted nucleic acid should be stored at -70°C or lower.

## Specimen Referral to CDC

Referring a specimen to the CDC

- Ship all specimens overnight to CDC.
- Ship frozen specimens on dry ice and non-frozen specimens on cold packs.
- Refer to the International Air Transport Association (IATA - www.iata.org) for requirements for shipment of human or potentially infectious biological specimens. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens.
- Prior to shipping, notify CDC Division of Viral Diseases (see contact information below) that you are sending specimens.

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FDA-CVD-SHURENJ-000201200107 MULTI-HHS-20-0522-B, 20-0523-A-003325

- Send all samples to the following recipient:

Centers for Disease Control and Prevention
c/o STATT
Attention: Dr. Stephen Lindstrom (Unit 84)
1600 Clifton Rd., Atlanta, GA 30329-4027
Phone: (404) 639-1587

**The emergency contact number for CDC Emergency Operations Center (EOC) is 770-488-7100.**

## Reagent and Controls Preparation

**Primer and Probe Preparation:**

1) Upon receipt, store dried primers and probes at 2-8°C.
2) Precautions: These reagents should only be handled in a clean area and stored at appropriate temperatures (see below) in the dark. Freeze-thaw cycles should be avoided. Maintain cold when thawed.
3) Using aseptic technique, suspend dried reagents in 1.5 mL of nuclease-free water (50X working concentration) and allow to rehydrate for 15 min at room temperature in the dark.
4) Mix gently and aliquot primers/probe in 300 µL volumes into 5 pre-labeled tubes. Store a single aliquot of primers/probe at 2-8°C in the dark. Do not refreeze (stable for up to 4 months). Store remaining aliquots at ≤ -20°C in a non-frost-free freezer.

**2019-nCoV Positive Control (nCoVPC) Preparation:**

1) Precautions: This reagent should be handled with caution in a dedicated nucleic acid handling area to prevent possible contamination. Freeze-thaw cycles should be avoided. Maintain on ice when thawed.
2) Resuspend dried reagent in each tube in 1 mL of nuclease-free water to achieve the proper concentration. Make single use aliquots (approximately 30 µL) and store at ≤ -70°C.
3) Thaw a single aliquot of diluted positive control for each experiment and hold on ice until adding to plate. Discard any unused portion of the aliquot.

**Human Specimen Control (HSC) (not provided)**

1) Human Specimen Control (HSC) must be extracted and processed with each specimen extraction run.
2) Refer to the Human Specimen Control (HSC) package insert for instructions for use.

**No Template Control (NTC) (not provided)**

1) Sterile, nuclease-free water
2) Aliquot in small volumes
3) Used to check for contamination during specimen extraction and/or plate set-up

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## General Preparation

**Equipment Preparation**

Clean and decontaminate all work surfaces, pipettes, centrifuges, and other equipment prior to use. Decontamination agents should be used including 5% bleach, 70% ethanol, and *DNAzap*™ or *RNase AWAY*® to minimize the risk of nucleic acid contamination.

## Nucleic Acid extraction

Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is dependent upon the amount and quality of template RNA purified from human specimens. The following commercially available RNA extraction kits and procedures have been qualified and validated for recovery and purity of RNA for use with the panel:

**Qiagen QIAamp® DSP Viral RNA Mini Kit**

Recommendation(s): Utilize 100 µL of sample and elute with 100 µL of buffer or utilize 140 µL of sample and elute with 140 µL of buffer.

**Qiagen EZ1 Advanced XL**

Kit: Qiagen EZ1 DSP Virus Kit and Buffer AVL (supplied separately) for offboard lysis
Card: EZ1 Advanced XL DSP Virus Card
Recommendation(s): Add 120 µL of sample to 280 µL of pre-aliquoted Buffer AVL (total input sample volume is 400 µL). Proceed with the extraction on the EZ1 Advanced XL. Elution volume is 120 µL.

Manufacturer's recommended procedures (except as noted in recommendations above) are to be followed for sample extraction. HSC must be included in each extraction batch.

***Disclaimer: Names of vendors or manufacturers are provided as examples of suitable product sources. Inclusion does not imply endorsement by the Centers for Disease Control and Prevention.***

## Assay Set Up

**Reaction Master Mix and Plate Set Up**

Note: Plate set-up configuration can vary with the number of specimens and work day organization. NTCs and nCoVPCs must be included in each run.

1) In the reagent set-up room clean hood, place rRT-PCR buffer, enzyme, and primer/probes on ice or cold-block. Keep cold during preparation and use.
2) Thaw 4X Reaction Mix prior to use.
3) Mix buffer, enzyme, and primer/probes by inversion 5 times.
4) Centrifuge buffer and primers/probes for 5 seconds to collect contents at the bottom of the tube, and then place the tube in a cold rack.
5) Label one 1.5 mL microcentrifuge tube for each primer/probe set.
6) Determine the number of reactions (N) to set up per assay. It is necessary to make excess reaction mix for the NTC, nCoVPC, HSC (if included in the RT-PCR run), and RP reactions and for pipetting error. Use the following guide to determine N:

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- If number of samples (n) including controls equals 1 through 14, then N = n + 1
- If number of samples (n) including controls is 15 or greater, then N = n + 2

7) For each primer/probe set, calculate the amount of each reagent to be added for each reaction mixture (N = # of reactions).

**TaqPath™ 1-Step RT-qPCR Master Mix**

| Step # | Reagent | Vol. of Reagent Added per Reaction |
|---|---|---|
| 1 | Nuclease-free Water | N x 8.5 µL |
| 2 | Combined Primer/Probe Mix | N x 1.5 µL |
| 3 | TaqPath™ 1-Step RT-qPCR Master Mix (4x) | N x 5.0 µL |
| | **Total Volume** | **N x 15.0 µL** |

8) Dispense reagents into each respective labeled 1.5 mL microcentrifuge tube. After addition of the reagents, mix reaction mixtures by pipetting up and down. ***Do not vortex***.
9) Centrifuge for 5 seconds to collect contents at the bottom of the tube, and then place the tube in a cold rack.
10) Set up reaction strip tubes or plates in a 96-well cooler rack.
11) Dispense 15 µL of each master mix into the appropriate wells going across the row as shown below (**Figure 1**):

**Figure 1: Example of Reaction Master Mix Plate Set-Up**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | N1 | N1 | N1 | N1 | N1 | N1 | N1 | N1 | N1 | N1 | N1 | N1 |
| **B** | N2 | N2 | N2 | N2 | N2 | N2 | N2 | N2 | N2 | N2 | N2 | N2 |
| **C** | N3 | N3 | N3 | N3 | N3 | N3 | N3 | N3 | N3 | N3 | N3 | N3 |
| **D** | RP | RP | RP | RP | RP | RP | RP | RP | RP | RP | RP | RP |
| **E** | | | | | | | | | | | | |
| **F** | | | | | | | | | | | | |
| **G** | | | | | | | | | | | | |
| **H** | | | | | | | | | | | | |

12) Prior to moving to the nucleic acid handling area, prepare the No Template Control (NTC) reactions for column #1 in the assay preparation area.
13) Pipette 5 µL of nuclease-free water into the NTC sample wells (**Figure 2**, column 1). Securely cap NTC wells before proceeding.
14) Cover the entire reaction plate and move the reaction plate to the specimen nucleic acid handling area.

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FDA-CVD-SHURENJ-00020121 MULTI-HHS-20-0522-B, 20-0523-A-003328

**Nucleic Acid Template Addition**

1) Gently vortex nucleic acid sample tubes for approximately 5 seconds.
2) Centrifuge for 5 seconds to collect contents at the bottom of the tube, and then place the tube in a cold rack.
3) After centrifugation, place extracted nucleic acid sample tubes in the cold rack.
4) Samples should be added to columns 2-11 (column 1 and 12 are for controls) to the specific assay that is being tested as illustrated in **Figure 2**. Carefully pipette 5.0 µL of the first sample into all the wells labeled for that sample (i.e. Sample "S1" down column #2). *Keep other sample wells covered during addition. Change tips after each addition.*
5) Securely cap the column to which the sample has been added to prevent cross contamination and to ensure sample tracking.
6) Change gloves often and when necessary to avoid contamination.
7) Repeat steps #3 and #4 for the remaining samples.
8) If necessary, add 5 µL of Human Specimen Control (HSC) extracted sample to the HSC wells (**Figure 2**, column 11). Securely cap wells after addition. NOTE: Per CLIA regulations, HSC must be tested at least once per day.
9) Cover the entire reaction plate and move the reaction plate to the positive template control handling area.

**Assay Control Addition**

1) Pipette 5 µL of nCoVPC RNA to the sample wells of column 12 (**Figure 2**). Securely cap wells after addition of the control RNA.

***NOTE:*** *If using 8-tube strips, label the TAB of each strip to indicate sample position.* ***DO NOT LABEL THE TOPS OF THE REACTION TUBES!***

*2)* Briefly centrifuge reaction tube strips for 10-15 seconds. After centrifugation return to cold rack.

***NOTE:*** *If using 96-well plates, centrifuge plates for 30 seconds at 500 x g, 4°C.*

**Figure 2. 2019-nCoV rRT-PCR Diagnostic Panel: Example of Sample and Control Set-up**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11[a] | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A | NTC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | S10 | nCoV PC |
| B | NTC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | S10 | nCoV PC |
| C | NTC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | S10 | nCoV PC |
| D | NTC | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | S10 | nCoV PC |
| E | | | | | | | | | | | | |
| F | | | | | | | | | | | | |
| G | | | | | | | | | | | | |
| H | | | | | | | | | | | | |

[a]Replace the sample in this column with extracted HSC if necessary

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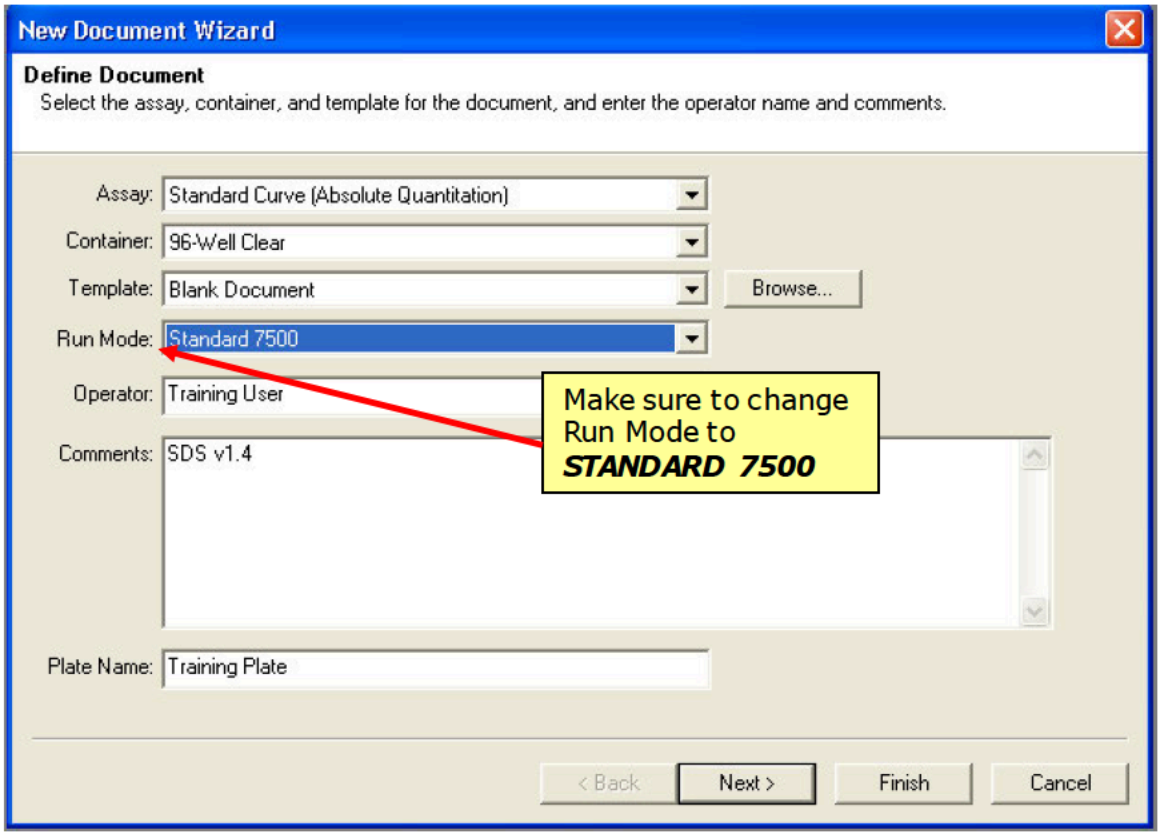
FDA-CVD-SHURENJ-00020121 MULTI-HHS-20-0522-B, 20-0523-A-003329

## Create a Run Template on the Applied Biosystems 7500 Fast Dx Real-time PCR Instrument (Required if no template exists)

If the template already exists on your instrument, please proceed to the **RUNNING A TEST** section.

1) Launch the Applied Biosystems 7500 Fast Dx Real-time PCR Instrument by double clicking on the Applied Biosystems 7500 Fast Dx System icon on the desktop.
2) A new window should appear, select **Create New Document** from the menu.

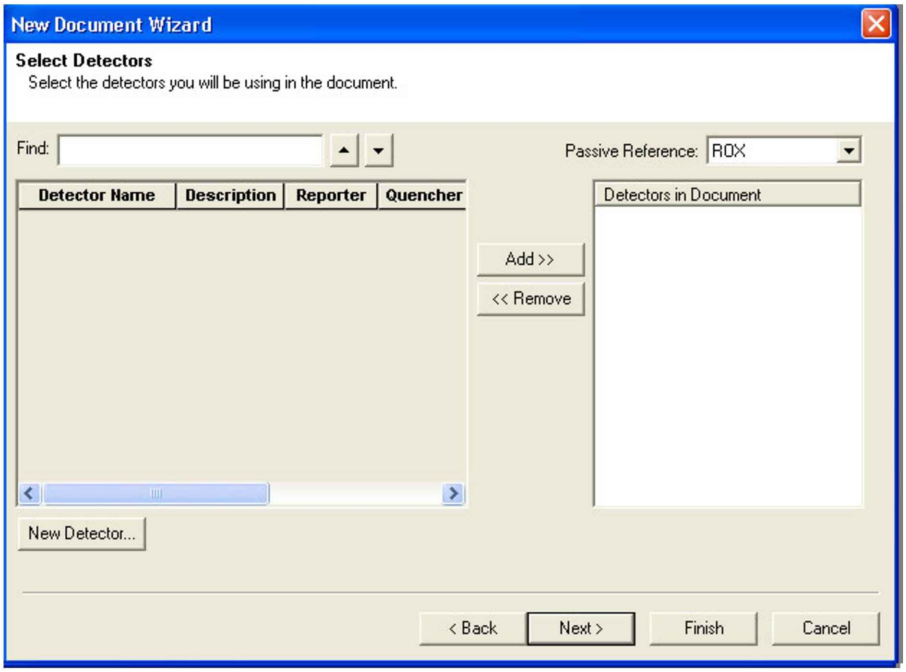
**Figure 3. New Document Wizard Window**




3) The **New Document Wizard** screen in **Figure 3** will appear. Select:
   a. Assay: **Standard Curve (Absolute Quantitation)**
   b. Container: **96-Well Clear**
   c. Template: **Blank Document**
   d. Run Mode: **Standard 7500**
   e. Operator: ***Your Name***
   f. Comments: **SDS v1.4**
   g. Plate Name: ***Your Choice***
4) After making selections click **Next** at the bottom of the window.

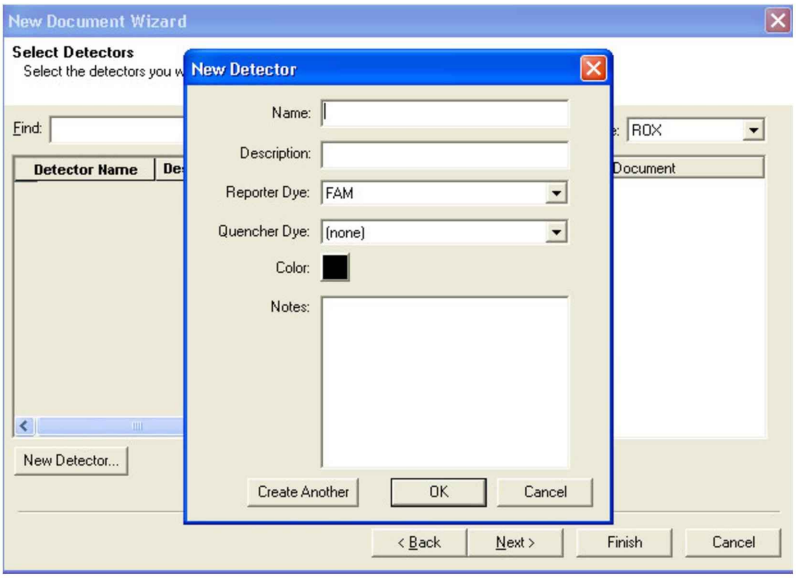
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**Figure 4. Creating New Detectors**




5) After selecting next, the ***Select Detectors*** screen (**Figure 4**) will appear.
6) Click the **New Detector** button (see **Figure 4**).
7) The **New Detector** window will appear (**Figure 5**). A new detector will need to be defined for each primer and probe set. Creating these detectors will enable you to analyze each primer and probe set individually at the end of the reaction.

**Figure 5. New Detector Window**




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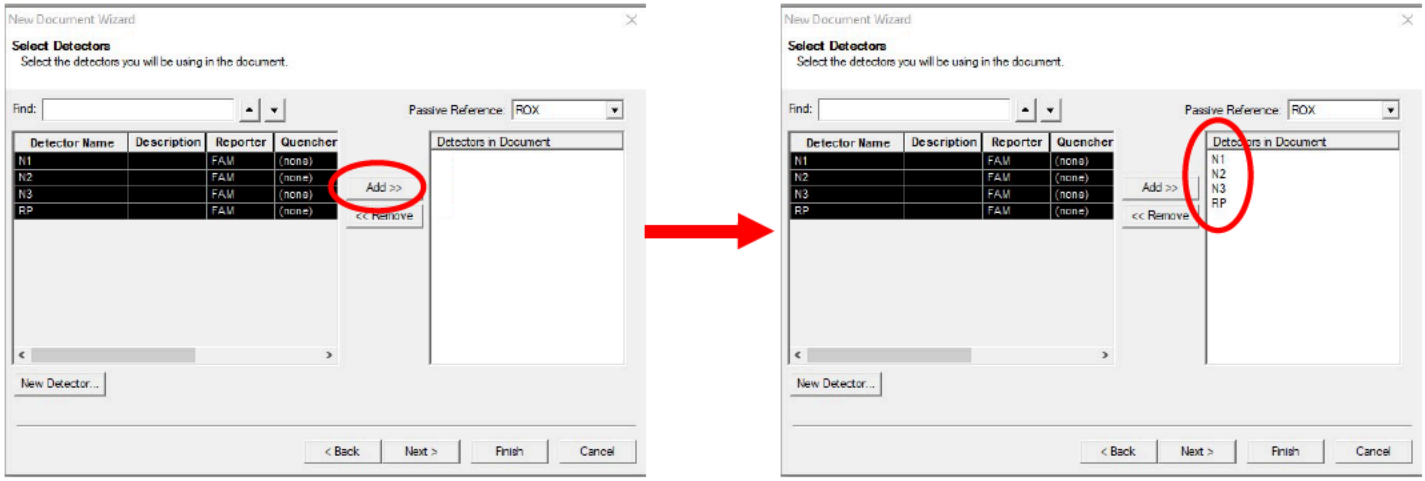

FDACDRH p3-AC-002642
FDA-CVD-SHURENJ-000201200107 MULTI-HHS-20-0522-B, 20-0523-A-003331

8) Start by creating the N1 Detector. Include the following:
   a. Name: **N1**
   b. Description: *leave blank*
   c. Reporter Dye: **FAM**
   d. Quencher Dye: **(none)**
   e. Color: *to change the color of the detector indicator do the following:*
      ⇒ Click on the color square to reveal the color chart
      ⇒ Select a color by clicking on one of the squares
      ⇒ After selecting a color click **OK** to return to the New Detector screen
   f. Click the **OK** button of the New Detector screen to return to the screen shown in **Figure 4**.
9) Repeat step 6-8 for each target in the panel.

| Name | Reporter Dye | Quencher Dye |
|---|---|---|
| N1 | FAM | (none) |
| N2 | FAM | (none) |
| N3 | FAM | (none) |
| RP | FAM | (none) |

10) After each Detector is added, the **Detector Name**, **Description**, **Reporter** and **Quencher** fields will become populated in the **Select Detectors** screen (**Figure 6**).
11) Before proceeding, the newly created detectors must be added to the document. To add the new detectors to the document, click **ADD** (see **Figure 6**). Detector names will appear on the right hand side of the **Select Detectors** window (**Figure 6**).

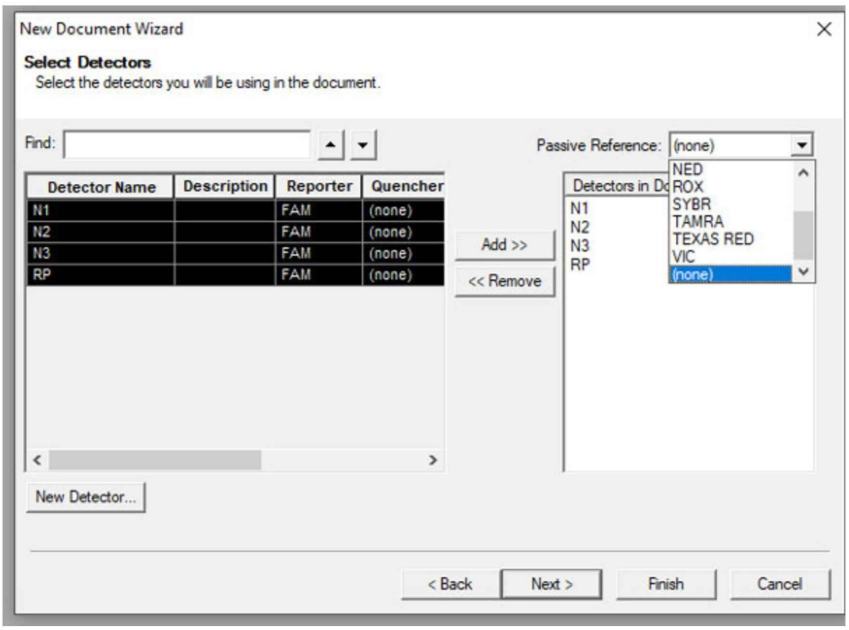
**Figure 6. Adding New Detectors to Document**




12) Once all detectors have been added, select **(none)** for **Passive Reference** at the top right hand drop down menu (**Figure 7**).

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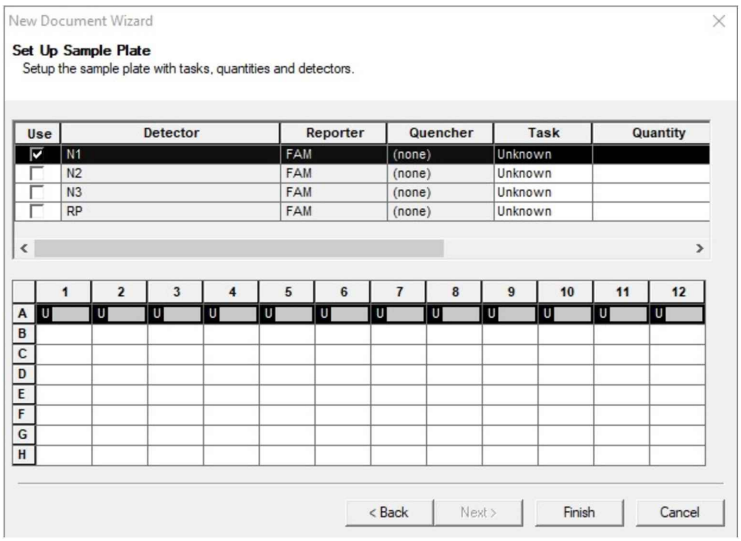
**Figure 7. Select Passive Reference**




**Passive reference should be set to "(none)" as described above.**

13) Click **Next** at the bottom of the **Select Detectors** window to proceed to the **Set Up Sample Plate** window (**Figure 8**).
14) In the **Set Up Sample Plate** window (**Figure 8**), use your mouse to select row A from the lower portion of the window, in the spreadsheet (see **Figure 8**).
15) In the top portion of the window, select detector **N1**. A check will appear next to the detector you have selected (**Figure 8**). You will also notice the row in the spreadsheet will be populated with a colored "U" icon to indicate which detector you've selected.
16) Repeat step 14-15 for each detector that will be used in the assay.

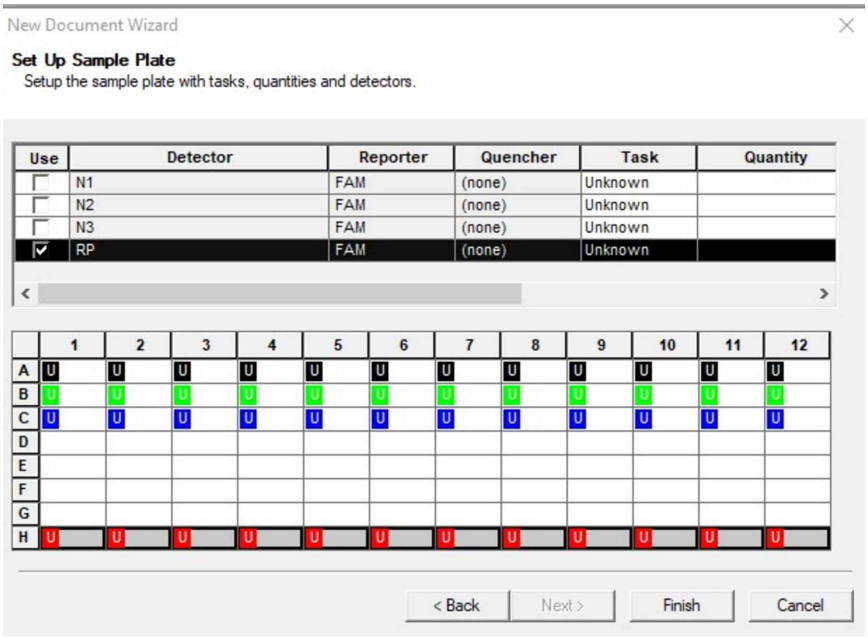
**Figure 8. Sample Plate Set-up**




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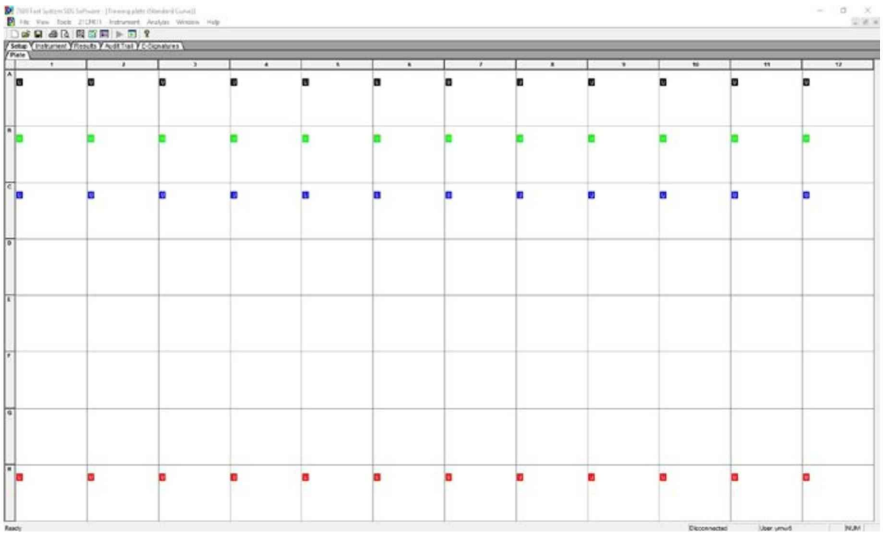
17) Select **Finish** after detectors have been assigned to their respective rows. (**Figure 9**).

**Figure 9. Finished Plate Set-up**




18) After clicking "Finish", there will be a brief pause allowing the Applied Biosystems 7500 Fast Dx to initialize. This initialization is followed by a clicking noise. ***Note: The machine must be turned on for initialization.***
19) After initialization, the **Plate** tab of the Setup (**Figure 10)** will appear.
20) Each well of the plate should contain colored U icons that correspond with the detector labels that were previously chosen. To confirm detector assignments, select **Tools** from the file menu, then select **Detector Manager.**

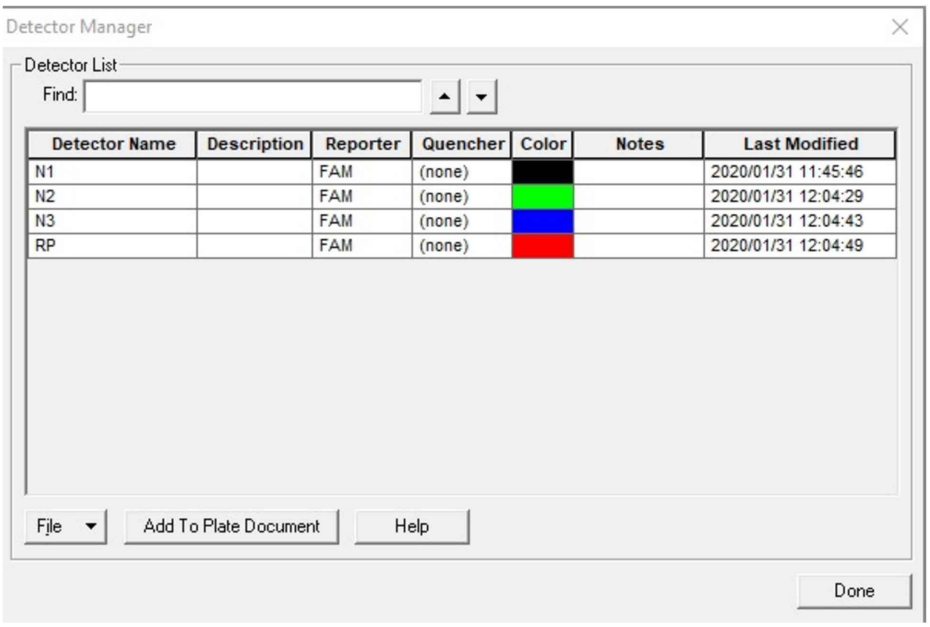
**Figure 10. Plate Set-up Window**



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21) The Detector Manager window will appear (**Figure 11**).

**Figure 11. Detector Manager Window**




22) Confirm all detectors are included and that each target has a **Reporter** set to **FAM** and the **Quencher** is set to **(none)**.
23) If all detectors are present, select **Done**. The detector information has been created and assigned to wells on the plate.

## Defining the Instrument Settings

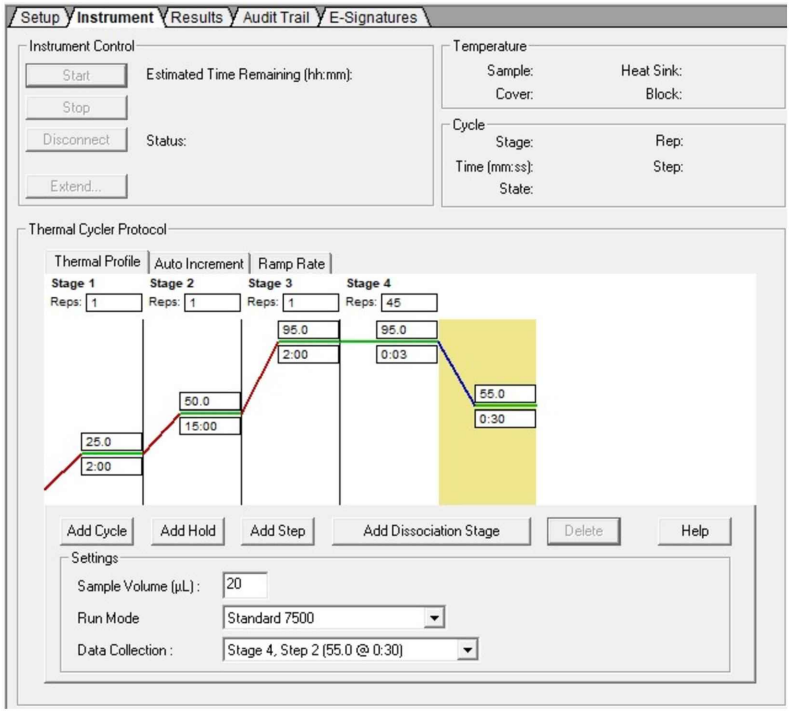
1) After detectors have been created and assigned, proceed to instrument set up.
2) Select the **Instrument** tab to define thermal cycling conditions.
3) Modify the thermal cycling conditions as follows (**Figure 12**):

**TaqPath™ 1-Step RT-qPCR Master Mix, CG (ThermoFisher)**

a. In Stage 1, Set to 2 min at **25°C**; **1 Rep**.
b. In Stage 2, Set to 15 min at **50°C**; **1 Rep**.
c. In Stage 3, Set to 2 min at **95°C, 1 Rep.**
d. In Stage 4, Step 1 set to **3 sec** at **95°C**.
e. In Stage 4, Step 2 set to **30 sec** at **55.0°C.**
f. In Stage 4, Reps should be set to **45.**
g. Under **Settings** (**Figure 12**), bottom left-hand box, change volume to 20 µL.
h. Under **Settings**, **Run Mode** selection should be **Standard 7500**.
**i.** Step 2 of Stage 4 should be highlighted in yellow to indicate data collection (see **Figure 12**).

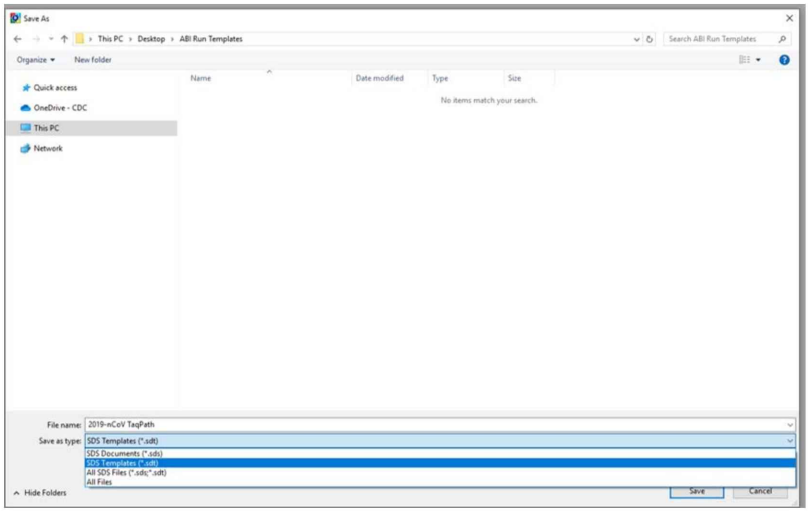
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**Figure 12. Instrument Window**




4) After making changes to the **Instrument** tab, the template file is ready to be saved. To save the template, select **File** from the top menu, then select **Save As**.
5) Save the template as **2019-nCoV TaqPath** as appropriate in the desktop folder labeled "***ABI Run Templates***" (*you must create this folder*). Save as type should be SDS Templates (*.sdt) (**Figure 13**).

**Figure 13. Saving Template**

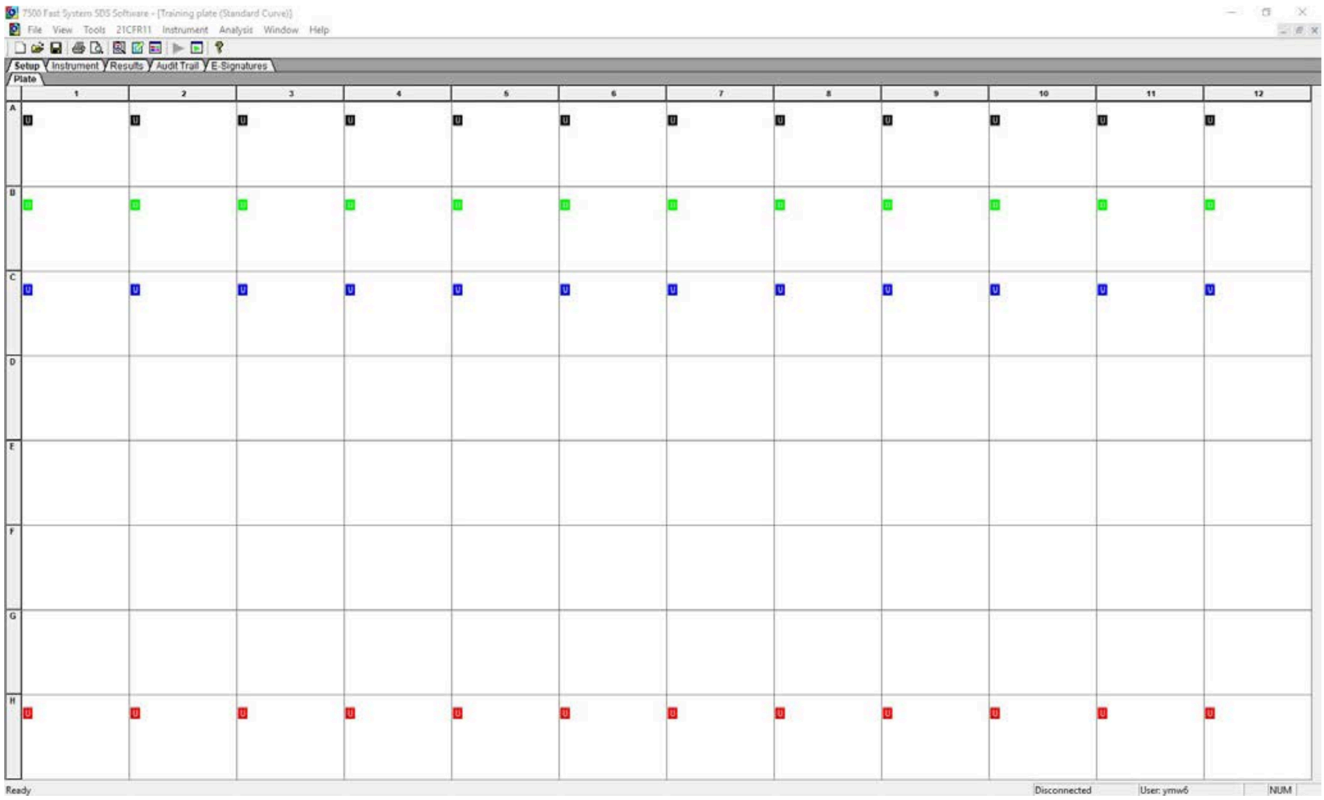



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## Running a Test

1) Turn on the ABI 7500 Fast Dx Real-Time PCR Instrument.
2) Launch the Applied Biosystems 7500 Fast Dx Real-time PCR System by double clicking on the 7500 Fast Dx System icon on the desktop.
3) A new window should appear, select **Open Existing Document** from the menu.
4) Navigate to select your ABI Run Template folder from the desktop.
5) Double click on the appropriate template file (**2019-nCoV TaqPath)**
6) There will be a brief pause allowing the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument to initialize. This initialization is followed by a clicking noise. ***Note: The machine must be turned on for initialization.***

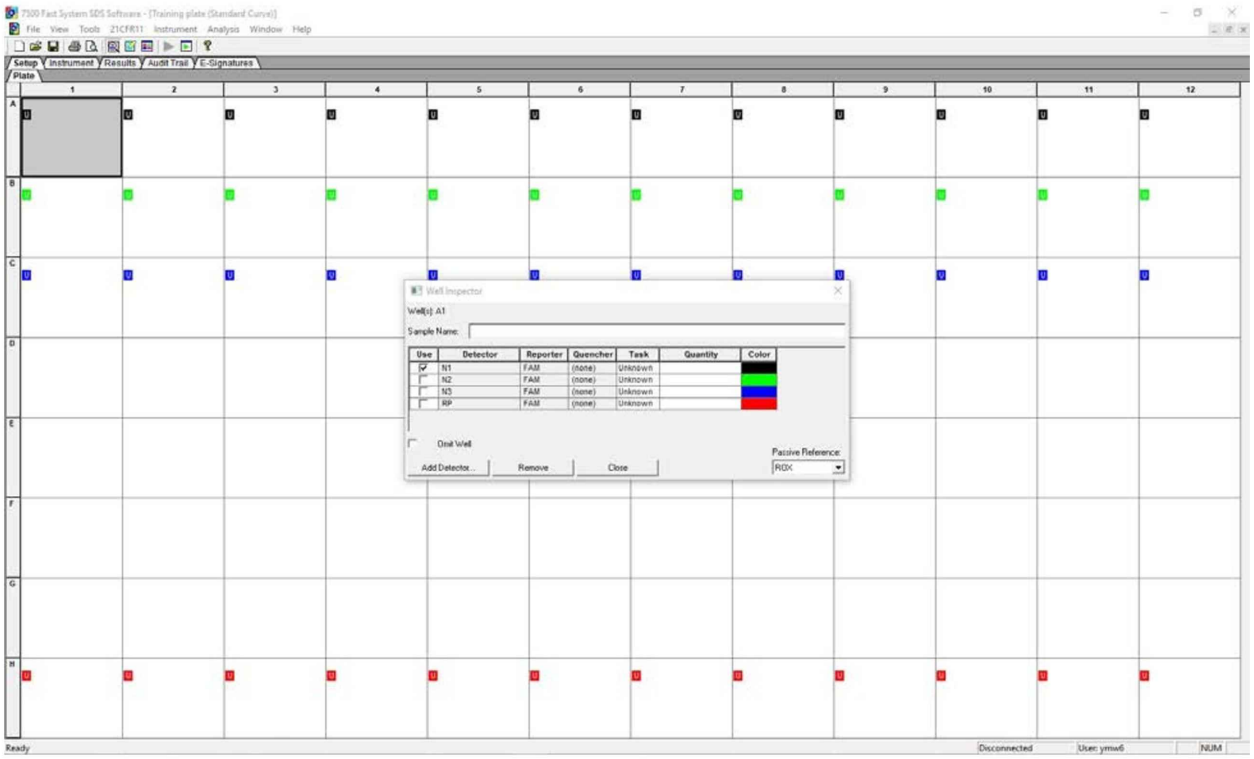
**Figure 14. Plate Set-up Window**



7) After the instrument initializes, a plate map will appear (**Figure 14**). The detectors and controls should already be labeled as they were assigned in the original template.
8) Click the **Well Inspector** icon  from the top menu.
9) Highlight specimen wells of interest on the plate map.
10) Type sample identifiers to **Sample Name** box in the **Well Inspector** window (**Figure 15**).

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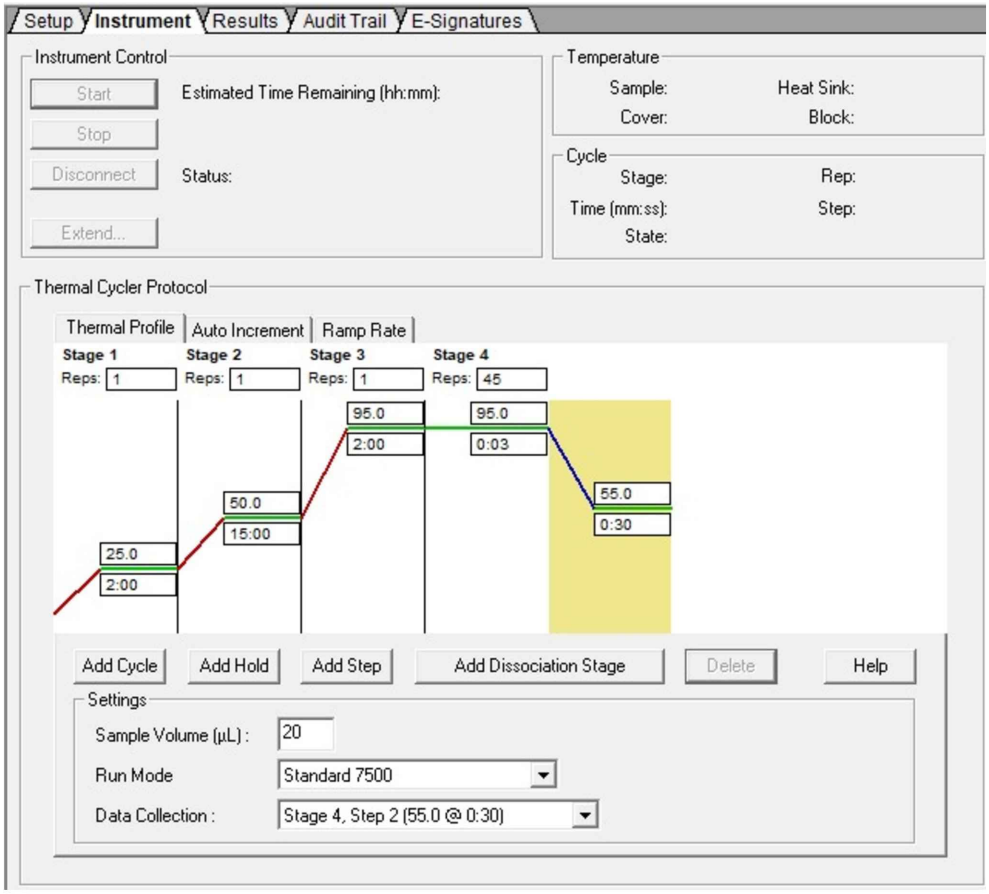
**Figure 15. Labeling Wells**




11) Repeat steps 9-10 until all sample identifiers are added to the plate setup.
12) Once all specimen and control identifiers are added click the **Close** button on the **Well Inspector** window to return to the **Plate** set up tab.
13) Click the **Instrument** tab at the upper left corner.
14) The reaction conditions, volumes, and type of 7500 reaction should already be loaded. (**Figure 16**).

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**Figure 16. Instrument Settings**



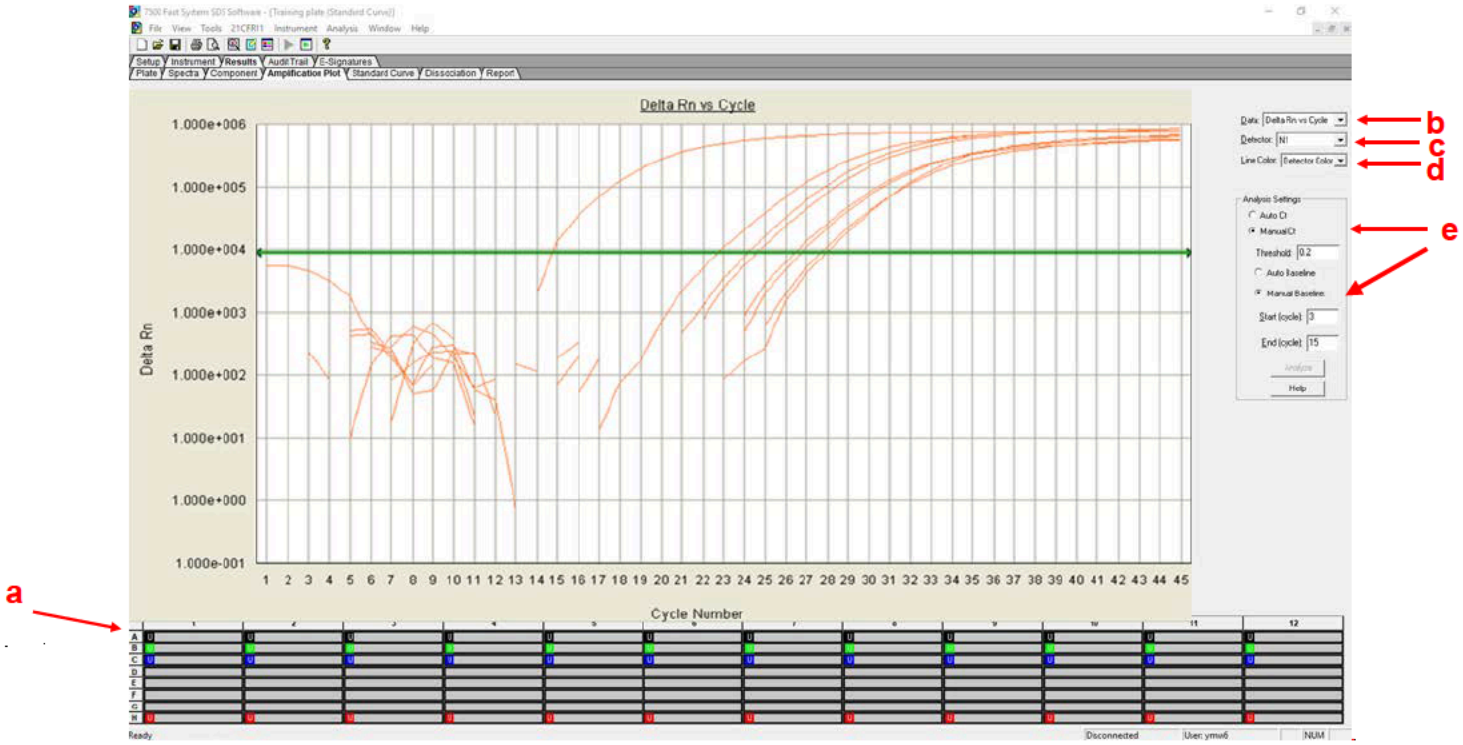

15) Ensure settings are correct (refer to the *Defining Instrument Settings*).
16) Before proceeding, the run file must be saved; from the main menu, select **File,** then **Save As**. Save in appropriate run folder designation.
17) Load the plate into the plate holder in the instrument. Ensure that the plate is properly aligned in the holder.
18) Once the run file is saved, click the **Start** button. *Note: The run should take approximately 1hr and 20 minutes to complete.*

## Data Analysis

1) After the run has completed, select the **Results** tab at the upper left corner of the software.
2) Select the **Amplification Plot** tab to view the raw data (**Figure 17**).

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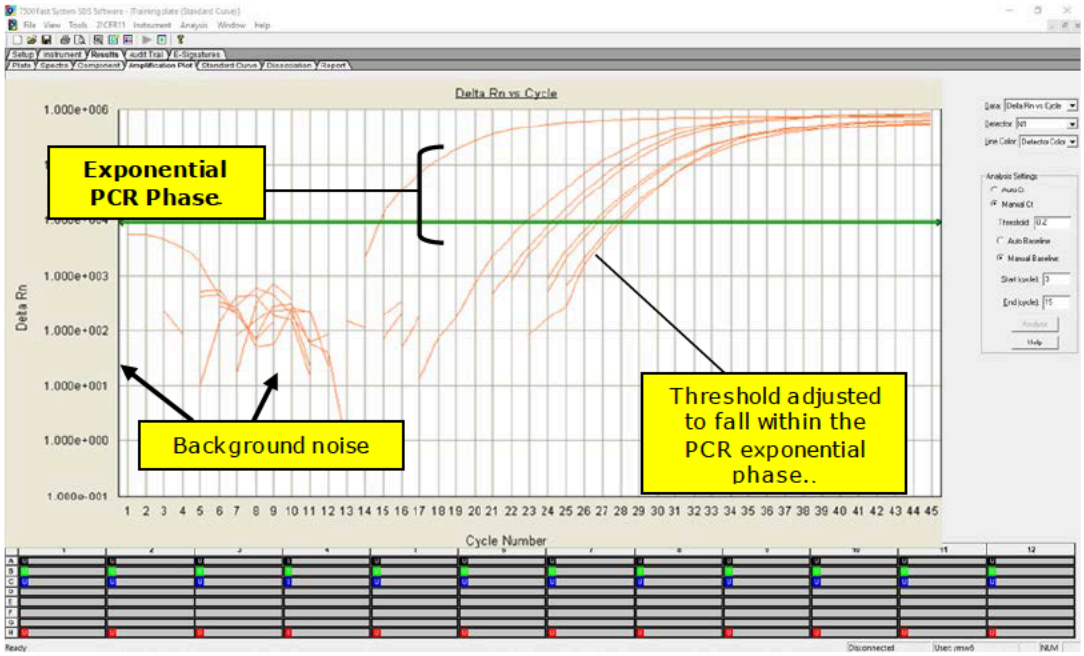
**Figure 17. Amplification Plot Window**




3) Start by highlighting all the samples from the run; to do this, click on the upper left hand box **(a)** of the sample wells (**Figure 17**). All the growth curves should appear on the graph.
4) On the right hand side of the window **(b)**, the **Data** drop down selection should be set to **Delta Rn vs. Cycle**.
5) Select **N1** from **(c)**, the **Detector** drop down menu, using the downward arrow.
    a. Please note that each detector is analyzed individually to reflect different performance profiles of each primer and probe set.
6) In the **Line Color** drop down **(d)**, **Detector Color** should be selected.
7) Under **Analysis Settings** select **Manual Ct (e)**.
    **b.** Do not change the **Manual Baseline** default numbers.
8) Using the mouse, click and drag the red threshold line until it lies within the exponential phase of the fluorescence curves and above any background signal (**Figure 18**).

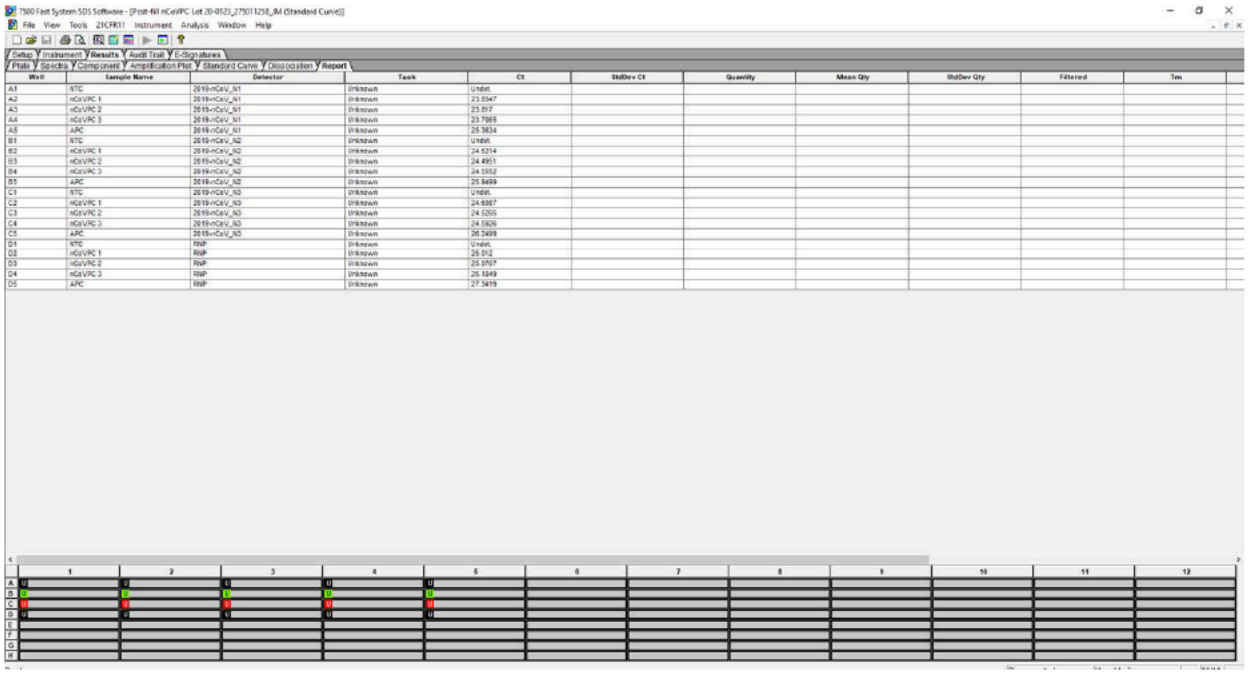
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**Figure 18. Amplification Plot**




9) Click the **Analyze** button in the lower right corner of the window. The red threshold line will turn to green, indicating the data has been analyzed.
10) Repeat steps 5-9 to analyze results generated for each set of markers (i.e. N1, N2, N3, etc).
11) Save analysis file by selecting **File** then **Save As** from the main menu.
12) After completing analysis for each of the markers, select the **Report** tab above the graph to display the Ct values (**Figure 19**). To filter report by sample name in ascending or descending order, simply click on **Sample Name** in the table.

**Figure 19. Report**



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## Interpretation of Results and Reporting

**Expected Performance of Controls Included in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel**

| Control Type | External Control Name | Used to Monitor | 2019 nCoV_N1 | 2019 nCoV_N2 | 2019 nCoV_N3 | RP | Expected Ct Values |
|---|---|---|---|---|---|---|---|
| Positive | nCoVPC | Substantial reagent failure including primer and probe integrity | + | + | + | + | < 40.00 Ct |
| Negative | NTC | Reagent and/or environmental contamination | - | - | - | - | None detected |
| Extraction | HSC | Failure in lysis and extraction procedure, potential contamination during extraction | - | - | - | + | < 40.00 Ct |

**If any of the above controls do not exhibit the expected performance as described, the assay may have been set up and/or executed improperly, or reagent or equipment malfunction could have occurred. Invalidate the run and re-test.**

**RNase P (Extraction Control)**

- All clinical samples should exhibit fluorescence growth curves in the RNase P reaction that cross the threshold line within 40.00 cycles (< 40.00 Ct), thus indicating the presence of the human RNase P gene. Failure to detect RNase P in any clinical specimens may indicate:
  - Improper extraction of nucleic acid from clinical materials resulting in loss of RNA and/or RNA degradation.
  - Absence of sufficient human cellular material due to poor collection or loss of specimen integrity.
  - Improper assay set up and execution.
  - Reagent or equipment malfunction.
- If the RP assay does not produce a positive result for human clinical specimens, interpret as follows:
  - If the 2019-nCoV N1, N2 and N3 are positive even in the absence of a positive RP, the result should be considered valid. It is possible, that some samples may fail to exhibit RNase P growth curves due to low cell numbers in the original clinical sample. A negative RP signal does not preclude the presence of 2019-nCoV virus RNA in a clinical specimen.

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- If all 2019-nCoV markers AND RNase P are negative for the specimen, the result should be considered invalid for the specimen. If residual specimen is available, repeat the extraction procedure and repeat the test. If all markers remain negative after re-test, report the results as invalid and a new specimen should be collected if possible.

**2019-nCoV Markers (N1, N2 and N3)**

- When all controls exhibit the expected performance, a specimen is considered negative if all 2019-nCoV marker (N1, N2, N3) cycle threshold growth curves DO NOT cross the threshold line within 40.00 cycles (< 40.00 Ct) AND the RNase P growth curve DOES cross the threshold line within 40.00 cycles (< 40.00 Ct).
- When all controls exhibit the expected performance, a specimen is considered presumptive positive for 2019-nCoV if all markers (N1, N2, N3) cycle threshold growth curve crosses the threshold line within 40.00 cycles (< 40.00 Ct) The RNase P may or may not be positive as described above, but the 2019-nCoV result is still valid.
- When all controls exhibit the expected performance and the growth curves for the 2019-nCoV markers (N1, N2, N3) AND the RNase P marker DO NOT cross the cycle threshold growth curve within 40.00 cycles (< 40.00 Ct), the result is invalid. The extracted RNA from the specimen should be re-tested. If residual RNA is not available, re-extract RNA from residual specimen and re-test. If the re-tested sample is negative for all markers and RNase P, the result is invalid and a new collection of specimen from the patient should be considered.
- When all controls exhibit the expected performance and the cycle threshold growth curve for any one or two markers (N1, N2, N3) (but not all three markers) crosses the threshold line within 40.00 cycles (< 40.00 Ct) the result is inconclusive. Repeat extraction and rRT-PCR.
- If HSC is positive for N1, N2, or N3, then contamination may have occurred during extraction or sample processing. Re-extract specimens and HSC and re-test.

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## 2019-nCoV rRT-PCR Diagnostic Panel Results Interpretation Guide

The table below lists the expected results for the 2019-nCoV rRT-PCR Diagnostic Panel. If results are obtained that do not follow these guidelines, re-extract and re-test the sample. If repeat testing yields similar results, contact CDC for consultation and possible specimen referral. See pages 8 and 31 for referral and contact information.

| 2019 nCoV_N1 | 2019 nCoV_N2 | 2019 nCoV_N3 | RP | Result Interpretation[a] | Report | Actions |
|---|---|---|---|---|---|---|
| + | + | + | ± | 2019-nCoV detected | Presumptive positive 2019-nCoV | Report results to CDC and sender. Contact CDC immediately for instructions for transfer of the specimen to CDC for additional testing and further guidance. |
| If only one, or two, of the three targets is positive | | | ± | Inconclusive Result | Inconclusive | Repeat extraction and rRT-PCR. If the repeated result remains inconclusive, contact CDC immediately for instructions for transfer of the specimen to CDC for additional testing and further guidance. |
| - | - | - | + | 2019-nCoV not detected | Not Detected | Report results to sender. Consider testing for other respiratory viruses.[b] |
| - | - | - | - | Invalid Result | Invalid | Repeat extraction and rRT-PCR. If the repeated result remains invalid, consider collecting a new specimen from the patient. |

**[a]Laboratories should report their diagnostic result as appropriate and in compliance with their specific reporting system.**

**[b]Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens from the same patient may be necessary to detect the virus.**

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## Quality Control

- Quality control requirements must be performed in conformance with local, state, and federal regulations or accreditation requirements and the user's laboratory's standard quality control procedures. For further guidance on appropriate quality control practices, refer to 42 CFR 493.1256.
- Quality control procedures are intended to monitor reagent and assay performance.
- Test all positive controls prior to running diagnostic samples with each new kit lot to ensure all reagents and kit components are working properly.
- Good laboratory practice (cGLP) recommends including a positive extraction control in each nucleic acid isolation batch.
- Although HSC is not included with the 2019-nCov rRT-PCR Diagnostic Panel, the HSC extraction control must proceed through nucleic acid isolation per batch of specimens to be tested.
- Always include a negative control (NTC), and the appropriate positive control (nCoVPC) in each amplification and detection run. All clinical samples should be tested for human RNAse P gene to control for specimen quality and extraction.

## Limitations

- All users, analysts, and any person reporting diagnostic results should be trained to perform this procedure by a competent instructor. They should demonstrate their ability to perform the test and interpret the results prior to performing the assay independently. CDC Division of Viral Diseases will limit the distribution of this device to only those users who have successfully completed training provided by CDC instructors or designees.
- Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has only been established in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).
- Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.
- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely when prevalence of disease is high. False positive test results are more likely when prevalence is moderate to low.
- Do not use any reagent past the expiration date.
- If the virus mutates in the rRT-PCR target region, 2019-nCoV may not be detected or may be detected less predictably. Inhibitors or other types of interference may produce a false negative result. An interference study evaluating the effect of common cold medications was not performed.
- Test performance can be affected because the epidemiology and clinical spectrum of infection caused by 2019-nCoV is not fully known. For example, clinicians and laboratories may not know the optimum types of specimens to collect, and when during the course of infection these specimens are most likely to contain levels of viral RNA that can be readily detected.

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- Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms.
- The performance of this test has not been established for monitoring treatment of 2019-nCoV infection.
- The performance of this test has not been established for screening of blood or blood products for the presence of 2019-nCoV.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.

## Conditions of Authorization for the Laboratory

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website:
https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm
Use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel must follow the procedures outlined in these manufacturer's Instructions for Use and the conditions of authorization outlined in the Letter of Authorization. Deviations from the procedures outlined are not permitted under the Emergency Use Authorization (EUA). To assist clinical laboratories running the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, the relevant Conditions of Authorization are listed verbatim below, and are required to be met by laboratories performing the EUA test.

- Authorized laboratories[1] will include with reports of the results of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

- Authorized laboratories will perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel as outlined in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use. Deviations from the authorized procedures, including the authorized RT-PCR instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel are not permitted.

- Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

- Authorized laboratories will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and CDC (respvirus@cdc.gov) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

[1]Authorized Laboratories: For ease of reference, the Letter of Authorization refers to "qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests" as "authorized laboratories."

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FDACDRH p3-AC-002657
FDA-CVD-SHURENJ-00020120 MULTI-HHS-20-0522-B, 20-0523-A-003346

- All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the test in accordance with the authorized labeling.

- CDC and authorized laboratories will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

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# Performance Characteristics

***Analytical Performance:***

*Limit of Detection (LoD):*

LoD studies determine the lowest detectable concentration of 2019-nCoV at which approximately 95% of all (true positive) replicates test positive. The LoD was determined by limiting dilution studies using characterized samples.

The analytical sensitivity of the rRT-PCR assays contained in the CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel were determined in Limit of Detection studies. Since no quantified virus isolates of the 2019-nCoV are currently available, assays designed for detection of the 2019-nCoV RNA were tested with characterized stocks of in vitro transcribed full length RNA (N gene; GenBank accession: MN908947.2) of known titer (RNA copies/µL) spiked into a diluent consisting of a suspension of human A549 cells and viral transport medium (VTM) to mimic clinical specimen. Samples were extracted using the QIAGEN EZ1 Advanced XL instrument and EZ1 DSP Virus Kit (Cat# 62724) and manually with the QIAGEN DSP Viral RNA Mini Kit (Cat# 61904). Real-Time RT-PCR assays were performed using the ThemoFisher Scientific TaqPath™ 1-Step RT-qPCR Master Mix, CG (Cat# A15299) on the Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use.

A preliminary LoD for each assay was determined testing triplicate samples of RNA purified using each extraction method. The approximate LoD was identified by extracting and testing 10-fold serial dilutions of characterized stocks of in vitro transcribed full-length RNA. A confirmation of the LoD was determined using 3-fold serial dilution RNA samples with 20 extracted replicates. The LoD was determined as the lowest concentration where ≥ 95% (19/20) of the replicates were positive.

**Table 4. Limit of Detection Confirmation of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with QIAGEN EZ1 DSP**

| Targets | 2019-nCoV_N1 | | | 2019-nCoV_N2 | | | 2019-nCoV_N3 | | |
|---|---|---|---|---|---|---|---|---|---|
| RNA Concentration[1] | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ |
| Positives/Total | 20/20 | 19/20 | 13/20 | 20/20 | 17/20 | 9/20 | 19/20 | 17/20 | 8/20 |
| Mean Ct[2] | 32.5 | 35.4 | NA | 35.8 | NA | NA | 33.2 | NA | NA |
| Standard Deviation (Ct) | 0.5 | 0.8 | NA | 1.3 | NA | NA | 0.9 | NA | NA |

[1] Concentration is presented in RNA copies/µL

[2] Mean Ct reported for dilutions that are ≥ 95% positive. Calculations only include positive results.

NA not applicable

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**Table 5. Limit of Detection Confirmation CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with QIAGEN QIAmp DSP Viral RNA Mini Kit**

| Targets | 2019-nCoV_N1 | | | 2019-nCoV_N2 | | | | 2019-nCoV_N3 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| RNA Concentration[1] | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ | $10^{-1.0}$ | $10^{0.5}$ | $10^{0.0}$ | $10^{-0.5}$ |
| Positives/Total | 20/20 | 20/20 | 6/20 | 20/20 | 20/20 | 20/20 | 8/20 | 20/20 | 20/20 | 5/20 |
| Mean Ct[2] | 32.0 | 32.8 | NA | 33.0 | 35.4 | 36.2 | NA | 32.4 | 32.7 | NA |
| Standard Deviation (Ct) | 0.7 | 0.8 | NA | 1.4 | 0.9 | 1.9 | NA | 0.7 | 0.8 | NA |

[1] Concentration is presented in RNA copies/µL

[2] Mean Ct reported for dilutions that are ≥ 95% positive. Calculations only include positive results.

NA not applicable

**Table 6. Limit of Detection of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel**

| Virus | Material | Limit of Detection (RNA copies/µL) | |
|---|---|---|---|
| | | QIAGEN EZ1 Advanced XL | QIAGEN DSP Viral RNA Mini Kit |
| 2019 Novel Coronavirus | N Gene RNA Transcript | $10^{0.5}$ | $10^{0}$ |

FDA Sensitivity Evaluation: The analytical sensitivity of the test will be further assessed by evaluating an FDA-recommended reference material using an FDA developed protocol if applicable and/or when available.

*In Silico Analysis of Primer and Probe Sequences:*

An alignment was performed with the oligonucleotide primer and probe sequences of the CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel with all publicly available nucleic acid sequences for 2019-nCoV in GenBank as of February 1, 2020 to demonstrate the predicted inclusivity of the CDC 2019 nCoV Real-Time RT-PCR Diagnostic panel. All the alignments show 100% identity of the CDC panel to the available 2019-nCoV sequences with the exception of one nucleotide mismatch with the N1 forward primer in one deposited sequence. Similarly, a single mismatch is observed in the alignment of the N3 probe. The risk assessment of these single mismatches resulting in a significant loss in reactivity, and false negative result, is low due to the design of the primers and probes with melting temperatures > 60°C and run conditions of the assay with annealing temperature at 55°C to tolerate one to two mismatches. The alignment of the 2019-nCoV_N3 assay includes additional sequences for SARS, MERS, and other Bat coronaviruses to show that other than SARS viruses, the alignment shows low identities and would not predict significant reactivity.

*Specificity/Exclusivity Testing: In Silico Analysis*

BLASTn analysis queries of the 2019-nCoV rRT-PCR assays primers and probes were performed against public domain nucleotide sequences. The database search parameters were as follows: 1) The nucleotide collection consists of GenBank+EMBL+DDBJ+PDB+RefSeq sequences, but excludes EST, STS, GSS, WGS, TSA, patent sequences as well as phase 0, 1, and 2 HTGS sequences and sequences longer than 100Mb; 2) The database is non-redundant. Identical sequences have been merged into one entry, while preserving the accession, GI, title and taxonomy information for each entry; 3) Database was updated on 10/03/2019; 4) The search

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parameters automatically adjust for short input sequences and the expect threshold is 1000; 5) The match and mismatch scores are 1 and -3, respectively; 6) The penalty to create and extend a gap in an alignment is 5 and 2 respectively.

2019-nCoV_N1 Assay:
Probe sequence of 2019-nCoV rRT-PCR assay N1 showed high sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome. However, forward and reverse primers showed no sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome. Combining primers and probe, there is no significant homologies with human genome, other coronaviruses or human microflora that would predict potential false positive rRT-PCR results.

2019-nCoV_N2 Assay:
The forward primer sequence of 2019-nCoV rRT-PCR assay N2 showed high sequence homology to Bat SARS-like coronaviruses. The reverse primer and probe sequences showed no significant homology with human genome, other coronaviruses or human microflora. Combining primers and probe, there is no prediction of potential false positive rRT-PCR results.

2019-nCoV_N3 Assay:
Analysis of the forward and reverse primer and probe sequences of 2019-nCoV rRT-PCR assay N3 showed significant homology only to human SARS coronavirus and bat SARS coronavirus. No significant homology with human genome, other coronaviruses or human microflora was observed. that would predict potential false positive rRT-PCR results.

In summary, the 2019-nCoV rRT-PCR assay N1 and N2, designed for the specific detection of 2019-nCoV, showed no significant combined homologies with human genome, other coronaviruses, or human microflora that would predict potential false positive rRT-PCR results.

The 2019-nCoV rRT-PCR assay N3 was designed for universal detection of 2019-nCoV, human SARS coronavirus and bat SARS coronavirus. The 2019-nCoV rRT-PCR assay 3 showed no significant combined homologies with human genome, other human coronaviruses other than human SARS coronavirus or human microflora that would predict potential false positive rRT-PCR results.

In addition to the *in silico* analysis, several organisms were extracted and tested with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel to demonstrate analytical specificity and exclusivity. Studies were performed with nucleic acids extracted using the QIAGEN EZ1 Advanced XL instrument and EZ1 DSP Virus Kit. Nucleic acids were extracted from high titer preparations (typically ≥ $10^5$ PFU/mL or ≥ $10^6$ CFU/mL). Testing was performed using the ThemoFisher Scientific TaqPath™ 1-Step RT-qPCR Master Mix, CG on the Applied Biosystems™ 7500 Fast Dx Real-Time PCR instrument. The data demonstrate that the expected results are obtained for each organism when tested with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

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**Table 7. Specificity/Exclusivity of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel**

| Virus | Strain | Source | 2019-nCoV_N1 | 2019-nCoV_N2 | 2019-nCoV_N3 | Final Result |
|---|---|---|---|---|---|---|
| Human coronavirus | 229E | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Human coronavirus | OC43 | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Human coronavirus | NL63 | clinical specimen | 0/3 | 0/3 | 0/3 | Neg. |
| Human coronavirus | HKU1 | clinical specimen | 0/3 | 0/3 | 0/3 | Neg. |
| MERS-coronavirus | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| SARS-coronavirus | | isolate | 0/3 | 0/3 | 3/3 | Inc. |
| bocavirus | - | clinical specimen | 0/3 | 0/3 | 0/3 | Neg. |
| *Mycoplasma pneumoniae* | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| *Streptococcus* | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Influenza A(H1N1) | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Influenza A(H3N2) | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Influenza B | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Human adenovirus, type 1 | Ad71 | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| Human metapneumovirus | - | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| respiratory syncytial virus | Long A | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| rhinovirus | | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| parainfluenza 1 | C35 | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| parainfluenza 2 | Greer | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| parainfluenza 3 | C-43 | isolate | 0/3 | 0/3 | 0/3 | Neg. |
| parainfluenza 4 | M-25 | isolate | 0/3 | 0/3 | 0/3 | Neg. |

*Endogenous Interference Substances Studies*:

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel uses conventional well-established nucleic acid extraction methods and based on our experience with CDC's other EUA assays, including the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay for the presumptive detection of novel influenza A (H7N9) virus that are both intended for use with a number of respiratory specimens, we do not anticipate interference from common endogenous substances.

*Specimen Stability and Fresh-frozen Testing:*

To increase the likelihood of detecting infection, CDC recommends collection of three specimen types, lower respiratory and upper respiratory specimens for testing. If possible, additional specimen types (e.g., stool, urine) should be collected and should be stored initially until decision is made by CDC whether additional specimen sources should be tested. Specimens should be collected as soon as possible once a PUI is identified regardless of symptom onset. Maintain proper infection control when collecting specimens. Store specimens at 2-8°C and ship overnight to CDC on ice pack. Label each specimen container with the patient's ID number (e.g., medical record number), unique specimen ID (e.g., laboratory requisition number), specimen type (e.g., nasal swabs) and the date the sample was collected. Complete a CDC Form 50.34 for each specimen submitted.

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***Clinical Performance:***

As of January 27, 2020, CDC has tested 253 respiratory specimens from 102 persons under investigation (PUI) in the U.S. using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Specimen types include buccal swab, nasal washes, nasopharyngeal swab, oral swab, sputum, and oropharyngeal (throat) swab.

**Table 8: Summary of CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Data Generated by Testing Human Respiratory Specimens Collected from PUI Subjects in the U.S.**

| Specimen Type | Number of Specimens | CDC 2019-nCoV Panel Positive | CDC 2019-nCoV Panel Negative | CDC 2019-nCoV Panel Inconclusive |
|---|---|---|---|---|
| Buccal Swab | 4 | 1 | 3 | 0 |
| Nasal Wash | 2 | 0 | 2 | 0 |
| Nasopharyngeal Swab | 103 | 5 | 98 | 0 |
| Oral Swab | 52 | 5 | 47 | 0 |
| Sputum | 50 | 5 | 45 | 0 |
| Swab[1] | 13 | 0 | 13 | 0 |
| Oropharyngeal (Throat) Swab | 29 | 2 | 27 | 0 |
| Total | 253 | 18 | 235 | 0 |

[1]Actual swab type information was missing from these upper respiratory tract specimens.

For 85 of the 102 PUI subjects, multiple respiratory specimens were collected from each subject and tested by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. A single respiratory specimen was collected and tested for each of the 17 remaining PUI subjects. Respiratory specimens for 97 of the 102 PUI subjects tested negative by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Most but not all of the specimens collected from the five remaining PUI subjects tested positive by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. The positive results were further investigated and confirmed by genetic sequencing. Longitudinal specimens were collected from two of the five confirmed 2019-nCoV positive patients and tested using the CDC 2019-nCoV Panel. For three of the five confirmed 2019-nCoV positive patients all samples collected tested positive by the CDC 2019-nCoV Panel. For the two remaining confirmed 2019-nCoV positive patients, upper and lower respiratory tract specimens were collected and tested from the first patient at one time point only, and from the second patient longitudinally over three time points. One buccal swab and one sputum specimen from the first patient tested positive by the CDC 2019-nCoV Panel, one nasopharyngeal swab specimen collected on the same day tested negative. For the second patient, one oral swab, one nasopharyngeal swab and one sputum specimen collected approximately eight days post onset of symptoms tested positive by the CDC 2019-nCoV Panel. While one sputum specimen collected approximately 10 days post symptoms onset tested positive, two oral swabs and two nasopharyngeal swabs collected on the same day tested negative. Approximately 12 days post onset of symptoms, one sputum specimen and one oral swab specimen from the second patient tested positive, but two nasopharyngeal swabs taken on the same day were negative.

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During the early phase of the testing, a total of 117 respiratory specimens collected from 46 PUI subjects were also tested with two analytically validated real-time RT-PCR assays that target separate and independent regions of the nucleocapsid protein gene of the 2019-nCoV, N4 and N5 assays. The nucleocapsid protein gene targets for the N4 and N5 assays are different and independent from the nucleocapsid protein gene targets for the three RT-PCR assays included in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, N1, N2, and N3. Any positive result from the N4 and/or the N5 assay was further investigated by genetic sequencing.

The performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel was estimated against a composite comparator. A specimen was considered comparator negative if both the N4 and the N5 assays were negative. A specimen was considered comparator positive when the N4 and/or the N5 assay generated a positive result, and the comparator positive result(s) were further investigated and confirmed to be 2019-nCoV RNA positive by genetic sequencing.

**Table 9: Percent Agreement of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with the Composite Comparator**

| CDC 2019-nCoV Panel Result | Composite Comparator Result | |
|---|---|---|
| | Positive | Negative |
| Positive | 13[1] | 0 |
| Inconclusive | 0 | 0 |
| Negative | 0 | 104 |

[1]Composite comparator results were available for 13 of 18 CDC 2019-nCoV Panel positive specimens only.

Positive percent agreement = 13/13 = 100% (95% CI: 77.2% - 100%)
Negative percent agreement = 104/104 = 100% (95% CI: 96.4% - 100%)

## Disposal

Dispose of hazardous or biologically contaminated materials according to the practices of your institution.

## References

1. Ballew, H. C., *et al.* "Basic Laboratory Methods in Virology," DHHS, Public Health Service 1975 (Revised 1981), Centers for Disease Control and Prevention, Atlanta, Georgia 30333.

2. Clinical Laboratory Standards Institute (CLSI), "Collection, Transport, Preparation and Storage of Specimens for Molecular Methods: Proposed Guideline," MM13-A

3. Lieber, M., *et al.* "A Continuous Tumor Cell Line from a Human Lung Carcinoma with Properties of Type II Alveolar Epithelial Cells." *International Journal of Cancer* 1976, 17(1), 62-70.

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## Contact Information, Ordering, and Product Support

For technical and product support, contact the CDC Division of Viral Diseases directly.

Send email to: respvirus@cdc.gov

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FDACDRH p3-AC-002665

FDA-CVD-SHURENJ-00020120 MULTI-HHS-20-0522-B, 20-0523-A-003354

| | |
|---|---|
| | *Division of Viral Diseases/Respiratory Viruses Branch* |
| **2019-nCoV EUA-01** | **CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Product Information Sheet** |

****DO NOT DISCARD: Important product-specific information****

# CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

**For use under EMERGENCY USE AUTHORIZATION (EUA) only.**

**Rx only**

**CATALOG: 2019-nCoVEUA-01**

**KIT LOT:**

**EXPIRATION DATE:**

## INTENDED USE

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization .

## PACKAGE CONTENTS

| PACKAGING | COMPONENT | PART NUMBER | COMPONENT LOT NUMBER | VIALS PER KIT | QUANTITY /VIAL | STATE |
|---|---|---|---|---|---|---|
| Oligonucleotide Box | 2019-nCoV_N1 Combined Primer/Probe Mix | RV202001 | | 1 | 22.5 nmol | Dried |
| | 2019-nCoV_N2 Combined Primer/Probe Mix | RV202002 | | 1 | 22.5 nmol | Dried |
| | 2019-nCoV_N3 Combined Primer/Probe Mix | RV202003 | | 1 | 22.5 nmol | Dried |
| | RP Combined Primer/Probe Mix | RV202004 | | 1 | 22.5 nmol | Dried |
| Control Box | nCoVPC 2019-nCoV Positive Control (non-infectious) | RV202005 | | 4 | $1 \times 10^4$ copies/µL | Dried |

## STORAGE INSTRUCTIONS

Upon receipt, store at 2-8°C. Refer to the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use before opening and preparing reagents for use.

## PROCEDURE/INTERPRETATION/LIMITATIONS

Users should refer to the **CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use** posted on the FDA website for all IVD products used under Emergency Use Authorization, http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm.

**IVD**

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| | |
|---|---|
| | *Division of Viral Diseases/Respiratory Viruses Branch* |
| **2019-nCoV EUA-01** | **CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Product Information Sheet** |

**PRECAUTIONS**

This reagent should be handled in an approved BSL-2 handling area to avoid contamination of laboratory equipment and reagents that could cause false positive results. This product is non-infectious. However, this product should be handled in accordance with Good Laboratory Practices.

**REAGENT COMPLAINTS/QUESTIONS**

If you have a question/comment about this product, please contact the CDC Division of Viral Diseases/Respiratory Viruses Branch by email at respvirus@cdc.gov.

**DISTRIBUTED BY**

Manufactured by the Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia, 30329, USA

IVD

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**** DO NOT DISCARD: Important product-specific information ****

# CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel – Verification Requirements

Please consult the following guidance from CMS regarding Emergency Use Authorized diagnostic tests: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/QSO18-19-CLIA

## INTENDED USE

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the presumptive identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization.

## REQUIRED MATERIALS

The 2019 novel coronavirus positive control (nCoVPC) is provided with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel and should be prepared according to the instructions for use. The nCoVPC consists of an RNA transcript of the 2019-nCoV N gene as well as human RNase P gene segment. nCoVPC will yield a positive result with the following primer and probe sets: 2019-nCoV_N1, 2019-nCoV_N2, 2019-nCoV_N3 and RP.

Approximately 2 mL of an upper respiratory specimen (e.g. nasopharyngeal swabs (NPS) in transport media) will be needed for testing. Specimens may be pooled if less than 2mL of one specimen is available.

Refer to CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel package insert (manufacturer instructions) for additional reagents, materials, and instructions.

## PRECAUTIONS

This reagent should be handled in an approved BSL-2 handling area to avoid contamination of laboratory equipment and reagents that could cause false positive results. This product is an RNA transcript and is non-infectious. However, the nCoVPC should be handled in accordance with Good Laboratory Practices.

Store reagent at appropriate temperatures (see below) and hold on ice when thawed.

Please use standard precautions when handling respiratory specimens.

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# CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel – Verification Requirements

****** DO NOT DISCARD: Important product-specific information ******

## INSTRUCTIONS FOR PREPARING SAMPLES BEFORE EXTRACTION WITH THE QIAmp DSP VIRAL RNA MINI KIT

- Refer to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use for reconstitution of the materials for use. RNA should be kept cold during preparation and use.
- Make a 1/10 dilution of nCoVPC in by adding 5 µL of nCoVPC into 45 µL of nuclease-free water or 10 mM Tris
- Aliquot 560 µL of lysis buffer into each of nine tubes labeled 1-9.
- Add 140 µL of upper respiratory specimen (e.g. NPS in viral transport media) into each of the nine labeled tubes with lysis buffer
- To prepare samples at a moderate concentration, spike 14 µL of undiluted nCoVPC (rehydrated as described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use) into each tube labeled 1-3 containing lysis buffer and specimen
- To prepare samples at a low concentration, spike 14 µL of 1/10 dilution of nCoVPC into each tube labeled 4-6 containing lysis buffer and specimen
- To prepare negative samples, spike 14 µL of nuclease-free water into each tube labeled 7-9 containing lysis buffer and specimen
- Perform extractions of all nine samples according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use

## INSTRUCTIONS FOR PREPARING SAMPLES BEFORE EXTRACTION WITH THE QIAGEN EZ1 ADVANCED XL

- Refer to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use for reconstitution of the materials for use. RNA should be kept cold during preparation and use.
- Make a 1/10 dilution of nCoVPC in by adding 5 µL of nCoVPC into 45 µL of nuclease-free water or 10 mM Tris
- Aliquot 280 µL of lysis buffer into each of nine tubes labeled 1-9.
- Add 120 µL of upper respiratory specimen (e.g. NPS in viral transport media) into each of the nine labeled tubes with lysis buffer
- To prepare samples at a moderate concentration, spike 12 µL of undiluted nCoVPC (rehydrated as described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use) into each tube labeled 1-3 containing lysis buffer and specimen
- To prepare samples at a low concentration, spike 12 µL of 1/10 dilution of nCoVPC into each tube labeled 4-6 containing lysis buffer and specimen
- To prepare negative samples, spike 12 µL of nuclease-free water into each tube labeled 7-9 containing lysis buffer and specimen
- Perform extractions of all nine samples according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use

## PROCEDURE

Follow the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use for testing the 9 extracted samples at least once.

## EXPECTED RESULTS

Moderate nCoVPC samples should be presumptive positive for 2019-nCoV.
Low nCoVPC samples should be presumptive positive for 2019-nCoV.
Negative upper respiratory samples should be negative for 2019-nCoV.

≥ 90% of test results should be in agreement with the expected results. If test results are less than 90% in agreement with expected results, contact CDC at respvirus@cdc.gov.

## QUESTIONS

Please send questions or comments by email to respvirus@cdc.gov.

## DISTRIBUTION:

Distributed to qualified laboratories designated by Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA, 30329 USA

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| | |
|---|---|
| **From:** | Shuren, Jeff |
| **To:** | Shuren, Jeff |
| **Subject:** | Fwd: FYI - Signed copy: CDC 2019-nCoV EUA |
| **Date:** | Saturday, February 15, 2020 5:45:45 PM |
| **Attachments:** | SIGNED_CDC_2019_nCoV_EUA_Ltr.pdf<br>CDC 2019-nCoV Letter of Authorization 02042020 FINAL.doc<br>CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel HCP FS 02042020 FINAL.docx<br>CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel HCP FS 02042020 FINAL.pdf<br>CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Patient FS 02042020 FINAL.docx<br>CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Patient FS 02042020 FINAL.pdf<br>CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Instructions for Use 02042020.docx<br>CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel PIS and VR 02042020.pdf<br>image003.png |

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Date:** February 4, 2020 at 3:28:14 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>, McFarland, Scott <Scott.McFarland@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Russ, Wanda <Wanda.Russ@fda.hhs.gov>, Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Subject:** FYI - Signed copy: CDC 2019-nCoV EUA

Hello,

Please find attached the pdf and Word documents of the EUA package for CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel

- Letter (Signed pdf and Word)
- Fact Sheet for Healthcare Providers (Word and pdf)
- Fact Sheet for Patients (Word and pdf)
- Instructions for Use (Word only)
- PIS and VR (pdf only)

A hard copy is being sent to CDC via UPS today.

Thanks,

Jennifer

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**Jennifer Ross, PhD, JD**
*Senior Regulatory Counsel*

**Office of Counterterrorism and Emerging Threats**
**Office of the Chief Scientist / U.S. Food and Drug Administration**
Tel: 240-402-8155
Jennifer.Ross@fda.hhs.gov



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| | |
|---|---|
| **From:** | Shuren, Jeff |
| **To:** | Shuren, Jeff |
| **Subject:** | Fwd: Request for Input for 20 Feb Update on FDA 2019-nCoV SITREP |
| **Date:** | Sunday, February 23, 2020 1:10:03 PM |
| **Attachments:** | Copy of PPE summary information 20 feb 2020.xlsx<br>image001.png<br>image003.jpg<br>image005.jpg<br>image007.jpg<br>image009.jpg<br>image011.jpg |

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Date:** February 20, 2020 at 3:59:14 PM EST
**To:** Cho, David S (CBER) <David.Cho@fda.hhs.gov>, Measer, Gregory <Gregory.Measer@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>, 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Mitchell, Diane <Diane.Mitchell@fda.hhs.gov>, Sutton, William <William.Sutton@fda.hhs.gov>
**Subject:** RE: Request for Input for 20 Feb Update on FDA 2019-nCoV SITREP

Good afternoon,

Below are CDRH's updates for today's Sitrep. Also we have attached a chart for more specific information on our outreach to manufacturers.

**Personal Protective Equipment (PPE) Outreach to Manufacturers:**

- FDA continues to prioritize outreach to PPE facilities (based on 2014 market share report):

(b) (4)

- Exact facility numbers are likely to change as more information becomes available through outreach.

- **N95 surgical respirators:**
  - As of 2/20/20, we are aware of (b) (4) that make N95 surgical respirators (manufacturers and contract manufacturers). This number is likely to change as more information becomes available through outreach.
  - Out of (b) (4)
  - Out of (b) (4) irms indicated that they were affected by nCoV.
  - Attached table provides average monthly production volumes, based on

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information received to date.

- **Non-surgical, industrial N95 respirators:**
  - As of 2/20/20, we are aware (b) (4) that make non-surgical, industrial N95 respirators. There are likely many more manufacturers (not regulated by FDA). This number is likely to change as more information becomes available through outreach.
  - Out (b) (4)
  - Outreach to NIOSH is being performed to receive a list of non-surgical, industrial N95 manufacturers.
  - Out of (b) (4) firms indicated that they were affected by nCoV.
  - 3M has a de novo for N95 for use in public health emergencies.

- **Surgical masks**:
  - There are (b) (4) known to FDA (manufactures and contract manufactures).
  - Out of (b) (4), (b) (4)
  - Out of (b) (4) indicated that they were affected by nCoV.
  - We have received substantive responses from (b) (4) (b) (4)

- **Gloves:**
  - There are (b) (4) known to FDA (manufacturers and contract manufactures).
  - Out of (b) (4)
  - Out of (b) (4) indicated that they were affected by nCoV.
  - We have received substantive responses from (b) (4)

- **Isolation gowns:**
  - There are (b) (4) known to FDA (manufactures and contract manufactures).
  - Out of (b) (4).
  - Out of (b) (4) indicated that they were affected by nCoV.
  - We have received substantive responses from (b) (4)

- **Surgical gowns:**
  - There are (b) (4) known to FDA (manufactures and contract manufactures). There are (b) (4)
  - Out of (b) (4) indicated that they were affected by nCoV.
  - We have received substantive responses from (b) (4)

**<u>Outreach to Stakeholders:</u>**

**NIOSH:**

- CDRH spoke with NIOSH the evening of 2/21/20 about EUAs for N95s. Key takeaways from this discussion were as follows:

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(b) (4), (b) (5)

**Hospital Associations/Distributors/GPOS:**

- CDRH is reaching out to hospital associations/Distributors/GPOs to gather information regarding novel coronavirus and access to PPE to determine any potential supply chain disruptions and possible shortages.

**Congressional Briefings**

- CDRH participated in the Senate HSGAC Minority staff briefing focused on nCoV supply chain and foreign inspections. Key takeaways from this meeting were as follows:

(b) (5)

(b) (5)

**Communication Updates**

- On 2/20/20, ARC and OCE developed a strategy to meet the COVID-19 communication needs with an emphasis on what is needed for the communication rollout for the imminent Emergency Use Authorizations for N95 respirators. This rollout will be closely coordinated with CDC/NIOSH Communication team. The type of comms products that are currently being considered include webpage updates, email distribution to N95 manufacturers and healthcare facilities, talking points/FAQs for CDC to align the messaging, joint blog and/or joint webinar with CDC. We anticipate having a draft comms plan ready by end of this week and will share with the JIC.

**Non-diagnostic EUAs:**

(b) (5)

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- CDRH received a new EUA request on (b) (4), (b) (5) [redacted]
- [redacted]

Please let us know if you have any questions.

Thank you,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: (b) (6) [redacted]
Email: Heather.Agler@fda.hhs.gov

---

**From:** Cho, David S (CBER)
**Sent:** Thursday, February 20, 2020 2:50 PM
**To:** Measer, Gregory <Gregory.Measer@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
**Subject:** RE: Request for Input for 20 Feb Update on FDA 2019-nCoV SITREP

Hi Greg, Michael,
Here is CBER's new items for today's SITREP.
Thanks,
David

CBER Activities for 02/20/2020

(b) (4) [redacted]

- Vaccines: FDA participated in a SARS-CoV-2 Vaccine Working Group meeting.
- Supply Chain: FDA has reached out to (b) (4) [redacted] biologics manufacturers to determine if there are any potential disruptions in their supply chain. To date, no firms have reported a supply disruption.

---

**From:** Measer, Gregory <Gregory.Measer@fda.hhs.gov>

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**Sent:** Thursday, February 20, 2020 11:54 AM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hall, Valerie <Valerie.Hall@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Lucas, Tanisha <Tanisha.Lucas@fda.hhs.gov>; Gutierrez, Sacha <Sacha.Gutierrez@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Harrison, Tina <Tina.Harrison@fda.hhs.gov>; Arsenault, Sam <Samuel.Arsenault@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>
**Cc:** FDA Emergency Operations <emergency.operations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>
**Subject:** Request for Input for 20 Feb Update on FDA 2019-nCoV SITREP
**Importance:** High

Hi All,

Attached is the draft 20 Feb SITREP on the FDA response to the 2019-nCoV outbreak.

Please **provide any additional updates by 3:30 PM if possible.**

Please highlight any info that should not be shared outside of FDA in **red**.

Thank you for your continued assistance with this effort. Let me know if you have any questions or concerns.

Best,
Greg

**Gregory Measer, JD**
*Regulatory Counsel*

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist, Office of the Commissioner
U.S. Food and Drug Administration
202-774-4146 / Gregory.Measer@fda.hhs.gov



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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 10:14:01 PM
**To:** Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: If possible to review by 9pm

Thank you

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:10 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: If possible to review by 9pm

FWIW, here's the talkers CDC sent up.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:43 PM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: If possible to review by 9pm

(b) (5)

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:42 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: If possible to review by 9pm

(b) (5)

Thanks! I think we are set, will update with all this feedback. Thank you!!!

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:37 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: If possible to review by 9pm

That is a good point.

---

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

**Date:** February 29, 2020 at 8:33:25 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: If possible to review by 9pm

2 cents - For the 2nd question, (b) (5) [redacted]

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:14 PM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: If possible to review by 9pm

I edited the last bullet in the first question, which I highlighted. (b) (5) [redacted]

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:36 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** If possible to review by 9pm

HHS just asked us to provide some TPs to FDA, CDC, ASPR for VP/Secretary to use tomorrow in TV interviews. I've pulled out the relevant FDA Qs. TPs look ok?

(b) (5) [redacted]

AMERICAN OVERSIGHT

(b) (5)



**Stephanie Caccomo**
*Press Officer*

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: 240.762.8873
stephanie.caccomo@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 3/1/2020 8:12:21 PM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** Re: URGENT REVIEW NEEDED TODAY: (b) (5)

I agree with (b) (5)

Jeff

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** March 1, 2020 at 8:03:07 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** FW: URGENT REVIEW NEEDED TODAY: (b) (5)
**Importance:** High

Just reading this one now.

I assume (b) (5) Is that correct?

I note the following (b) (5)

(b) (5)

suzanne
**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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AMERICAN OVERSIGHT

**From:** Hertzog, Christian (HHS/OGC) <Christian.Hertzog@hhs.gov>
**Sent:** Sunday, March 1, 2020 6:55 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Mango, Paul (OS) <Paul.Mango@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>; Blackwell, Edith (OS) <Edith.Blackwell@hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Kehoe, Brian (OS) <Brian.Kehoe@hhs.gov>
**Subject:** RE: URGENT REVIEW NEEDED TODAY: (b) (5)
**Importance:** High

Everyone,

(b) (5)

Thanks

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 9:46 AM
**To:** Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hertzog, Christian (HHS/OGC) <Christian.Hertzog@hhs.gov>
**Cc:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; McBride, Maren (FDA/OC) <Maren.McBride@fda.hhs.gov>; Tantillo, Andrew (FDA/OC) <Andrew.Tantillo@fda.hhs.gov>; Anderson, Erika (FDA/OC) <Erika.Anderson@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Schipper, Jodi (FDA/OC) <Jodi.Schipper@fda.hhs.gov>; Black, Jennifer (FDA/OC) (CTR) <Jennifer.Black@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Marders, Julia A (FDA/CDRH) <Julia.Marders@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Kannan, Lakshmi (FDA/CDRH) <Lakshmi.Kannan@fda.hhs.gov>; Blackwell, Edith (HHS/OGC) <Edith.Blackwell@hhs.gov>; Paulos, Lauren (FDA/OC) <Lauren.Paulos@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Kehoe, Brian (HHS/ASL) <Brian.Kehoe@hhs.gov>
**Subject:** RE: URGENT REVIEW NEEDED TODAY: (b) (5)

Christian – thank you so much for all of your help! Please let us know if (b) (5)

Best,

AMERICAN OVERSIGHT

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

---

**From:** Gross, Karas <Karas.Gross@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 9:17 AM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hertzog, Christian P (OS) <Christian.Hertzog@hhs.gov>
**Cc:** Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Mango, Paul (OS) <Paul.Mango@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>; Blackwell, Edith (OS) <Edith.Blackwell@hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Kehoe, Brian (OS) <Brian.Kehoe@hhs.gov>
**Subject:** Re: URGENT REVIEW NEEDED TODAY: (b) (5)

Yes thank you!!

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** March 1, 2020 at 9:13:25 AM EST
**To:** Hertzog, Christian P (OS) <Christian.Hertzog@hhs.gov>
**Cc:** Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>, Mango, Paul (OS) <Paul.Mango@hhs.gov>, Pence, Laura (OS) <Laura.Pence@hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>, Schipper, Jodi <jodi.schipper@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>, Blackwell, Edith (OS) <Edith.Blackwell@hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Kehoe, Brian (OS) <Brian.Kehoe@hhs.gov>
**Subject:** Re: URGENT REVIEW NEEDED TODAY: (b) (5)

AMERICAN OVERSIGHT

Excellent. Thank you Christian.

Sent from my iPhone

On Mar 1, 2020, at 9:04 AM, Hertzog, Christian (HHS/OGC) <Christian.Hertzog@hhs.gov> wrote:

(b) (5)

Thanks everyone for your work this weekend.

**From:** Hertzog, Christian (HHS/OGC)
**Sent:** Saturday, February 29, 2020 7:02 PM
**To:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
**Cc:** McBride, Maren (FDA/OC) <Maren.McBride@fda.hhs.gov>; Tantillo, Andrew (FDA/OC) <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Anderson, Erika (FDA/OC) <Erika.Anderson@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Schipper, Jodi (FDA/OC) <Jodi.Schipper@fda.hhs.gov>; Black, Jennifer (FDA/OC) (CTR) <Jennifer.Black@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Tomasello, Jennifer (FDA/CDRH) <Jennifer.Tomasello@fda.hhs.gov>; Marders, Julia A (FDA/CDRH) <Julia.Marders@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Kannan, Lakshmi (FDA/CDRH) <Lakshmi.Kannan@fda.hhs.gov>; Blackwell, Edith (HHS/OGC) <Edith.Blackwell@hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Kehoe, Brian (HHS/ASL) <Brian.Kehoe@hhs.gov>
**Subject:** RE: URGENT REVIEW NEEDED TODAY: (b) (5)
**Importance:** High

Removing my colleagues (to save their inboxes) and adding my boss (Edith)

Sarah, Laura, and Paul,

(b) (5)

Christian

**From:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 1:14 PM
**To:** Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hertzog, Christian (HHS/OGC) <Christian.Hertzog@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
**Cc:** McBride, Maren (FDA/OC) <Maren.McBride@fda.hhs.gov>; Tantillo, Andrew (FDA/OC) <Andrew.Tantillo@fda.hhs.gov>; Kehoe, Brian (HHS/ASL) <Brian.Kehoe@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Anderson, Erika (FDA/OC) <Erika.Anderson@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Schipper, Jodi (FDA/OC) <Jodi.Schipper@fda.hhs.gov>; Black, Jennifer (FDA/OC) (CTR) <Jennifer.Black@fda.hhs.gov>; OS GCL, EMAIL (HHS/OGC) <EMAIL.GCL@HHS.GOV>; Friedman, Richard (HHS/OGC) <Richard.Friedman@HHS.GOV>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Tomasello, Jennifer (FDA/CDRH) <Jennifer.Tomasello@fda.hhs.gov>; Marders, Julia A (FDA/CDRH) <Julia.Marders@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Kannan, Lakshmi (FDA/CDRH) <Lakshmi.Kannan@fda.hhs.gov>
**Subject:** Re: URGENT REVIEW NEEDED TODAY: (b) (5)

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Adding Julie Marders, Suzanne Schwartz, Jennifer Tomasello and Lakshmi Kannan for any questions on the language.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 29, 2020 at 12:53:55 PM EST
**To:** Hertzog, Christian P (OS) <Christian.Hertzog@hhs.gov>, Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>, Mango, Paul (OS) <Paul.Mango@hhs.gov>
**Cc:** McBride, Maren <Maren.McBride@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Kehoe, Brian (OS) <Brian.Kehoe@hhs.gov>, Pence, Laura (OS) <Laura.Pence@hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Schipper, Jodi <jodi.schipper@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>, OS GCL, EMAIL (HHS/OGC) <EMAIL.GCL@hhs.gov>, Friedman, Richard (OS) <Richard.Friedman@HHS.GOV>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** Re: URGENT REVIEW NEEDED TODAY: (b) (5)

Adding (b) (5)

Sent from my iPhone

On Feb 29, 2020, at 12:51 PM, Hertzog, Christian (HHS/OGC) <Christian.Hertzog@hhs.gov> wrote:

(b) (5)

Sent from my iPhone

On Feb 29, 2020, at 12:25 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

(b) (5)

Sent from my iPhone

On Feb 29, 2020, at 12:24 PM, McBride, Maren <Maren.McBride@fda.hhs.gov> wrote:

I do think it will be harder to get in the package now that it's not in our section's base text, but will be good to have done in case we have another chance.

Christian, if you think we could get it to OMB today (or even early tomorrow) that'd be great if possible. I just want everyone to be aware of the dynamics (that the mad rush I was getting this morning is less pressing).

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:12 PM
**To:** Hertzog, Christian P (OS) <Christian.Hertzog@hhs.gov>
**Cc:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Kehoe, Brian (OS) <Brian.Kehoe@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; OS GCL, EMAIL (HHS/OGC) <EMAIL.GCL@hhs.gov>; Friedman, Richard (OS)

AMERICAN OVERSIGHT

<Richard.Friedman@HHS.GOV>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** Re: URGENT REVIEW NEEDED TODAY: (b) (5)

(b) (5)

Sent from my iPhone

On Feb 29, 2020, at 12:04 PM, Hertzog, Christian (HHS/OGC) <Christian.Hertzog@hhs.gov> wrote:

Thanks for the quick action.

(b) (5)

Christian Hertzog
HHS/OGC/Legislation Division
Christian.Hertzog@hhs.gov
202.260.6183

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:30 AM
**To:** Tantillo, Andrew (FDA/OC) <Andrew.Tantillo@fda.hhs.gov>; Hertzog, Christian (HHS/OGC) <Christian.Hertzog@hhs.gov>; OS GCL, EMAIL (HHS/OGC) <EMAIL.GCL@HHS.GOV>; Friedman, Richard (HHS/OGC) <Richard.Friedman@HHS.GOV>
**Cc:** Kehoe, Brian (HHS/ASL) <Brian.Kehoe@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Anderson, Erika (FDA/OC) <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Paulos, Lauren (FDA/OC) <Lauren.Paulos@fda.hhs.gov>; Schipper, Jodi (FDA/OC) <Jodi.Schipper@fda.hhs.gov>; Black, Jennifer (FDA/OC) (CTR) <Jennifer.Black@fda.hhs.gov>
**Subject:** Re: URGENT REVIEW NEEDED TODAY: (b) (5)

Folks- I just got off the phone w Approps. Sounds like our section of the bill just closed. That means I think we have a bit more time- so, I sincerely apologize for the fire drill this morning but I also don't want you unnecessarily ruining your Saturday.

I do think there is still a possibility this could get legs because of member interest, (b) (5)

(b) (5)

Again apologies to all but wanted you to have the same info I do.

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
**Date:** February 29, 2020 at 11:21:13 AM EST
**To:** Hertzog, Christian P (OS) <Christian.Hertzog@hhs.gov>, email.gcl@hhs.gov <email.gcl@hhs.gov>,

AMERICAN OVERSIGHT

Friedman, Richard (OS) <Richard.Friedman@HHS.GOV>
**Cc:** Kehoe, Brian (OS) <Brian.Kehoe@hhs.gov>, Pence, Laura (OS) <Laura.Pence@hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Schipper, Jodi <jodi.schipper@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>
**Subject:** URGENT REVIEW NEEDED TODAY: (b) (5)

Christian (and copying some OGC colleagues given the time (b) (5)

(b) (5)

Thank you, and we are on standby to do whatever we can to help you (b) (5)

**Andrew Tantillo**
*Deputy Director*

**Office of Legislation**
**U.S. Food and Drug Administration**
O: 301-796-8919 M: (b) (6)
andrew.tantillo@fda.hhs.gov

<image001.png>

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 3/1/2020 12:33:35 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** RE: Need help asap--test kits

Those numbers are not from us. They came from the CDC.

There is an issue with semantics which can be confusing. (b) (5) [redacted]

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 12:08 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Need help asap--test kits
**Importance:** High

Can you pls help with the numbers?

---

**From:** Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
**Sent:** Sunday, March 1, 2020 12:01 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
**Cc:** Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>
**Subject:** Need help asap--test kits
**Importance:** High

CDC/FDA---see below. (b) (5) [redacted]

[redacted] Thanks!

DRAFT PRE-DECISIONAL DELIBERATIVE

---

**From:** Westwood, Sarah <Sarah.Westwood@turner.com>
**Sent:** Sunday, March 1, 2020 11:03 AM
**To:** Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
**Subject:** Quick question

Hi Caitlin! Hope you're doing well. This is possibly a dumb question but we just wanted to touch base to understand the correct number of available or soon-to-be-available coronavirus test kits out there so we don't say the wrong number...

VP Pence said this morning that 15,000 test kits had been released and the administration is working with a commercial provider to get 50,000 more distributed.

Secretary Azar said we have the ability to test 75,000 people in the field right now and that will increase.

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So I just wanted to check for clarification – is it the case that each kit can test more than one person? Or that there was already 10,000 kits in the field before the 15k and 50k that the VP mentioned? Sorry if this betrays my ignorance of how testing kits work, we just wanted to see if the number is 65k or 75k. Thank you!

Sarah

Sarah Westwood
CNN White House Reporter
(b) (6)

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 3/1/2020 3:50:22 PM
**To**: Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: Update re Hill Calls Tomorrow

Tim, Suzanne, and I should be on the 2 PM call.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 3:19 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** Update re Hill Calls Tomorrow
**Importance:** High

Good afternoon all –

(b) (5)



Best,

Jennifer

AMERICAN OVERSIGHT

**From:** Pence, Laura (HHS/ASL)
**Sent:** Sunday, March 1, 2020 2:06 PM
**To:** Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>
**Cc:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>
**Subject:** testing call

(b) (5)

Here's my suggested invite:

## Telebriefing for Hill Staff on 2019-nCoV Testing

Please join us on Monday, March 2, at 2 pm for a bipartisan, bicameral telebriefing on 2019-nCoV Testing. CDC and FDA will provide updates regarding 2019-nCoV testing and actions to increase the availability of tests.

**What** Briefing for hill staff on the 2019 Novel Coronavirus response and testing

**Who** Representatives from the Centers for Disease Control and Prevention and the Food and Drug Administration will provide updates. Representatives from the interagency response will be available to answer questions about broader questions related to the coronavirus response.

**When** February 28, 2:00 pm

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: (b) (6)
jennifer.tomasello@fda.hhs.gov






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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 8:11:30 PM
**To:** Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]; Stephanie Caccomo (Stephanie.Caccomo@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
**Subject:** RE: NYS EUA

I guess. It's not my call.

Stephanie – is 10 AM a good time for the media or should we shoot for earlier in the morning to post comms?

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:09 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: NYS EUA

Just circling back.

10am tomorrow morning okay for rollout?

Web/comms folks are willing to stay on tonight if you want it out tonight at ~11pm.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:06 PM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** Re: NYS EUA

Ok. Thanks.

Sent from my iPhone

On Feb 29, 2020, at 7:00 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

I think AM is fine. Most reporters wouldn't cover til AM anyway.

Tweets are more optimal in AM as well, at least for better visibility with folks.

**Stephanie Caccomo**
*Press Officer*

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: 240.762.8873
stephanie.caccomo@fda.hhs.gov

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**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 29, 2020 at 6:57:28 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** Re: NYS EUA

Stephanie, thoughts? I am fine waiting.

Sent from my iPhone

On Feb 29, 2020, at 6:55 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

NYS will know and they may start telling others, although it will be a late hour. How early could the documents be posted? Tweets would then need to go out at that time.

Adding Keagan to get her perspective on whether the comms can be posted in the morning given that the EUA won't likely be authorized until late tonight.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 6:49 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

Just trying to set expectations for folks standing by from the two web teams…

Since we're looking at a late hour, possibly beyond 11pm is it okay to post comms (EUA documents to the web and social) in the morning?

---

**From:** Witters, Alicia
**Sent:** Saturday, February 29, 2020 6:05 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

Understood. We're standing by.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 6:05 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

Yes, but the time is fluid.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 6:04 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

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Got it. That's target to have the docs to us for posting as well?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 5:57 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

FYI – target is now around 11 PM.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 3:29 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

Thanks! Letting team know

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 3:27 PM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

FYI — target is to approve the EUA tonight around 7 PM.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 29, 2020 at 2:35:00 PM EST
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

Sounds good

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:34 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

We are issuing tweets from Dr. Hahn, which are queued up and ready to go when EUA authorized.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:32 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

We'll see. Also need OCET and then HHS sign off.

Adding Stephanie – EUA for NYS could be granted today or tomorrow. Are comms in the works/ready to go?

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:28 PM

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**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS EUA

Got it—earlier today Uwe was predicting this evening at the earliest. Sounds like that may be optimistic.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:25 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

FYI – All the NYS testing is now in house so it's possible we get the EUA done this weekend.

Jeff

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 1:12 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

Sounds good, and thank you and your team for the great work!

Jeff

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 1:07 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS EUA

Got it, thanks!

We posted the guidance and webinar info on LinkedIn, so other than the tweet we're done with the guidance and EUA template comms and outreach for today. (b) (5) [redacted] I see a note from Elizabeth with some thoughts on that as well and will share with IC as well.

I've released CDRH comms folks from mission control but can reach them for EUA posting when the time comes. Lori and the JIC are monitoring and looped into everything too so I think we're covered.

I'll continue to monitor, but please let me know if there's anything else I'm missing here or you need from me short-term on this.

Alicia

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:27 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

It has not been authorized but they can go ahead and test patients now under our new policy since they already notified us, and, in fact, have an EUA in house.

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**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:23 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** NYS EUA

OMA is saying Gov Cuomo is telling folks the EUA for NYS has been authorized.

Comms is standing by for word on that and next steps.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:12 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

TYVM

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:55 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Yes—email is attached

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:47 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Also, can you please send me the email, as well, so I have it for my reference?

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 11:38 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

TY!!!

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:37 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Page is up. Our email is going out now. Commish is clearing FDA's tweets --- those should be up soon. We'll retweet them.

---

**From:** Witters, Alicia
**Sent:** Saturday, February 29, 2020 11:31 AM

AMERICAN OVERSIGHT

**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Just got the word from FDA web—their last page is in the queue and should be live momentarily. Once we've confirmed that's a-okay the email and social will happen.

Is there any update on the NY state EUA expected later today?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:21 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

How's it going? Our announcement is already out in the press and being communicated by others.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:20 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

☺

FDA web is working on finishing up their EUA and Corona web postings. Once all live we'll push out the outreach (email for guidance/webinar and social)

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:51 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Awesome … and I think I am running out of superlatives to use!

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:46 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Content loading is in progress—we're coordinating all the cross-linkages with FDA web team.

I provided the live link to the guidance Lauren Roth per her ask.

Here's everything in the works—we're eyeballing content in preview now. Note live links will not work until everything is published. They're just for reference.

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(b) (5)



**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:42 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Fantastic.

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:40 AM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Yes, loading the template to ready it for posting on the CDRH EUA page when the guidance is live. 508 is complete on the template.

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:37 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

I just had a separate exchange with Alicia. They are loading it now.

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:36 AM
**To:** Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** FW: For OMB Review: Diagnostics (FDA Guidance)

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If the updated EUA template is done please send it to Alicia now so they can 508 proof and get it ready.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:31 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

We need an hour to prep the guidance and EUA template.

Also, once we post it takes between 15-30 minutes for the documents to appear online.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:26 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Great. How much time do you need to post the guidance and the updated EUA template?

Jeff

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:23 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

CDRH Comms is online now and on standby for the final guidance.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:18 AM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>;

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Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Adding Alicia.

Our web folks need about an hour from the time they receive the materials to post to get them up on the website.

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:15 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

If guidance is online, we can get press release out to reporters asap.

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:14 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** FW: For OMB Review: Diagnostics (FDA Guidance)

Jeff, Elizabeth, Keagan, Stephanie –

HHS asking whether we will post before 10 am. I'm not familiar with our rollout plans (press release, etc), can you let me know if this is doable?

Thanks,
Lauren

---

**From:** Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
**Sent:** Saturday, February 29, 2020 8:00 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Re: For OMB Review: Diagnostics (FDA Guidance)

Good morning,

The Secretary is having a 10am meeting and will share our progress.

(b) (5)

AMERICAN OVERSIGHT

Thank you

On Feb 29, 2020, at 7:36 AM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

Fyi

Begin forwarded message:

**From:** "Hirsch, Quinn N. EOP/OMB" (b) (6)
**Date:** February 29, 2020 at 7:03:13 AM EST
**To:** "Malliou, Ekaterini (OS/IOS)" <Ekaterini.Malliou@hhs.gov>
**Subject: Re: For OMB Review: Diagnostics (FDA Guidance)**

Received. Will circulate and ask for ASAP sign off, no later than 8:30 am

Sent from my iPhone, please excuse brevity and typos

On Feb 28, 2020, at 10:46 PM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

Hi Quinn,

The FDA guidance is attached. We look forward to your concur or comments (redline/bubble comments, please).

Thank you

<IIE nCoV guidance_Passback 2-28-20 1030pm_CLEAN.docx>

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 3/1/2020 5:24:24 PM
**To:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** RE: idea for ACLA speech

Elizabeth,

Please let me know if you have a minute to discuss.

Jeff

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 3:42 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: idea for ACLA speech

Jeff,

I know you are busy, and its Sunday, but I wanted to give you an opportunity to look at the Commissioner's speech for ACLA. I made some suggestions but don't yet love it. I can go back through it again but would be interested in your initial reactions (or substantive feedback if you have it).

Elizabeth

---

**From:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 4:40 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: idea for ACLA speech

Hi Elizabeth,

I'm not sure if you'll see this before Monday, but I wanted to get you something to play with. (b) (5) [redacted] Please add or delete as needed.

(b) (5) [redacted]

Feel free to edit or rewrite as much as needed. Length right now is about right, so if we add a lot of stuff, probably need to take out some as well.

Thanks,
Alex

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**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 9:56 AM
**To:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
**Subject:** RE: idea for ACLA speech

I will be around. (b) (5) [redacted]

(b) (5) [redacted]

Elizabeth

**From:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 9:52 AM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: idea for ACLA speech

Hi Elizabeth,
I'm hoping to get you a draft of the remarks for your to review later this afternoon. Will you be around? Also, are there a lot of people who need to be in on the clearance process? (b) (5) [redacted]
Thanks,
Alex

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 3:41 PM
**To:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
**Subject:** RE: idea for ACLA speech

I know they are interested in hearing about the broader strategy for COVID-19 response, if that can be addressed.

CDC has the only authorized EUA right now, but it can be run in public health labs throughout the country in addition to CDC Atlanta. (Be sure to say "authorized" and not "approved.") We should touch base next week as this is rapidly evolving.

**From:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 3:08 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: idea for ACLA speech

Thanks. That's very helpful and clear. (b) (5) [redacted]

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 3:03 PM
**To:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
**Subject:** RE: idea for ACLA speech

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(b) (5)

[redacted]

**From:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 2:21 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: idea for ACLA speech

Hi,
Just checking in – any updates?

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 10:46 AM
**To:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
**Subject:** RE: idea for ACLA speech

I look forward to connecting Monday. I don't think you need a lot of history for this group. I would use the term LDTs and maybe follow the following story arc:

(b) (5)

[redacted]

Elizabeth

**From:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
**Date:** February 21, 2020 at 9:52:19 AM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: idea for ACLA speech

AMERICAN OVERSIGHT

Hi Elizabeth.
I'll try for Monday morning as originally scheduled.
A couple of quick (b) (5) [redacted]
Thanks,
Alex

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 21, 2020 8:42 AM
**To:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
**Subject:** RE: idea for ACLA speech

Hi Alex,

We expect the bill to be introduced by the end of next week. My Monday late afternoon/evening is up in the air (b) (6) [redacted] but feel free to try my cell at your convenience. I am also available Tuesday before 10 or after 3. We'll figure something out!

Elizabeth
(b) (6) [redacted]

-----Original Appointment-----
**From:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 6:23 PM
**To:** Hillebrenner, Elizabeth J
**Subject:** New Time Proposed: idea for ACLA speech
**When:** Monday, February 24, 2020 9:00 AM-9:15 AM (UTC-05:00) Eastern Time (US & Canada).
**Where:** phone

Hi Elizabeth,
I definitely would like to chat about it. (b) (5) [redacted] Updates. I can do tomorrow or Monday. Might be able to call you at the time you suggested, but may have to push it back to later in the day.
Thanks.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 3/1/2020 2:03:27 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** RE: Need help asap--test kits

(b) (5)

[redacted]

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 1:54 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: Need help asap--test kits

?

Sent from my iPhone

Begin forwarded message:

**From:** "McKeogh, Katherine (OS/ASPA)" <Katherine.McKeogh@hhs.gov>
**Date:** March 1, 2020 at 1:53:31 PM EST
**To:** "Murphy, Ryan (OS)" <Ryan.Murphy1@hhs.gov>, "Galatas, Kate (CDC)" <kkg2@cdc.gov>
**Cc:** "Caccomo, Stephanie" <Stephanie.Caccomo@fda.hhs.gov>, "Oakley, Caitlin B (OS)" <Caitlin.Oakley@HHS.GOV>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Bonds, Michelle E (CDC)" <meb0@cdc.gov>, "Janik, Heather" <Heather.Janik@fda.hhs.gov>, "Hall, Bill (OS)" <bill.hall@hhs.gov>, "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>, "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>
**Subject: RE: Need help asap--test kits**

CDC and FDA -(b) (5) [redacted]

---

**From:** Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
**Sent:** Sunday, March 1, 2020 1:29 PM
**To:** Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>
**Cc:** McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Janik, Heather (FDA/OC) <Heather.Janik@fda.hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
**Subject:** Re: Need help asap--test kits

(b) (5)

[redacted]

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draft, pre-decisional, deliberative

On Mar 1, 2020, at 12:32 PM, Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov> wrote:

(b) (5)

We are working on lab TPs right now and will include this in what we send up.

Thanks,
Kate

Get Outlook for iOS

---

**From:** McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>
**Sent:** Sunday, March 1, 2020 12:27:59 PM
**To:** Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>
**Cc:** Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; Janik, Heather (FDA/OC) <Heather.Janik@fda.hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>
**Subject:** Re: Need help asap--test kits

Kate or Michelle - (b) (5)

Draft response for review/edits based on this info:

(b) (5)

Katie McKeogh
Press Secretary
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services

On Mar 1, 2020, at 12:23 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

(b) (5)

This is FDA's understanding and should be confirmed with CDC.

---

**From:** Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
**Sent:** Sunday, March 01, 2020 12:01 PM

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**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Bonds, Michelle E (CDC) <meb0@cdc.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
**Cc:** Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>
**Subject:** Need help asap--test kits
**Importance:** High

CDC/FDA---see below. (b) (5) [redacted]

[redacted] Thanks!

DRAFT PRE-DECISIONAL DELIBERATIVE

---

**From:** Westwood, Sarah <Sarah.Westwood@turner.com>
**Sent:** Sunday, March 1, 2020 11:03 AM
**To:** Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
**Subject:** Quick question

Hi Caitlin! Hope you're doing well. This is possibly a dumb question but we just wanted to touch base to understand the correct number of available or soon-to-be-available coronavirus test kits out there so we don't say the wrong number…

VP Pence said this morning that 15,000 test kits had been released and the administration is working with a commercial provider to get 50,000 more distributed.

Secretary Azar said we have the ability to test 75,000 people in the field right now and that will increase.

So I just wanted to check for clarification – is it the case that each kit can test more than one person? Or that there was already 10,000 kits in the field before the 15k and 50k that the VP mentioned? Sorry if this betrays my ignorance of how testing kits work, we just wanted to see if the number is 65k or 75k. Thank you!

Sarah

Sarah Westwood
CNN White House Reporter
(b) (6) [redacted]

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 3/1/2020 1:57:43 PM
**To:** 'Hahn, Stephen' (b) (6) Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
**Subject:** RE: HHS Secretary's News Briefing for Sunday, March 01, 2020

So here's the deal. (b) (5)

---

**From:** Shuren, Jeff
**Sent:** Sunday, March 1, 2020 1:34 PM
**To:** 'Hahn, Stephen' (b) (6) @fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
**Subject:** RE: HHS Secretary's News Briefing for Sunday, March 01, 2020

I'll follow up when I have more (b) (5)

(b) (5)

Will follow up when I have more.

---

**From:** Shuren, Jeff
**Sent:** Sunday, March 1, 2020 1:27 PM
**To:** 'Hahn, Stephen' (b) (6) da.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
**Subject:** RE: HHS Secretary's News Briefing for Sunday, March 01, 2020

(b) (5)

---

**From:** Hahn, Stephen (b) (6) da.hhs.gov>
**Sent:** Sunday, March 1, 2020 12:56 PM
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: HHS Secretary's News Briefing for Sunday, March 01, 2020

NYT article. Interesting about the WHO test. Are you aware?

Sent from my iPhone

Begin forwarded message:

**From:** Bulletin Intelligence <HHS@BulletinIntelligence.com>
**Date:** March 1, 2020 at 12:29:32 PM EST
**To:** "HHS@BulletinIntelligence.com" <HHS@BulletinIntelligence.com>
**Subject: HHS Secretary's News Briefing for Sunday, March 01, 2020**

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**Click to access** mobile-optimized online version, including download options and an audio reader.

HHS.gov Secretary's News Briefing Bulletin INTELLIGENCE a CISION company

**SUNDAY, MARCH 1, 2020 12:30 PM EST**

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## Top National Stories

### F.D.A. Expands Coronavirus Testing In The United States

*New York Times (2/29, Knvul Sheikh)*

The New York Times reports the Food and Drug Administration (FDA) "announced Saturday that testing for the coronavirus would be greatly expanded in the United States, giving laboratories and hospitals around the country the go-ahead to conduct tests that had until now been severely limited to those analyzed by the Centers for Disease Control and Prevention." The move "should

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improve the pace of detecting coronavirus infections and make it possible to more rapidly spot patterns of suspected or confirmed cases." In a statement, FDA Commissioner Stephen Hahn said, "This action today reflects our public health commitment to addressing critical public health needs and rapidly responding and adapting to this dynamic and evolving situation."

## Coronavirus

### How Prepared Are US Hospitals For Coronavirus Outbreak

*NBC Nightly News (2/29)*

On NBC Nightly News, correspondent Steve Patterson discussed the measures hospitals like Kaiser Medical Center in Oakland are taking to prepare for a potential coronavirus outbreak in the US. Kaiser Permanente's Dr. Stephen Parodi said, "We have teams that are working right now to take care of patients to make sure we're getting it right." Patterson explained that process "involves training...staff by conducting drills used by isolation rooms that have separate ventilation symptoms designed to contain the spread of infections like the coronavirus." Kaiser Permanente's Dr. Mary Meyer said, "At all of our hospitals, we are really pushing to have a significant proportion of our clinical staff trained. ... We have been planning for this for months." However, Patterson reported, "Even hospitals that are doing proper training are facing supply shortages, for things like masks and respirators, because of shipping delays and an active flu season that has already put a strain on resources."

### China Officials Knew Of Coronavirus In December, Ordered Cover-up, Report Says

*New York Post (2/29, Sara Dorn)*

The New York Post reports, "Chinese scientists knew about the coronavirus and its deadly effects as early as December – but were ordered by government officials to suppress the evidence, according to a report" from the Sunday Times of London, which cited Chinese business news site Caixin Global. In December, "several genomics companies tested samples from sick patients in Wuhan – the center of the coronavirus outbreak – and noticed alarming similarities between their illnesses and the 2002 SARS virus," and while "researchers alerted Beijing of their findings," they "received a gag order" on Jan. 3 "from China's National Health Commission, with instructions to destroy the samples." According to the Post, "The alleged cover-up continued when representatives from the US Centers for Disease Control and Prevention visited Wuhan Jan. 8, where officials intentionally withheld information that hospital workers had been infected by patients – a telltale sign of contagion."

### Millions Locked Down Across The Globe Due To Coronavirus

*NBC Nightly News (2/29)*

NBC Nightly News reported, "The coronavirus has the world on edge," as the disease continues to spread "into even more countries, causing major disruptions in every day life." Correspondent Bill Neely outlined some of the preventative measures affected countries have taken. For example, South Korea has "ask[ed] its entire population of 51 million to stay indoors" after "reporting

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hundreds more cases" on Saturday. Meanwhile, "Switzerland and France have banned all large gatherings," and Japan's Prime Minister on Saturday sought "to reassure the world" that the 2020 Olympics will proceed as planned.

***More Coverage.*** Coronavirus Has Spread To 59 Countries (CBS Weekend News, 2/29)

## Coronavirus Tests Limits Of Central Bank Firepower

*New York Times (2/29, Jeanna Smialek And Jack Ewing)*

In a front-page article, the New York Times reports, "Federal Reserve officials and their global counterparts are staring down an economic threat unlike any they have ever faced, as markets look to them to contain the fallout" from the coronavirus despite "limited ammunition and tools ill-suited to deal with broken supply chains and quarantined consumers." There is "no playbook...for dealing with the economic threat posed by the coronavirus," but "in the best case scenario, the virus is quickly contained and the global economy suffers a hiccup." Should the outbreak become a worldwide pandemic, however, "the Fed and other central bankers are poised to respond. The Fed chair, Jerome H. Powell, issued a rare statement on Friday saying that policymakers would 'act as appropriate' to support the economy, which investors and analysts took as a sign that officials would cut rates at their March meeting, if not earlier."

## Gig Workers Face The Spread Of The New Coronavirus With No Safety Net

*Washington Post (2/29, Nitasha Tiku)*

The Washington Post reports, "As coronavirus spreads globally, prompting some companies to instruct employees to stop traveling or to work remotely, one of the most vulnerable groups is likely to be tens of thousands of gig workers," who often "find themselves with few health protections but with a potentially higher risk of coming into contact with infected people." That's because "app-using companies such as Uber, Lyft, the grocery delivery service Instacart and the food delivery service DoorDash have classified the workers who deliver meals or transport passengers as independent contractors," meaning they do not receive "health insurance and other benefits" and "do not have the right to unionize." Author Alex Rosenblat said the health risks posed by the novel coronavirus could prompt some companies to change their policies toward independent contractors as they consider liability concerns.

## Pence Says Risk Of Coronavirus For Americans Is Low.

*CNN's State Of The Union (3/1)*

Vice President Pence discussed the Trump Administration's efforts to combat the coronavirus. Pence said, "The good news is of the 22 Americans who have contracted the coronavirus, more than half of them are almost fully recovered. I think that it is all a reflection of the fact that early on in this crisis in January the President took the unprecedented step of suspending all travel from China and establishing a quarantine effect. As you know, in addition to the 22 Americans, we have had 46 other Americans that have been through quarantine who have contracted the virus, but they are all being treated and all doing well, but the President took that action and established the quarantines out of an abundance of caution. ... Dr. Fauci and others have said the risk of the

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coronavirus for Americans is low and that's largely because of the decision the President made and the energetic efforts of CDC and local health officials and we will continue to lean in that in a hopeful way. We know that there are going to be more cases."

***More Coverage.*** US Enhances Screenings At Airports, Pence Says. (Fox News Sunday Morning Futures, 3/1); Schools May Shut Down Over Coronavirus, Pence Says (NBC's Meet The Press, 3/1)

## Secretary Azar Emphasizes Importance Of Testing For Coronavirus

*ABC's This Week (3/1)*

HHS Secretary Azar said, "We have said publicly from day one we would see more cases spreading here in the United States and this is exactly what we've been predicting all along. We're deployed out there with state officials and the health department. In Seattle, we're working closely, we're trying to discern how did these individuals contract the coronavirus. We're ramping up testing. We now have 75,000 tests available out there in the United States and over the next week that will expand radically on top of the 75,000 tests available. ... It's important we test people who have any respiratory illness that's unidentified. A week and a half ago we expanded to six key cities. If anyone is tested for flu they should also be tested for novel coronavirus. That's a key part of our emergency supplementals. I want to expand that kind of testing nationwide as soon as Congress gets us the money that will be out there throughout the country."

## Secretary Azar Concerned About Community Transmission

*Fox News Sunday (3/1)*

HHS Secretary Azar said, "We've got about 23 cases here in the United States that are not a result of us repatriating individuals from Japan or China. Of those individuals, we've got cases in Chicago, as well as Washington, Oregon, two in California, where we do not yet know why they contracted the novel coronavirus. We have employed state and local people and we're looking to get to the bottom of it. ... Any community transmission is concerning, that is why we have been very clear from the outset, we are going to have more cases here in the United States in spite of the President's aggressive efforts at containment. We will see more cases, we will see some forms of community spreading. But the risk to any individual American remains low thanks to the efforts of the President has taken, they will stay low, we are working to keep it that way, but things can change rapidly, but they should know we have the best public health system in the world looking out for them."

***More Coverage.*** Azar Reiterates Risk Remains Low (CBS' Face The Nation 3/1)

## Rubio Criticizes China's Handling Of Coronavirus.

*Fox News Sunday Morning Futures (3/1)*

Sen. Marco Rubio (R-FL) said, "The way you deal with a global pandemic is you become transparent and you share information about the actual virus. You make sure researchers around the world can start working and developing treatments and vaccines, they didn't do that. You share best practices and infection numbers and statistics. The reason why you do that is so

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researchers all over the world and other governments can take steps and measures to adjust to that. They didn't do that. ... The Communist Party of China are more interested in protecting their global image than they are in containing this. That's really the fundamental challenge."

## Health Care & Insurance Reform

### VA Secretary: Care For Veterans 'Would Disappear' If America Descends Into Socialism

*Breitbart (2/29, Edwin Mora)*

Breitbart reports, "The United States would not be able to care for its millions of veterans if it becomes a socialist country, the US Department of Veterans Affairs (VA) secretary cautioned Breitbart News at the annual Conservative Political Action Conference (CPAC) on Saturday." Said VA Secretary Wilkie, "If America were suddenly to descend into a socialists State, that promise [to take care of our veterans' that [Abraham] Lincoln made [when he created the department] 150 years ago is wiped out. There's no longer any care for veterans. … An incredibly high percentage of our warriors are with missing limbs." Wilkie also said that "under President Donald Trump, the VA is providing care for those veterans with special needs," and added that "if socialism became the coin of the realm, that would be gone," and "that place that was promised for warriors would disappear."

## National Front Page News

### Headlines From Today's Front Pages.

**New York Times:**

Coronavirus Tests Limits Of Central Bank Firepower
How Prepared Is The US For A Coronavirus Outbreak?
Taliban And US Strike Deal To Withdraw American Troops From Afghanistan
After 18 Years, Is This Afghan Peace, Or Just A Way Out?
The Pied Pipers Of The Dirtbag Left Want To Lead Everyone To Bernie Sanders
How South Carolina Could Change The Democratic Race

**Washington Post:**

After Humbling Start, The 18 Days That Resuscitated Joe Biden's Candidacy
Miranda's Rebellion
Joe Biden Wins South Carolina Primary, Reshaping The Democratic Race
Spreading Coronavirus Kills First US Patient
A Confused Effort To Show Calm Control
Deal With Taliban Short On Answers For Afghans

**Story Lineup From Last Night's Network News:**

**ABC:** Coronavirus-First US Death Confirmed; Coronavirus-Travel Restrictions; Coronavirus-US Screening; South Carolina-Democratic Candidates; South Carolina-Biden; US-Taliban Peace Deal; Weather Forecast; Philadelphia-Police Chase; Los Angeles-Warehouse Explosion; Colorado-SWAT Standoff; Houston-Leap Year Birthday.

**CBS:** Coronavirus-White House Response; Coronavirus-First US Death Confirmed; Coronavirus-

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Global Spread; South Carolina-Democratic Candidates; Trump-Ratcliffe Nomination; US-Taliban Peace Deal; Texas-Rocket Explosion; New York-Severe Weather; Trader Joe's Founder Dies; South Carolina-Unemployment Rate; New York-Experts Backing New Calendar; Denver Choir.
**NBC:** Coronavirus-First US Death Confirmed; Coronavirus-White House Response; Coronavirus-Global Spread; Coronavirus-Impact; South Carolina-Democratic Candidates; South Carolina-African American Voters; US-Taliban Peace Deal; New York-Severe Weather; Ireland-Severe Weather; Coronavirus-US Hospital Preparation; Miami-Music Therapy To Treat Pediatric Patient.
**Network TV At A Glance:**
Coronavirus-First US Death Confirmed – 7 minutes, 30 seconds
South Carolina-Democratic Candidates – 6 minutes, 35 seconds
US-Taliban Peace Deal – 4 minutes, 50 seconds
Coronavirus-White House Response – 4 minutes, 15 seconds
Coronavirus-Global Spread – 3 minutes, 10 seconds
New York-Severe Weather – 35 seconds

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 3/1/2020 10:31:47 PM
**To:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** Re: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Elizabeth,

Yes, please send it to Keagan, Laura Caliguiri, Karas Gross, Lauren Paulos, and Stephanie since the participants may subsequently speak to the media and/or the Hill and/or some of those folks may attend the webinar

Jeff

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Date:** March 1, 2020 at 10:18:06 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Jeff- do you want me to send this to the Commissioner's office? Anyone besides Keagan?

---

**From:** Hillebrenner, Elizabeth J
**Sent:** Sunday, March 1, 2020 8:50 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Thank you, all. I incorporated all feedback and spoke with Marcy to confirm we are good to go.

Jeff – The attached is ready for the Commissioner's office.

Elizabeth

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 8:39 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

I am sorry, but (b) (5) [redacted]

AMERICA'S OVERSIGHT

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 8:32 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Hi Elizabeth,

See attached with my comment on slide 13. Deleted an "s" on slide 9. Rest of the changes look acceptable to me.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 8:06 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy

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<Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Tim, just following up to see if you can respond to (b) (5) [redacted]

Uwe and Tim, do you have any technical concerns with the other edits? If not I will proceed to clean the deck so Jeff can share with the Commissioner's office before tomorrow.

Elizabeth

---

**From:** Hillebrenner, Elizabeth J
**Sent:** Sunday, March 1, 2020 3:11 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Marcy, thank you!

Tim, Uwe, I flipped through quickly but think it needs your review. In particular (b) (5) [redacted]

Elizabeth

---

**From:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 3:08 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Subject:** RE: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Thanks Elizabeth! I included some suggested edits (in red on the slides, and in the comments for 1 slide) in the attached. I tried to explain my thinking in comment bubbles, but happy to discuss further if you have any questions/concerns.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Sunday, March 1, 2020 11:57 AM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>
**Subject:** EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

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Hi Marcy,

Attached is an updated webinar deck for your review. I will be out for an hour but otherwise available to answer questions. Thanks for all your help!

Elizabeth

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 4:19:57 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**Subject:** Re: PREP Act - N95 Masks

That works for me. Can you please reply to the email from Michael with the preference?

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 29, 2020 at 4:11:27 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Re: PREP Act - N95 Masks

I would prefer (b) (5)
(b) (5)

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 29, 2020 at 3:48:16 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Fwd: PREP Act - N95 Masks

Do you have any concerns or edits?

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Date:** February 29, 2020 at 3:44:36 PM EST
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Raza, Mark <Mark.Raza@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

AMERICAN OVERSIGHT

Hi. Attaching the revised TA we drafted (b) (5) [redacted] - m

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 3:43 PM
**To:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

(b) (5) [redacted]

---

**From:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Date:** February 29, 2020 at 3:29:16 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

(b) (5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 3:10 PM
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire

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<Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

We worked that out.

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 3:01 PM
**To:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

(b) (5) [redacted]

---

**From:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:59 PM
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

Attached is the bill text for H.R. 4982, which I believe is the bill is being considered although that is not totally clear. Also attached is our TA to that bill that was sent to HHS earlier this week. (b) (5) [redacted] Adding Marcy Busch since she led this for OCC.

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:54 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

The PREP Act provides liability protection for manufacturers and health care providers but (b) (5) [redacted]

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(b) (5) [redacted]

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:45 PM
**To:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** Fwd: PREP Act - N95 Masks

Folks - ASFR looking for guidance on PREP Act. Working on supplemental. Anything we can provide her?

Sent from my iPhone

Begin forwarded message:

**From:** "Moughalian, Jen (HHS/ASFR)" <Jen.Moughalian@hhs.gov>
**Date:** February 29, 2020 at 2:34:22 PM EST
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
**Cc:** "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>, "Shuy, Caitrin (OS)" <Caitrin.Shuy@hhs.gov>
**Subject: FW: PREP Act - N95 Masks**

(b) (5) [redacted] thx

**From:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
**Sent:** Saturday, February 29, 2020 2:19 PM
**To:** McMillin, Virginia D. EOP/WHO <Virginia.D.McMillin@who.eop.gov>
**Cc:** Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>
**Subject:** Re: PREP Act - N95 Masks

+ Jen who is the HHS lead on supp negotiations

On Feb 29, 2020, at 2:05 PM, McMillin, Virginia D. EOP/WHO (b) (6) [redacted] @who.eop.gov> wrote:

+Arbes — need to sort this out in the next couple of hours (b) (5) [redacted]

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On Feb 29, 2020, at 1:53 PM, McMillin, Virginia D. EOP/WHO (b) (6) [redacted] @who.eop.gov> wrote:

Hey, just us. (b) (5) [redacted]

Virginia Heppner McMillin
Special Assistant to the President
Office of Legislative Affairs
(202) 881-6454

---

**From:** Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>
**Sent:** Friday, February 28, 2020 8:32 AM
**To:** Baehr, James S. EOP/WHO (b) (6) [redacted]@who.eop.gov>
**Cc:** Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; McMillin, Virginia D. EOP/WHO (b) (6) [redacted]@who.eop.gov>; Bonner, Maria K. EOP/WHO (b) (6) [redacted])who.eop.gov>; Heilig, Rebecca B. EOP/WHO (b) (6) [redacted])who.eop.gov>; Daravi, Kamran S. EOP/WHO (b) (6) [redacted]@who.eop.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
**Subject:** Re: PREP Act - N95 Masks

+ Danielle Steele, Brian Shuy

Sent from my iPhone

On Feb 28, 2020, at 3:53 AM, Baehr, James S. EOP/WHO (b) (6) [redacted]@who.eop.gov> wrote:

Paula, Laura,

Do you have a few minutes to walk me through (b) (5) [redacted]

We spoke with industry reps on this issue and, on first blush, I found their points compelling, but I understand there may be different views out there.

Best,

---

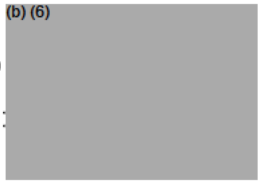
James S. C. Baehr
Special Assistant to the President
Domestic Policy Council

AMERICAN OVERSIGHT

O

C:

(b) (6)



AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/29/2020 10:39:54 PM
**To**: Witters, Alicia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5901a9f9d0c34942bea0bd09734e732b-ALW]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**CC**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject**: RE: NYS EUA

Outstanding! Good work by you, Edie, and the rest of the team.

Jeff

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:31 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: NYS EUA

New EUA content is live on CDRH site: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

OCET/JIC content is going up now, but CDRH web posts for this evening are complete.

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**From:** Witters, Alicia
**Sent:** Saturday, February 29, 2020 10:15 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: NYS EUA

We're pushing the content out now—should be live in ~15 mins.

OCET/JIC is working on theirs now. We should be up by right around 10:30pm or so.

---

**From:** Witters, Alicia
**Sent:** Saturday, February 29, 2020 9:51 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: NYS EUA

Yes—team is ready and starting to work on it now. Need some time to prep docs, but will get an estimated time on that from the team.

AMERICAN OVERSIGHT

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:47 PM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: NYS EUA

Alicia – if that's okay with you and your team then let's get it out tonight.

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:47 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: NYS EUA

Yes, if all ok pushing out tonight, I say we push. I'll flag for reporters. And then social media can go in AM.

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:46 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Cc:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: NYS EUA

Stephanie – okay for pushing out to press tonight. The EUA is done so it could get posted tonight.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:34 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: NYS EUA

We just heard the EUAs were signed. Should we prep to go tonight?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:06 PM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** Re: NYS EUA

Ok. Thanks.

Sent from my iPhone

On Feb 29, 2020, at 7:00 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

I think AM is fine. Most reporters wouldn't cover til AM anyway.

Tweets are more optimal in AM as well, at least for better visibility with folks.

AMERICA OVERSIGHT

**Stephanie Caccomo**
*Press Officer*

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: 240.762.8873
stephanie.caccomo@fda.hhs.gov

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**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 29, 2020 at 6:57:28 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** Re: NYS EUA

Stephanie, thoughts? I am fine waiting.

Sent from my iPhone

On Feb 29, 2020, at 6:55 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

NYS will know and they may start telling others, although it will be a late hour. How early could the documents be posted? Tweets would then need to go out at that time.

Adding Keagan to get her perspective on whether the comms can be posted in the morning given that the EUA won't likely be authorized until late tonight.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 6:49 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

Just trying to set expectations for folks standing by from the two web teams…

Since we're looking at a late hour, possibly beyond 11pm is it okay to post comms (EUA documents to the web and social) in the morning?

---

**From:** Witters, Alicia
**Sent:** Saturday, February 29, 2020 6:05 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

Understood. We're standing by.

AMERICAN OVERSIGHT

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 6:05 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

Yes, but the time is fluid.

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 6:04 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

Got it. That's target to have the docs to us for posting as well?

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 5:57 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

FYI – target is now around 11 PM.

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 3:29 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

Thanks! Letting team know

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 3:27 PM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

FYI — target is to approve the EUA tonight around 7 PM.

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 29, 2020 at 2:35:00 PM EST
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

Sounds good

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:34 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

We are issuing tweets from Dr. Hahn, which are queued up and ready to go when EUA authorized.

AMERICAN OVERSIGHT

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:32 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** RE: NYS EUA

We'll see. Also need OCET and then HHS sign off.

Adding Stephanie – EUA for NYS could be granted today or tomorrow. Are comms in the works/ready to go?

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:28 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS EUA

Got it—earlier today Uwe was predicting this evening at the earliest. Sounds like that may be optimistic.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:25 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

FYI – All the NYS testing is now in house so it's possible we get the EUA done this weekend.

Jeff

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 1:12 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

Sounds good, and thank you and your team for the great work!

Jeff

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 1:07 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: NYS EUA

Got it, thanks!

We posted the guidance and webinar info on LinkedIn, so other than the tweet we're done with the guidance and EUA template comms and outreach for today. (b) (5) [redacted] I see a note from Elizabeth with some thoughts on that as well and will share with IC as well.

I've released CDRH comms folks from mission control but can reach them for EUA posting when the time comes. Lori and the JIC are monitoring and looped into everything too so I think we're covered.

I'll continue to monitor, but please let me know if there's anything else I'm missing here or you need from me short-term on this.

AMERICAN OVERSIGHT

Alicia

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:27 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: NYS EUA

It has not been authorized but they can go ahead and test patients now under our new policy since they already notified us, and, in fact, have an EUA in house.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:23 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** NYS EUA

OMA is saying Gov Cuomo is telling folks the EUA for NYS has been authorized.

Comms is standing by for word on that and next steps.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 12:12 PM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

TYVM

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:55 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Yes—email is attached

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:47 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Also, can you please send me the email, as well, so I have it for my reference?

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 11:38 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

TY!!!

AMERICAN OVERSIGHT

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:37 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Page is up. Our email is going out now. Commish is clearing FDA's tweets --- those should be up soon. We'll retweet them.

---

**From:** Witters, Alicia
**Sent:** Saturday, February 29, 2020 11:31 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Just got the word from FDA web—their last page is in the queue and should be live momentarily. Once we've confirmed that's a-okay the email and social will happen.

Is there any update on the NY state EUA expected later today?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 11:21 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

How's it going? Our announcement is already out in the press and being communicated by others.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 10:20 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

☺

FDA web is working on finishing up their EUA and Corona web postings. Once all live we'll push out the outreach (email for guidance/webinar and social)

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:51 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Awesome … and I think I am running out of superlatives to use!

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 9:46 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

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Content loading is in progress—we're coordinating all the cross-linkages with FDA web team.

I provided the live link to the guidance Lauren Roth per her ask.

Here's everything in the works—we're eyeballing content in preview now. Note live links will not work until everything is published. They're just for reference.

(b) (5)



---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:42 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Fantastic.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:40 AM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Yes, loading the template to ready it for posting on the CDRH EUA page when the guidance is live. 508 is complete on the template.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:37 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Witters, Alicia

AMERICAN OVERSIGHT

<Alicia.Witters@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

I just had a separate exchange with Alicia. They are loading it now.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:36 AM
**To:** Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** FW: For OMB Review: Diagnostics (FDA Guidance)

If the updated EUA template is done please send it to Alicia now so they can 508 proof and get it ready.

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:31 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

We need an hour to prep the guidance and EUA template.

Also, once we post it takes between 15-30 minutes for the documents to appear online.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:26 AM
**To:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Great. How much time do you need to post the guidance and the updated EUA template?

Jeff

---

**From:** Witters, Alicia <Alicia.Witters@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:23 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

AMERICAN OVERSIGHT

CDRH Comms is online now and on standby for the final guidance.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:18 AM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

Adding Alicia.

Our web folks need about an hour from the time they receive the materials to post to get them up on the website.

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**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:15 AM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: For OMB Review: Diagnostics (FDA Guidance)

If guidance is online, we can get press release out to reporters asap.

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**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:14 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** FW: For OMB Review: Diagnostics (FDA Guidance)

Jeff, Elizabeth, Keagan, Stephanie –

HHS asking whether we will post before 10 am. I'm not familiar with our rollout plans (press release, etc), can you let me know if this is doable?

Thanks,
Lauren

---

**From:** Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
**Sent:** Saturday, February 29, 2020 8:00 AM

AMERICAN OVERSIGHT

**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Re: For OMB Review: Diagnostics (FDA Guidance)

Good morning,

The Secretary is having a 10am meeting and will share our progress.

(b) (5)

Thank you

On Feb 29, 2020, at 7:36 AM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

Fyi

Begin forwarded message:

**From:** "Hirsch, Quinn N. EOP/OMB" (b) (6)
**Date:** February 29, 2020 at 7:03:13 AM EST
**To:** "Malliou, Ekaterini (OS/IOS)" <Ekaterini.Malliou@hhs.gov>
**Subject: Re: For OMB Review: Diagnostics (FDA Guidance)**

Received. Will circulate and ask for ASAP sign off, no later than 8:30 am

Sent from my iPhone, please excuse brevity and typos

On Feb 28, 2020, at 10:46 PM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

Hi Quinn,

The FDA guidance is attached. We look forward to your concur or comments (redline/bubble comments, please).

Thank you

<IIE nCoV guidance_Passback 2-28-20 1030pm_CLEAN.docx>

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 3:50:29 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: NYS Wadsworth Center COVID-19

TY

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 29, 2020 at 3:46:04 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: NYS Wadsworth Center COVID-19

Here it is again.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 29, 2020 at 8:49:00 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: NYS Wadsworth Center COVID-19

Sorry, didn't realize you weren't copied. Just spoke to Dan. Sounds like to today the CDC is willing to have (b) (4) under their EUA and they are willing to do lot release testing. Stay tuned.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

AMERICAN OVERSIGHT

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:10 AM
**To:** Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19

Thank you Dan! We will follow up with similar requests for (b) (4) which have built kits on the CDC design.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

**From:** Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Sent:** Saturday, February 29, 2020 8:06 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
**Subject:** NYS Wadsworth Center COVID-19

Dr Hahn:
Yes, The New York State Wadsworth Center can reference the data in the CDC's 2019 nCoV EUA application.
Dan

Daniel B. Jernigan, MD MPH
Director, Influenza Division
Captain, USPHS (RET)
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Atlanta, GA 30329
Phone 404-639-2621, Cell 404-375-7508
djernigan@cdc.gov, www.cdc.gov/flu

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:50 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** NYS Wadsworth Center COVID-19 Test
**Importance:** High

Wendi, Dan, Laura,

(b) (5)

[redacted]

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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(b) (5)

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 3:48:15 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**Subject:** Fwd: PREP Act - N95 Masks
**Attachments:** FDA comments on H.R. 4982 - 2-25-2020.docx

Do you have any concerns or edits?

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Date:** February 29, 2020 at 3:44:36 PM EST
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Raza, Mark <Mark.Raza@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

Hi. Attaching the revised TA we drafted (b) (5) [redacted] - m

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 3:43 PM
**To:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

(b) (5) [redacted]

---

**From:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Date:** February 29, 2020 at 3:29:16 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Hinton, Denise

AMERICAN OVERSIGHT

<Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

(b) (5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 3:10 PM
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

We worked that out.

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 3:01 PM
**To:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

(b) (5) [redacted]

---

**From:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:59 PM
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

Attached is the bill text for H.R. 4982, which I believe is the bill is being considered although that is not totally clear. Also attached is our TA to that bill that was sent to HHS earlier this week. (b) (5) [redacted] Adding Marcy Busch since she led this for OCC.

AMERICAN OVERSIGHT

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:54 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
**Subject:** RE: PREP Act - N95 Masks

The PREP Act provides liability protection for manufacturers and health care providers but (b) (5) [redacted]

(b) (5) [redacted]

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 2:45 PM
**To:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** Fwd: PREP Act - N95 Masks

Folks - ASFR looking for guidance on PREP Act. Working on supplemental. Anything we can provide her?

Sent from my iPhone

Begin forwarded message:

**From:** "Moughalian, Jen (HHS/ASFR)" <Jen.Moughalian@hhs.gov>
**Date:** February 29, 2020 at 2:34:22 PM EST
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
**Cc:** "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>, "Shuy, Caitrin (OS)" <Caitrin.Shuy@hhs.gov>
**Subject: FW: PREP Act - N95 Masks**

(b) (5) [redacted] thx

**From:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
**Sent:** Saturday, February 29, 2020 2:19 PM
**To:** McMillin, Virginia D. EOP/WHO <(b) (6) [redacted]@who.eop.gov>
**Cc:** Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>
**Subject:** Re: PREP Act - N95 Masks

+ Jen who is the HHS lead on supp negotiations

On Feb 29, 2020, at 2:05 PM, McMillin, Virginia D. EOP/WHO (b) (6) [redacted]@who.eop.gov> wrote:

AMERICAN OVERSIGHT

+Arbes — need to sort this out in the next couple of hours (b) (5) [redacted]

On Feb 29, 2020, at 1:53 PM, McMillin, Virginia D. EOP/WHO <(b) (6) [redacted]@who.eop.gov> wrote:

Hey, just us. (b) (5) [redacted]

Virginia Heppner McMillin
Special Assistant to the President
Office of Legislative Affairs
(b) (6) [redacted]

---

**From:** Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>
**Sent:** Friday, February 28, 2020 8:32 AM
**To:** Baehr, James S. EOP/WHO (b) (6) [redacted]@who.eop.gov>
**Cc:** Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; McMillin, Virginia D. EOP/WHO (b) (6) [redacted]@who.eop.gov>; Bonner, Maria K. EOP/WHO (b) (6) [redacted]@who.eop.gov>; Heilig, Rebecca B. EOP/WHO (b) (6) [redacted]@who.eop.gov>; Daravi, Kamran S. EOP/WHO (b) (6) [redacted]@who.eop.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
**Subject:** Re: PREP Act - N95 Masks

+ Danielle Steele, Brian Shuy

Sent from my iPhone

On Feb 28, 2020, at 3:53 AM, Baehr, James S. EOP/WHO (b) (6) [redacted]@who.eop.gov> wrote:

Paula, Laura,

Do you have a few minutes to walk me through (b) (5) [redacted]

We spoke with industry reps on this issue and, on first blush, I found their points compelling, but I understand there may be different views out there.

Best,

---

James S. C. Baehr
Special Assistant to the President
Domestic Policy Council
O (b) (6) [redacted]
C: [redacted]

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/25/2020 10:01:03 PM
**To**: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
**Subject**: RE: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

Yes, (b) (5)
Adding Ellen.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 9:53 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** Re: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

CDRH working to respond to that letter.

Sent from my iPhone

On Feb 25, 2020, at 9:06 PM, Mair, Michael <Michael.Mair@fda.hhs.gov> wrote:

http://www.cidrap.umn.edu/news-perspective/2020/02/cdc-warns-us-covid-19-spread-labs-frustrated-over-lack-tests

just FYI – realize u r responding to APHL

## Test kits available 'soon,' but labs frustrated

Messonnier also addressed the stall in getting testing kits to state and local health departments.

"I am frustrated that we have had issues with our test. I want to assure you we are hoping to modify the kits and hope to send them soon," Messonnier said.

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She also pointed out that the CDC was testing as many as 400 samples at a time and providing overnight results. "There is no current backlog or delay," she said.

On Feb 12, the CDC announced that several test kits sent to public health labs had an issue with a test reagent, which caused the negative control to generate a test response where there should have been none.

When pressed on when specifically the kits will be made available, Messonnier did not provide a date.

Currently, only 12 labs outside of the CDC—located in California, Illinois, Nebraska, Nevada, and Tennessee—have the capability to test for the virus. Peter Kyriacopoulos, the chief policy officer for APHL, told CIDRAP News the testing process could be dramatically shortened and expanded if 100 APHL-member labs receive authorization to do their own tests.

He said yesterday that the Association of Public Health Laboratories (APHL) addressed a letter to the Food and Drug Administration (FDA) asking for permission for member laboratories to use lab-developed tests between now and when the improved CDC kit is re-sent. Permission has to be granted because the FDA already issued an Emergency Use Authorization (EUA) authority for the CDC's test.

"We know because of the prevalence of this issue in the media, many of our labs may be called to do testing, and they will want to be responsive," said Kyriacopoulos. He explained that the labs could do manual extraction of the virus RNA, but testing would be more streamlined if they were allowed to use automated RNA extraction platforms. He said the automatic extraction devices would cost each lab about $200,000.

Joanne Barkus, PhD, the director of the Public Health Laboratory at the Minnesota Department of Health, said she is frustrated by the delay.

"We are trying to prepare for what I feel will be inevitable—a case in Minnesota—and we will want to expand testing," she told CIDRAP News. Right now, Barkus said the CDC was keeping up with test demands. But that could easily be changed if multiple community detections occur across the country and state epidemiologists begin testing case contacts en masse.

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 6:56:42 AM
**To:** Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** Re: (b) (5) [redacted]

Thank you, Heather. I think (b) (5) [redacted]

Jeff

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Date:** February 27, 2020 at 6:37:03 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** FW: (b) (5) [redacted]

Hi Jeff and Elizabeth,

Jennifer Ross from OCET sent Tremel a response. See below. I will let you decide if a call is still needed.

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: 240-507-3139
Email: Heather.Agler@fda.hhs.gov

---

**From:** Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
**Sent:** Thursday, February 27, 2020 6:33 AM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** Fw: CDC assay failure question

FYI

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 6:15:47 PM
**To:** Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
**Subject:** RE: CDC assay failure question

Tremel,

AMERICAN OVERSIGHT

Thanks for the inquiry. FDA very much appreciates the critical role of BARDA and public health laboratories in our nation's response to public health emergencies, as well as the severity of the current situation with the 2019 novel coronavirus disease. In the context of a public health emergency, false diagnostic test results can lead to significant adverse public health consequences - not only serious implications for individual patient care, but also serious implications for the analyses of disease progression and for public health decision-making. The EUA provisions help ensure that FDA has appropriate oversight over the emergency use of certain unapproved products, as well as over unapproved use of approved products, including diagnostic tests, regardless of who makes them. FDA welcomes the review of submissions of diagnostic test information on a rolling basis and is committed to a prompt and interactive review of them. In past experiences with these rolling reviews, FDA has been able to authorize tests for public health emergencies within as little as 1 day upon receipt of the complete validation. The Agency is currently supporting over 70 developers in the diagnostics space, including some public health laboratories, and FDA looks forward to collaboration with additional developers as well.

I'm not sure if you are aware, but we have a couple laboratory IVD pre-EUA and EUA focused webpages, including some info with regard to LDTs.

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/how-submit-pre-eua-vitro-diagnostics-fda

Thanks,

Jennifer

---

**From:** Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
**Sent:** Wednesday, February 26, 2020 10:37 AM
**To:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Subject:** CDC assay failure question

Hi Jennifer,

(b) (5)

Thanks, Tremel

*Tremel A. Faison, MS, RAC, SCT(ASCP)*
Director (Acting)
Regulatory and Quality Affairs Division (RQA)
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Emergency Response and Preparedness (ASPR)
U.S. Department of Health and Human Services (HHS)

AMERICAN OVERSIGHT

330 Independence Avenue, SW
Room G644
Washington, DC 20201

Phone: (202) 692-4764
Cell: (b) (6)
tremel.faison@hhs.gov

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/29/2020 6:58:54 AM
**To**: Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]
**CC**: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject**: Re: Diagnostics

Paul,

Thank you. The kudos go across the Agency. This was truly an FDA effort. And thank you and the rest of our HHS colleagues for the quick turnaround, and on a Friday night. Very impressive, as well.

Jeff

---

**From:** Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
**Date:** February 29, 2020 at 6:53:46 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Re: Diagnostics

Jeff- a special thanks to you and your team for leaning in so quickly on this. Truly impressive.

Sent from my iPhone

On Feb 28, 2020, at 9:31 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

The policy applies to all CLIA-certified, high complexity laboratories who make a test and use it in their lab – an LDT – which includes private labs and commercial manufacturers who have a lab, such as Roche. It does not include commercial manufacturers making a test kit for distribution to laboratories. Of note, several of those manufacturers have been working with us and are developing tests for the US market.

Under the policy, all test developers are meeting the EUA standard in their validation of their tests, which they would do anyway. The change is that they can start testing patients before submitting an EUA request to the FDA and FDA reviewing their data to assure the test is accurate and reliable. In the case of an individual laboratory, if their tests turns out not to work it just impacts that one lab and the patients they tested. For a test kit in distribution that does not work, it may impact dozens of labs and all the patients they test.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 9:07 PM
**To:** Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Mango, Paul (OS) <Paul.Mango@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: Diagnostics

I am copying Jeff Shuren to clarify
Steve

AMERICAN OVERSIGHT

**From:** Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
**Date:** February 28, 2020 at 9:01:38 PM EST
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Mango, Paul (OS) <Paul.Mango@hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
**Subject:** Re: Diagnostics

Hi Dr. Hahn and Keagan,

(b) (5)

Best,
Bryan

Sent from my iPhone

On Feb 28, 2020, at 8:04 PM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

HHS Clearance due 9:00pm: The FDA guidance is attached. Please email your concur or comments (redline/bubble comments, only) to Ekaterini.Malliou@hhs.gov

Thank you.

---

**From:** Malliou, Ekaterini (OS/IOS)
**Sent:** Friday, February 28, 2020 6:37 PM
**To:** Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; ASPR Scheduler Ford-Barnes, Arwenthia (OS/ASPR/IO) <Arwenthia.FordBarnes@hhs.gov>; Ashton Pollard (OS/IEA) (Ashton.Pollard@hhs.gov) <Ashton.Pollard@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; OGC Exec Sec (ControlDesk.OGCIO@hhs.gov) <ControlDesk.OGCIO@hhs.gov>; Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>; Toye, Sally (CDC/OD/OCS) <slc0@cdc.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>
**Cc:** Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Keagan Lenihan (FDA/OC) (Keagan.Lenihan@fda.hhs.gov) <Keagan.Lenihan@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
**Subject:** RE: Diagnostics

Update: I(b) (5)

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

Thank you.

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**From:** Malliou, Ekaterini (OS/IOS)
**Sent:** Friday, February 28, 2020 4:49 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
**Cc:** Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; ASPR Scheduler Ford-Barnes, Arwenthia (OS/ASPR/IO) <Arwenthia.FordBarnes@hhs.gov>; Ashton Pollard (OS/IEA) (Ashton.Pollard@hhs.gov) <Ashton.Pollard@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; OGC Exec Sec (ControlDesk.OGCIO@hhs.gov) <ControlDesk.OGCIO@hhs.gov>; Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>; Toye, Sally (CDC/OD/OCS) <slc0@cdc.gov>
**Subject:** RE: Diagnostics

Heads-Up: (b) (5)

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**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:49 PM
**To:** Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
**Cc:** Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
**Subject:** RE: Diagnostics

FDA crashing on guidance now.

---

**From:** Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
**Sent:** Friday, February 28, 2020 1:41 PM
**To:** Malliou, Ekaterini (OS) <Ekaterini.Malliou@hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>
**Subject:** Re: Diagnostics

Kat- that is great. (b) (5)

Sent from my iPhone

On Feb 28, 2020, at 1:38 PM, Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov> wrote:

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Good afternoon,

WH Clearance (b) (5)

Olivia Troy from the Vice President's office is the point of contact, and she is working closely with OIRA.
Olivia is also running the National Security Council (NSC) process for coronavirus.
OIRA will include Olivia, and other staff from VP and EOP Offices for the (b) (5)

Note about FDA Plan: (b) (5)

(b) Clearance: (b) (5)

Thank you,

Kat.

**********
Ekaterini (Kat) Malliou, DrPH, MPH
Senior Policy Coordinator
Immediate Office of the Secretary, U.S. Department of Health and Human Services
200 Independence Ave SW, Suite 619H, Washington, DC 20201, USA
Tel: 202-690-6875, Cell: (b) (6) Email: Ekaterini.Malliou@hhs.gov

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**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:20 PM
**To:** Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Diagnostics
**Importance:** High

(b) (5)

Best,
Stacy

AMERICAN OVERSIGHT

**********

Stacy Cline Amin
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

<IIE nCoV guidance CDRH OCC cleared.docx>

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/25/2020 1:08:01 PM
**To:** Hahn, Stephen (b) (6) Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** Re: enforcement discretion request for COVID-19 for PHLs final.pdf

We are working on it.

Jeff

---

**From:** Hahn, Stephen (b) (6) @fda.hhs.gov>
**Date:** February 25, 2020 at 11:47:48 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** FW: enforcement discretion request for COVID-19 for PHLs final.pdf

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**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>
**Date:** Monday, February 24, 2020 at 6:37 PM
**To:** Stephen Hahn (b) (6) @fda.hhs.gov>
**Subject:** FW: enforcement discretion request for COVID-19 for PHLs final.pdf

FYI

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**From:** Becker, Scott | APHL <Scott.Becker@aphl.org>
**Sent:** Monday, February 24, 2020 10:39 AM
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Kubin, Grace <Grace.Kubin@dshs.texas.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** enforcement discretion request for COVID-19 for PHLs final.pdf

Dear Commissioner Hahn,

On behalf of our nation's state and local public health laboratories (PHLs), we are writing to urge you to consider enforcement discretion to allow this select group of governmental laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request. The letter attached details our request.

Please contact me for any follow up or questions you may have at 301-526-5704 or scott.becke@aphl.org

Sincerely,

Scott Becker

AMERICAN OVERSIGHT

**Scott J. Becker** (he/him)
Chief Executive Officer

**P** +1 240.485.2747 | **M** +1 301.526.5704
scott.becker@aphl.org | @scottjbecker

Association of Public Health Laboratories
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Silver Spring, MD 20910
www.aphl.org | APHL Blog
Facebook | Twitter | LinkedIn | Instagram

ID Lab Con 2020 | APHL 2020 Why Attend? (video)

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 8:30:41 AM
**To:** Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: NYS Wadsworth

FYI – (b) (5) [redacted]

---

**From:** Shuren, Jeff
**Sent:** Saturday, February 29, 2020 8:19 AM
**To:** 'Hahn, Stephen' (b) (6) [redacted]@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth

TY! We'll wait (b) (5) [redacted]

---

**From:** Hahn, Stephen (b) (6) [redacted]fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:18 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Re: NYS Wadsworth

Done

Sent from my iPhone

On Feb 29, 2020, at 7:53 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

Yes, will do. We asked them this morning to also include (b) (5) [redacted].

I do have another ask though. (b) (5) [redacted]

(b) (5) [redacted]

---

**From:** Hahn, Stephen (b) (6) [redacted]@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:50 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

AMERICAN OVERSIGHT

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Re: NYS Wadsworth

(b) (5) Would you keep me updated?
Thanks

Sent from my iPad

On Feb 28, 2020, at 10:10 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

Wadsworth sent us their EUA this afternoon. (b) (5)

(b) (5)

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/26/2020 3:23:35 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** RE: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

We could probably do it if the FDA person can participate by phone. I'm supposed to be flying to and back from (b) (6) that day so I can see if Tim could do it by phone.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 3:10 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Thoughts?

---

**From:** Julie Khani <jkhani@acla.com>
**Sent:** Wednesday, February 26, 2020 2:52 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available here.

I am reaching out because in addition to Commissioner Hahn's remarks, I think the ACLA meeting would provide an excellent opportunity for the FDA to address the diagnostics community about the Coronavirus. I've extended the same invitation to the CDC. There will be approximately 200 people in attendance at the meeting, including CEOs and senior leadership from companies such as LabCorp, Quest, Mayo Clinic Laboratories, Hologic, and Siemens. ACLA and several member companies have a weekly call with the CDC, and the FDA has participated on some of the calls. We have shared information with the CDC about lab capacity and other information, in the event that public health labs are unable to handle testing needs, and surge capacity is necessary.

While these calls have been helpful, numerous questions remain about the availability of the CDC assay to commercial labs, the FDA EUA process, and other issues. I'd be happy to modify the agenda to allow time for a representative from the FDA, CDC, or both, to provide an update an answer questions.

I know the situation is changing quickly, and I can only imagine how busy it is at the FDA. But, as a lot of the key players in the diagnostics community will be together at our meeting next week, I wanted to extend the opportunity.

My office and mobile numbers are below if you have questions or if you would like to discuss.

Thanks.

Julie

**Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) \ (b) (6) (m)**

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/28/2020 10:06:11 AM
**To:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** RE: Final "Plan for Improving Testing in the US"

Yes, good idea. Let's add to the guidance.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Date:** February 28, 2020 at 10:00:02 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Final "Plan for Improving Testing in the US"

Consider adding (b) (5) [redacted] (or something like that)

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:52 AM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** Fwd: Final "Plan for Improving Testing in the US"

---

**From:** Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Date:** February 28, 2020 at 7:55:40 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>, Smith, Lia H (CDC) <loh5@cdc.gov>, Carroll, Darin S (CDC) <zuz4@cdc.gov>
**Subject:** Final "Plan for Improving Testing in the US"

Jeff:
Here is the final document for the laboratory testing guidance. I will provide this to Dr. Redfield and others. Will you have Steve Hahn send this up?
Thanks
Dan

Daniel B. Jernigan, MD MPH
Director, Influenza Division
Captain, USPHS (RET)
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Atlanta, GA 30329
Phone 404-639-2621, Cell 404-375-7508
djernigan@cdc.gov, www.cdc.gov/flu

AMERICAN OVERSIGHT

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:29 AM
**To:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Busch, Marcy (FDA/OC) <Marcy.Busch@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Haynes, Lia (CDC/DDPHSIS/CPR/OD) <loh5@cdc.gov>; Carroll, Darin (CDC/DDID/NCEZID/OD) <zuz4@cdc.gov>
**Subject:** RE: Revised Plan for Improving Testing in the U.S.

Dan,

FDA has an additional edit from our attorneys that I've included in the attachment. If CDC is good with these edits please incorporate and send us back a clean copy so we can share with Dr. Hahn.

Thank you,

Jeff

**From:** Shuren, Jeff
**Sent:** Thursday, February 27, 2020 11:46 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>
**Subject:** RE: Revised Plan for Improving Testing in the U.S.

Dan,

Thank you for the quick turnaround. The draft looks very good. I added my edits to Uwe's.

Jeff

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 11:30 PM
**To:** Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: Revised Plan for Improving Testing in the U.S.

Dan,

Excellent document. Attached the document with a few edits.

Thanks,
Uwe

**From:** Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Sent:** Thursday, February 27, 2020 10:21 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>
**Subject:** Revised Plan for Improving Testing in the U.S.

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All:
Here is the revised, cleaned-up document with your inputs. Send revisions to me and I can finalize.
Thanks
Dan.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 7:55 PM
**To:** Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Busch, Marcy (FDA/OC) <Marcy.Busch@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Subject:** Re: 2019 nCoV One pager.docx

Uwe and discussed a bit more. We suggest (b) (5) [redacted]

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 27, 2020 at 7:44:12 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
**Subject:** 2019 nCoV One pager.docx

With title

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/28/2020 6:35:13 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: Guidance on Minimum Criteria for LDTs

(b) (5)

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 6:34 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Guidance on Minimum Criteria for LDTs

FYI. I didn't catch any substantive changes. Show Uwe if you want.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

**From:** Carroll, Darin (CDC/DDID/NCEZID/OD) <zuz4@cdc.gov>
**Sent:** Friday, February 28, 2020 6:20 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>
**Subject:** RE: Guidance on Minimum Criteria for LDTs

Hey Tim,
Sorry I missed you before you took off. This is coming from my email, but the revisions below are a collective effort from the Lab TF. Safe travels home.
Cheers,
Darin

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(b) (5)



Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

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APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

February 24, 2020

Stephen M. Hahn, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn,

On behalf of our nation's state and local public health laboratories (PHLs), we are writing to urge you to consider enforcement discretion to allow this select group of governmental laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request.

While we appreciate the many efforts underway at CDC to provide a diagnostic assay to our member labs under the Emergency Use Authorization (EUA), this has proven challenging and we find ourselves in a situation that requires a quicker local response. We are now many weeks into the response with still no diagnostic or surveillance test available outside of CDC for the vast majority of our member laboratories. While we understand that the EUA process is open to PHLs, we believe a more expeditious route is needed at this time.

To the extent possible, public health laboratories could work together to:

- Utilize a standard protocol or use a limited set of protocols
- Purchase reagents including primers and probes from a common source
- Utilize a standard validation panel
- Recommend a minimum standard validation approach
- Enable confirmation at another PHL while cases remain sporadic. It is also possible to consider the use of LRN advanced labs to serve as a confirmatory lab if resources are available to do so.

We recognize that not all PHL's will develop and implement an LDT. If PHL's decided against the use of an LDT for whatever reason, they could: 1) wait for the availability of the new CDC replacement kit, 2) coordinate with a PHL that has developed an LDT (this is not uncommon for PHLs to work together), or 3) use a commercially available assay once approved by FDA under an EUA.

We look forward to discussing this request with you and your staff as soon as possible. If you have questions, please contact Scott Becker at 301-526-5704 or via email at scott.becker@aphl.org.

Sincerely,

Grace Kubin

Scott J. Becker

Grace Kubin, Ph.D.
Director, Laboratory Services Section
Texas Department of State Health Services

Scott J. Becker, MS
Chief Executive Officer
Association of Public Health Laboratories

cc: Robert Redfield, MD, Director, Centers for Disease Control and Prevention

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/24/2020 3:55:42 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: Fwd: enforcement discretion request for COVID-19 for PHLs final.pdf
**Attachments**: enforcement discretion request for COVID-19 for PHLs final.pdf; ATT00001.htm

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 24, 2020 at 11:11:03 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** Fwd: enforcement discretion request for COVID-19 for PHLs final.pdf

(b) (5)

Sent from my iPhone

Begin forwarded message:

**From:** "Becker, Scott | APHL" <Scott.Becker@aphl.org>
**Date:** February 24, 2020 at 10:39:18 AM EST
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
**Cc:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Redfield, Robert R (CDC)" <olx1@cdc.gov>, "Kubin, Grace" <Grace.Kubin@dshs.texas.gov>, "Jernigan, Daniel B (CDC)" <dbj0@cdc.gov>
**Subject: enforcement discretion request for COVID-19 for PHLs final.pdf**

Dear Commissioner Hahn,

On behalf of our nation's state and local public health laboratories (PHLs), we are writing to urge you to consider enforcement discretion to allow this select group of governmental laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request. The letter attached details our request.

Please contact me for any follow up or questions you may have at 301-526-5704 or scott.becke@aphl.org

Sincerely,

Scott Becker

**Scott J. Becker** (he/him)
Chief Executive Officer
**P** +1 240.485.2747 | **M** +1 301.526.5704
scott.becker@aphl.org | @scottjbecker
Association of Public Health Laboratories

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8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
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ID Lab Con 2020 | APHL 2020 Why Attend? (video)

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(b) (5) Draft



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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 4:31:49 AM
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]
**Subject:** Fwd: Hill call tomorrow after 1:00
**Attachments:** FDA COVID Response Activities fact sheet comments.MM.docx

Here is initial material from Maren. She is requesting (b) (5) [redacted]

Jeff

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>
**Date:** February 26, 2020 at 11:14:38 PM EST
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Tyler, James <James.Tyler@fda.hhs.gov>, Tootle, William <William.Tootle@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>, Price, William <William.Price@fda.hhs.gov>, Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>, Stone, Eric <Eric.Stone@fda.hhs.gov>, Tierney, Julia <Julia.Tierney@fda.hhs.gov>
**Subject:** RE: Hill call tomorrow after 1:00

Folks-

I am still working with the Hill to find a time or us to all chat tomorrow afternoon but it will be after 2:00. Once I nail down a time from the Hill, I will also schedule a short, internal prep call for us all to talk through a good game plan for the call.

For awareness, below (the notes in red are mine) and attached are some of the questions I got from the committee earlier that I think we will need to cover on the call.

Again, thank you in advance for your help. I know there are a lot of moving pieces right now but hopefully this will be time well spent for the Agency's current and ongoing efforts.

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**Funding:**

- Provide a breakdown by center and field for all funding (b) (5)

- Which activities are currently being undertaken out of FY 2020 funds and how much has been spent to date? (b) (5)

- For all lines, explain why these activities cannot be funded out of the base. Some potential items are noted on the attachment. Can walk through on call

- What the cost drivers behind the estimates, (i.e., lab work, people, IT)?
  - Please share data/numbers on how the estimates were built and include an FTE estimate for each of the four COVID Response Activities ok

- Are any of these activities brand-new to FDA and if so, which ones and how was the cost estimate derived? Believe this answer is no but will confirm on call tomorrow

- Why is the funding proposed for two years? Would potential new FTEs become wrapped into the baseline S&E account in future years? Can walk through on call

**Overarching themes:**

- How does FDA envision managing this long-term? We can walk though ebola or zika in how we managed those to give you a sense of long term picture of efforts

- Does FDA need any new legislative authority to carry out these activities? Is so, please provide the language. We can discuss on call (CDRH/CDER)

- Do any of these activities implicate other HHS op-div activities? Yes—working with several. Can walk through tomorrow on which ones

**Centers:**

- Are any of these activities eligible for user fee funding? Some potential items are noted on the attachment. (also OB) Will walk through on call

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- For the planned hires, how many and how would the hires be completed (special authorities, contract…)? All

- What is the timeframe for a potential coronavirus vaccine? Can walk through on call (CBER/OC)

- Please explain in greater detail the potential for drug shortages should coronavirus continue to spread. Can walk through on call (CDER)

---

**From:** McBride, Maren
**Sent:** Wednesday, February 26, 2020 6:09 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Price, William <William.Price@fda.hhs.gov>
**Subject:** RE: Hill call tomorrow after 1:00

Thank you Keagan. Adding Judy bc I forgot earlier (sorry!)

Attached is what was sent to the Hill earlier based on info your teams shared with OB for your reference.

The preliminary feedback I just got from the Hill was they need to understand the big picture/message here—in very simple terms. They are working under a VERY expedited timeline here (will have the bill drafted by Friday) so they are looking for basic facts/needs in plain English.

The specific cost-drivers for our needs is what they need to better understand—and why that work can't be done with our base funds (say for example on MCMs—we get funding for that work so why is more needed?) Are we hiring staff? If not, what are the funds specifically for?

As I mentioned earlier, I am supposed to get some questions later tonight but wanted to relay the preliminary feedback I got. They are supportive—we just need to arm them with the details and justification so they can get members on board.

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I will also try to set up a quick pre-call tomorrow for us to touch base prior to speaking with the Hill so we can all get on the same page.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 5:36 PM
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Price, William <William.Price@fda.hhs.gov>
**Subject:** RE: Hill call tomorrow after 1:00

(b) (5)

Thank you!

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 4:38 PM
**To:** Tyler, James <James.Tyler@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Price, William <William.Price@fda.hhs.gov>
**Subject:** Hill call tomorrow after 1:00

Folks—the Approps staff would like to speak with us tomorrow (sometime after 1:00) related to the supplemental for coronavirus and FDA's needs. I am supposed to get some specific questions/areas they would like to discuss with us and can circulate tonight. Just wanted to put on everyone's radar. I'll keep you posted.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/26/2020 7:20:18 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** RE: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

That is a genius suggestion.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 7:19 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

(b) (5) [redacted]

Sent from my iPhone

On Feb 26, 2020, at 7:18 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thoughts? (b) (5) [redacted]

Sent from my iPhone

Begin forwarded message:

**From:** Julie Khani <jkhani@acla.com>
**Date:** February 26, 2020 at 7:16:24 PM EST
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
**Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing**

It's a hotel ballroom. I could look into videoconferencing?

Also, just FYI, I reached out to Danielle Steele on this as well, re both FDA and CDC participation.

Sent from my iPhone

On Feb 26, 2020, at 5:41 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Not sure we could get anyone to do it in person. Could the FDA person participate by phone?

---

**From:** Julie Khani <jkhani@acla.com>
**Sent:** Wednesday, February 26, 2020 2:52 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available here.

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I am reaching out because in addition to Commissioner Hahn's remarks, I think the ACLA meeting would provide an excellent opportunity for the FDA to address the diagnostics community about the Coronavirus. I've extended the same invitation to the CDC. There will be approximately 200 people in attendance at the meeting, including CEOs and senior leadership from companies such as LabCorp, Quest, Mayo Clinic Laboratories, Hologic, and Siemens. ACLA and several member companies have a weekly call with the CDC, and the FDA has participated on some of the calls. We have shared information with the CDC about lab capacity and other information, in the event that public health labs are unable to handle testing needs, and surge capacity is necessary.

While these calls have been helpful, numerous questions remain about the availability of the CDC assay to commercial labs, the FDA EUA process, and other issues. I'd be happy to modify the agenda to allow time for a representative from the FDA, CDC, or both, to provide an update an answer questions.

I know the situation is changing quickly, and I can only imagine how busy it is at the FDA. But, as a lot of the key players in the diagnostics community will be together at our meeting next week, I wanted to extend the opportunity.

My office and mobile numbers are below if you have questions or if you would like to discuss.

Thanks.

Julie

**Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) \ (b) (6) (m)**

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 4:27:52 AM
**To:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** Re: (b) (5)

Elizabeth,

I'm happy to talk with Tremel today, if Lindsay can make it work; if not, then you or Tim. I agree we should clarify for them now.

Jeff

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Date:** February 26, 2020 at 11:03:58 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: (b) (5)

(b) (5)

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**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Date:** February 26, 2020 at 9:31:33 PM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** FW: (b) (5)

Hi Elizabeth,

(b) (5)

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG

AMERICAN OVERSIGHT

U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: 240-507-3139
Email: Heather.Agler@fda.hhs.gov

---

**From:** Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
**Sent:** Wednesday, February 26, 2020 10:37 AM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** FW: (b) (5)

I just sent this to Jennifer and then realized I should have sent to you too. Any thoughts?

---

**From:** Faison, Tremel (OS/ASPR/BARDA)
**Sent:** Wednesday, February 26, 2020 10:37 AM
**To:** Ross, Jennifer (FDA/OC) <Jennifer.Ross@fda.hhs.gov>
**Subject:** (b) (5)

Hi Jennifer,

(b) (5)

Have you guys thought about this?

Thanks, Tremel

*Tremel A. Faison, MS, RAC, SCT(ASCP)*
Director (Acting)
Regulatory and Quality Affairs Division (RQA)
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Emergency Response and Preparedness (ASPR)
U.S. Department of Health and Human Services (HHS)
330 Independence Avenue, SW
Room G644
Washington, DC 20201

Phone: (202) 692-4764
Cell: (b) (6)
tremel.faison@hhs.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/26/2020 3:07:48 PM
**To:** Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]
**Subject:** RE: TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

They can send it out now. I already sent it by email.

Jeff

---

**From:** Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 2:21 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

(b) (5)

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 2:16 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
**Cc:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
**Subject:** Re: TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

Many thanks.

Jeff

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 26, 2020 at 2:11:30 PM EST
**To:** Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
**Subject:** Re: TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

Thanks all.

Sent from my iPhone

On Feb 26, 2020, at 2:09 PM, Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov> wrote:

Response attached.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 8:53 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
**Subject:** Re: TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

AMERICAN OVERSIGHT

Lindsay- can you make sure you format the letter when it comes back and get to Frank for a signature and he can scan and send it to you Jeff?

Sent from my iPhone

On Feb 26, 2020, at 4:48 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

Keagan,

Once Michael has the letter cleared, we would need the letter put on FDA letterhead, signed by Dr. Hahn, and then a scanned copy emailed to CDRH (me) so I can email it to APHL before 4:30 PM. Is that enough time and is there someone on your end who can take the hand off from Michael?

Jeff

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Date:** February 26, 2020 at 12:52:00 AM EST
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Fisher, Robert <Robert.Fisher@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

Will do thx

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 12:31 AM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

Hi Michael,

CDRH is submitting a response to the letter received by Dr. Hahn regarding a request from the Association of Public Health Laboratories (APHL) regarding enforcement discretion of LDTs for the coronavirus. We wanted to raise this to the IMG and obtain clearance. The deadline is to have clearance by **4 pm Wednesday (2/26/2020)** before a teleconference meeting with APHL at 4:30 pm. Please let us know if you have any questions.

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG

AMERICAN OVERSIGHT

U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: 240-507-3139
Email: Heather.Agler@fda.hhs.gov

<APHL Final Response Letter.pdf>
<EUA Review Template_NAT_Novel Coronavirus 1.19.2020.doc>

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/28/2020 10:22:22 PM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**Subject:** RE: FDA contact and potentials for KCDC assay (UNCLASSIFIED)

Great

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:19 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: FDA contact and potentials for KCDC assay (UNCLASSIFIED)

Ok thanks

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov




*Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.*

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:18 PM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** RE: FDA contact and potentials for KCDC assay (UNCLASSIFIED)

Uwe said they know the technology as the company used it for an Ebola and a Zika test, both of which were not granted EUA. (b) (4), (b) (5) [redacted]

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:14 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: FDA contact and potentials for KCDC assay (UNCLASSIFIED)

I wasn't sure if Heather or Uwe had passed this information on to you regarding the Korean CDC dx test., so forwarding below…

AMERICAN OVERSIGHT

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*

Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov




*Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.*

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:06 PM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Cc:** CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>
**Subject:** RE: FDA contact and potentials for KCDC assay (UNCLASSIFIED)

Heather, thanks for the update. Uwe

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 9:06 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
**Cc:** CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>
**Subject:** FW: FDA contact and potentials for KCDC assay (UNCLASSIFIED)

Hi Uwe and Kim,

As I expressed earlier (b) (5) [redacted] Please see the emails below. I believe they are looking to have a teleconference on Monday evening. I will let you know when they propose a time.

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: 240-507-3139

AMERICAN OVERSIGHT

Email: Heather.Agler@fda.hhs.gov

**From:** Kishimori, Jennifer M COL USARMY OSD OUSD P-R (USA) <jennifer.m.kishimori.mil@mail.mil>
**Sent:** Friday, February 28, 2020 8:04 PM
**To:** Murray, Clinton K COL USARMY INDOPACOM USFK (USA) <clinton.k.murray.mil@mail.mil>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Cc:** Deussing, Eric (CDC) <ncu0@cdc.gov>; Biggins, Julia E CTR (USA) <julia.e.biggins.ctr@mail.mil>; Ireland, Mark A COL USARMY DHA PUB HEALTH (USA) <mark.a.ireland.mil@mail.mil>; Cavicchia, Melinda A COL USARMY DHA PUB HLTH (USA) <melinda.a.cavicchia.mil@mail.mil>; Kording, Jonathan R CTR OSD HA (USA) <jonathan.r.kording.ctr@mail.mil>; Pawlicki, Nathan J CTR OSD HA (USA) <nathan.j.pawlicki.ctr@mail.mil>
**Subject:** Re: FDA contact and potentials for KCDC assay (UNCLASSIFIED)

Great, thx Clint. Let us know if there are others on your team to add to the telcon.

I'll plan to send out the invite with tc# for Monday pm if Heather can make it as well.

V/r,
Jenn

Sent from my Verizon, Samsung Galaxy smartphone

-------- Original message --------
From: "Murray, Clinton K COL USARMY INDOPACOM USFK (USA)" <clinton.k.murray.mil@mail.mil>
Date: 2/28/20 6:40 PM (GMT-05:00)
To: "Kishimori, Jennifer M COL USARMY OSD OUSD P-R (USA)" <jennifer.m.kishimori.mil@mail.mil>, Heather.Agler@fda.hhs.gov
Cc: "Deussing, Eric (CDC/OD/OCS)" <ncu0@cdc.gov>, "Biggins, Julia E CTR (USA)" <julia.e.biggins.ctr@mail.mil>, "Ireland, Mark A COL USARMY DHA PUB HEALTH (USA)" <mark.a.ireland.mil@mail.mil>, "Cavicchia, Melinda A COL USARMY DHA PUB HLTH (USA)" <melinda.a.cavicchia.mil@mail.mil>, "Kording, Jonathan R CTR OSD HA (USA)" <jonathan.r.kording.ctr@mail.mil>, "Pawlicki, Nathan J CTR OSD HA (USA)" <nathan.j.pawlicki.ctr@mail.mil>
Subject: RE: FDA contact and potentials for KCDC assay (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

My impression is the KCDC developed the test in combination with Ministry of Health and Welfare.

We are trying to get the lab director's information so we can do some communication.

Monday evening would work for me- say 1700 your time. Just give me a number and I'll call in.

Clint

-----Original Message-----
From: Kishimori, Jennifer M COL USARMY OSD OUSD P-R (USA)
Sent: Saturday, February 29, 2020 8:18 AM
To: Murray, Clinton K COL USARMY INDOPACOM USFK (USA) <clinton.k.murray.mil@mail.mil>; Heather.Agler@fda.hhs.gov
Cc: Deussing, Eric (CDC/OD/OCS) <ncu0@cdc.gov>; Biggins, Julia E CTR (USA) <julia.e.biggins.ctr@mail.mil>; Ireland, Mark A COL USARMY DHA PUB HEALTH (USA) <mark.a.ireland.mil@mail.mil>; Cavicchia, Melinda A COL USARMY DHA PUB HLTH (USA) <melinda.a.cavicchia.mil@mail.mil>; Kording, Jonathan R CTR OSD HA (USA) <jonathan.r.kording.ctr@mail.mil>; Pawlicki, Nathan J CTR OSD HA (USA) <nathan.j.pawlicki.ctr@mail.mil>

AMERICAN OVERSIGHT

Subject: RE: FDA contact and potentials for KCDC assay

Hi Clint,

Sorry, I was out of office and not able to respond, now logged in and have looped in Dr. Heather Agler from FDA/CDRH so we are all in communication. I also want to bring in a few more folks from DoD side (JPEO Jen Dabish who has diagnostic and EUA expertise, USAMMDA reg Emily Badraslioglu /FHP LTC Sandi Parriott who will have to carry the water on this).

For now and since it is late on Friday for East Coast, maybe we can do this via email so we can get our questions to you to then go to your KCDC POC via translator.

A questions Heather and I discussed are: (b) (5) ?

(b) (5)

Perhaps we should plan on a TC on Monday 5 or 6 pm? I can get something on the calendar - it might be good to chat with US folks first(?). not sure.

Heather - please jump in with your questions/and or a pathway.

V/r,
Jenn

COL Jennifer M. Kishimori, DVM, PhD
US Army Veterinary Corps
Director, CBRN Medical Countermeasures Policy Office of the Assistant Secretary of Defense for Health Affairs, Health Readiness Policy and Oversight
7700 Arlington Boulevard
Falls Church, Virginia 22042

(b) (6)

Veterinary Biomedical Science / 64E Consultant to the Army OTSG

-----Original Message-----
From: Murray, Clinton K COL USARMY INDOPACOM USFK (USA)
Sent: Friday, February 28, 2020 1:03 PM
To: Kishimori, Jennifer M COL USARMY OSD OUSD P-R (USA) <jennifer.m.kishimori.mil@mail.mil>
Cc: Deussing, Eric (CDC/OD/OCS) <ncu0@cdc.gov>; Biggins, Julia E CTR (USA) <julia.e.biggins.ctr@mail.mil>; Ireland, Mark A COL USARMY DHA PUB HEALTH (USA) <mark.a.ireland.mil@mail.mil>; Cavicchia, Melinda A COL USARMY DHA PUB HLTH (USA) <melinda.a.cavicchia.mil@mail.mil>; Kording, Jonathan R CTR OSD HA (USA) <jonathan.r.kording.ctr@mail.mil>; Pawlicki, Nathan J CTR OSD HA (USA) <nathan.j.pawlicki.ctr@mail.mil>
Subject: Re: FDA contact and potentials for KCDC assay

Great to hear. I have texted them.

The time change he is a killer for meetings as you can imagine and then getting a translator.

Are there specific questions that need to be considered?

Clint

AMERICAN OVERSIGHT

From: "Kishimori, Jennifer M COL USARMY OSD OUSD P-R (USA)" <jennifer.m.kishimori.mil@mail.mil <mailto:jennifer.m.kishimori.mil@mail.mil> >
Date: Saturday, February 29, 2020 12:15:08 AM
To: "Murray, Clinton K COL USARMY INDOPACOM USFK (USA)" <clinton.k.murray.mil@mail.mil <mailto:clinton.k.murray.mil@mail.mil> >
Cc: "Deussing, Eric (CDC/OD/OCS)" <ncu0@cdc.gov <mailto:ncu0@cdc.gov> >, "Biggins, Julia E CTR (USA)" <julia.e.biggins.ctr@mail.mil <mailto:julia.e.biggins.ctr@mail.mil> >, "Ireland, Mark A COL USARMY DHA PUB HEALTH (USA)" <mark.a.ireland.mil@mail.mil <mailto:mark.a.ireland.mil@mail.mil> >, "Cavicchia, Melinda A COL USARMY DHA PUB HLTH (USA)" <melinda.a.cavicchia.mil@mail.mil <mailto:melinda.a.cavicchia.mil@mail.mil> >, "Kording, Jonathan R CTR OSD HA (USA)" <jonathan.r.kording.ctr@mail.mil <mailto:jonathan.r.kording.ctr@mail.mil> >, "Pawlicki, Nathan J CTR OSD HA (USA)" <nathan.j.pawlicki.ctr@mail.mil <mailto:nathan.j.pawlicki.ctr@mail.mil> >
Subject: FDA contact and potentials for KCDC assay

Dear Clint,

(b) (5)

[redacted]

Heather said we can have a call together later today if you are available or your lead working this is free.

I welcome your thoughts.

V/r,
Jenn

Sent from my Verizon, Samsung Galaxy smartphone

CLASSIFICATION: UNCLASSIFIED

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 1:21:21 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

I've confirmed with Tim for participation by videoconference. Of note, he might be on the West Coast at some of the COVID-19 test manufacturing facilities.

Jeff

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 27, 2020 at 10:42:01 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

(b) (5)

Sent from my iPhone

Begin forwarded message:

**From:** "McGowan, Robert (Kyle) (CDC/OD/OCS)" <omc2@cdc.gov>
**Date:** February 26, 2020 at 8:16:26 PM EST
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
**Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing**

I was going to ask Dan tomorrow if he'd be available.

Get Outlook for iOS

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 8:07:35 PM
**To:** McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>
**Subject:** Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

(b) (5)

Sent from my iPhone

On Feb 26, 2020, at 7:51 PM, McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov> wrote:

Yeah. That could work.

Get Outlook for iOS

AMERICAN OVERSIGHT

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 7:32:02 PM
**To:** McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>
**Subject:** Fwd: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

(b) (5) [redacted]

Sent from my iPhone

Begin forwarded message:

**From:** Julie Khani <jkhani@acla.com>
**Date:** February 26, 2020 at 2:52:40 PM EST
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
**Subject: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing**

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available here.

I am reaching out because in addition to Commissioner Hahn's remarks, I think the ACLA meeting would provide an excellent opportunity for the FDA to address the diagnostics community about the Coronavirus. I've extended the same invitation to the CDC. There will be approximately 200 people in attendance at the meeting, including CEOs and senior leadership from companies such as LabCorp, Quest, Mayo Clinic Laboratories, Hologic, and Siemens. ACLA and several member companies have a weekly call with the CDC, and the FDA has participated on some of the calls. We have shared information with the CDC about lab capacity and other information, in the event that public health labs are unable to handle testing needs, and surge capacity is necessary.

While these calls have been helpful, numerous questions remain about the availability of the CDC assay to commercial labs, the FDA EUA process, and other issues. I'd be happy to modify the agenda to allow time for a representative from the FDA, CDC, or both, to provide an update an answer questions.

I know the situation is changing quickly, and I can only imagine how busy it is at the FDA. But, as a lot of the key players in the diagnostics community will be together at our meeting next week, I wanted to extend the opportunity.

My office and mobile numbers are below if you have questions or if you would like to discuss.

Thanks.

Julie

**Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o)** (b) (6) [redacted] **(m)**

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 6:08:46 PM
**To**: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]
**CC**: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]
**Subject**: RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

(b) (5)

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 6:02 PM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** Re: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Are we 20 mins away from sending to HHS?

Sent from my iPhone

On Feb 28, 2020, at 5:50 PM, Roth, Lauren <Lauren.Roth@fda.hhs.gov> wrote:

Talked to Kat. She thinks she is getting guidance no later than 6:30, and HHS will send comments/clearance by 7:30. OIRA will have it until 9:00.

Adding Joni to this chain as FYI

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 28, 2020 at 5:09:10 PM EST
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** Re: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Hopefully 6ish

Sent from my iPhone

AMERICAN OVERSIGHT

On Feb 28, 2020, at 4:50 PM, Roth, Lauren <Lauren.Roth@fda.hhs.gov> wrote:

I'll send it to her. Does anyone have a sense of what time? Before 6? closer to midnight?

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Date:** February 28, 2020 at 4:44:45 PM EST
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

I won't be able to reliably do that b/c my phone battery keeps dying and I have to leave for a DOJ event.

(Keagar(b) (5) I've been saving the phone one.)

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**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 4:42 PM
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** Re: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Once the guidance is FDA cleared, can someone send to Kat or do I need to?

Sent from my iPhone

On Feb 28, 2020, at 4:40 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

+ Keagan. Lauren I'm not sure who should be coordinating with Kat. Keagan could you do that or should it be Lauren?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 4:31 PM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

My responses are in bold in your email below.

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 4:07 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Stacy and Jeff –

(b) (5)

(b) (5)

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(b) (5) [redacted]

Thanks,
Lauren

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 2:29 PM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

(b) (5) [redacted]

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**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 2:10 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** FW: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Removing the Department, adding Jeff and Marcy

---

**From:** Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
**Sent:** Friday, February 28, 2020 2:08 PM
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>
**Subject:** OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Please find attached OMB edits on the plan.

OMB want to know: (b) (5) [redacted]

May I please ask whether it is possible to email me the guidance by 3pm?

Thank you.

AMERICAN OVERSIGHT

**********

Lowell and Lauren, update on the process, below for your information:

WH Clearance: (b) (5)

Olivia Troy from the Vice President's office is the point of contact, and she is working closely with OIRA.
Olivia is also running the National Security Council (NSC) process for coronavirus.
OIRA will include Olivia, and other staff from VP and EOP Offices for the 1 hour WH clearance.

HHS Clearance: (b) (5)

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:03 PM
**To:** Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>; Schiller, Lowell (FDA/OC) <Lowell.Schiller@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>
**Subject:** RE: Heads up: FDA guidance on clinical laboratories

Kat can you give me a call? I can explain. I just spoke to Judy. (b) (6)

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**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:01 PM
**To:** Malliou, Ekaterini (OS) <Ekaterini.Malliou@hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: Heads up: FDA guidance on clinical laboratories

Adding Stacy, deleting RPMS.

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 1:14:42 PM
**To**: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject**: RE: Posting

(b) (5)

[redacted]

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:12 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Posting

What is it that you plan to post on the website?

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 7:47:14 AM
**To:** Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

So rather than (b) (5) [redacted]

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:44 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

Yes, (b) (5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:44 AM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

(b) (5) [redacted]

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:38 AM
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

Just a couple suggestions attached. Looks good!

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 7:26 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

Morning!
Attached is the latest PR, aligned to the latest draft of guidance. I'd appreciate a technical proof of PR, to ensure I've captured guidance updates correctly (b) (5) [redacted]

AMERICAN OVERSIGHT

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:44 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

Here's what went back to HHS. I corrected a few typos, so wanted to make sure you had this for your records. Never mind my question about the footnote; the formatting in the redline makes it carryover in an odd way to the next page, but I see it now.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:39 PM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

(b) (5) [redacted]

Elizabeth

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:34 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

Thanks. Sending it to HHS. When you get a chance, can you check FN 5? Not clear to me what that is referring to. I skimmed the EUA guidance, (b) (5) [redacted]

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:23 PM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

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**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

Attached.

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 10:16 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

Another update – [redacted] (b) (5) [redacted] HHS asking me about ETA for the passback. Any sense?

---

**From:** Roth, Lauren
**Sent:** Friday, February 28, 2020 10:05 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

One non-legal comment (typo) from OGC in the attached.

---

**From:** Roth, Lauren
**Sent:** Friday, February 28, 2020 10:03 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

FYI that I asked HHS for an update on outstanding comments (b) (5) [redacted]

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 9:39 PM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie

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<Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

I can do that. I am circling back with some SMEs for some of the comments.

(b) (5) [redacted]

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 9:27 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

Does someone in CDRH have the pen on integrating the edits into a redline? Also, I believe HHS planned to circulate to CDC and OGC as well, so we may get additional comments. I will confirm once I know.

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 9:25 PM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

Might be an OCC question: (b) (5) [redacted]

[redacted]

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 9:16 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

All,

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Attached are next set of comments from ASPR

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 9:08 PM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

This language is on page 3 in footnote 4 of the document.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:58 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

In case it is helpful, (b) (5)

(b) (5)

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 8:38 PM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

The technical legal language (b) (5)

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Date:** February 28, 2020 at 8:32:29 PM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Mednick, David <David.Mednick@fda.hhs.gov>, Witters, Alicia <Alicia.Witters@fda.hhs.gov>, Foy, Jonette <Jonette.Foy@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** RE: IIE nCoV guidance CDRH OCC cleared.docx

AMERICAN OVERSIGHT

All,

Our HHS desk officer has asked for Department comments by 9 p.m. We can send back one response to all of the HHS comments, but I will pass them forward as I receive them. Below is the first (so far only) comment/question that we've received:

(b) (5)

[redacted]

Thanks,
Lauren

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 6:58 PM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Witters, Alicia <Alicia.Witters@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
**Subject:** IIE nCoV guidance CDRH OCC cleared.docx

Lauren and Keagan,

Attached is the CDRH and OCC cleared guidance. Thank you for coordinating HHS and OMB review. We will stand by in case updates are needed.

Elizabeth

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/25/2020 11:34:08 PM
**To**: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

They have not. We will shepherd it through the IMG and OC.

Jeff

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 10:12 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

Has IMG reviewed?

If so, OC.

Sent from my iPhone

On Feb 25, 2020, at 10:10 PM, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov> wrote:

OCC has cleared Jeff's edits.

I will clean it up. Who should get it next?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 25, 2020 at 10:08:05 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** Re: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

Thx all.

Sent from my iPhone

On Feb 25, 2020, at 10:01 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

AMERICAN OVERSIGHT

Yes, OCC cleared and I had some additional, minor edits so it should be heading to folks in the Commissioner's Office soon. Adding Ellen.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 9:53 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** Re: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

CDRH working to respond to that letter.

Sent from my iPhone

On Feb 25, 2020, at 9:06 PM, Mair, Michael <Michael.Mair@fda.hhs.gov> wrote:

http://www.cidrap.umn.edu/news-perspective/2020/02/cdc-warns-us-covid-19-spread-labs-frustrated-over-lack-tests

just FYI – realize u r responding to APHL

# Test kits available 'soon,' but labs frustrated

Messonnier also addressed the stall in getting testing kits to state and local health departments.

"I am frustrated that we have had issues with our test. I want to assure you we are hoping to modify the kits and hope to send them soon," Messonnier said.

She also pointed out that the CDC was testing as many as 400 samples at a time and providing overnight results. "There is no current backlog or delay," she said.

On Feb 12, the CDC announced that several test kits sent to public health labs had an issue with a test reagent, which caused the negative control to generate a test response where there should have been none.

When pressed on when specifically the kits will be made available, Messonnier did not provide a date.

Currently, only 12 labs outside of the CDC—located in California, Illinois, Nebraska, Nevada, and Tennessee—have the capability to test for the virus. Peter Kyriacopoulos, the chief policy officer for APHL, told CIDRAP News the testing process could be dramatically shortened and expanded if 100 APHL-member labs receive authorization to do their own tests.

He said yesterday that the Association of Public Health Laboratories (APHL) addressed a letter to the Food and Drug Administration (FDA) asking for permission for member laboratories to use lab-developed tests between now and when the improved CDC kit is re-sent. Permission has to be granted because the FDA already issued an Emergency Use Authorization (EUA) authority for the CDC's test.

"We know because of the prevalence of this issue in the media, many of our labs may be called to do testing, and they will want to be responsive," said Kyriacopoulos. He explained that the labs could do manual extraction of the virus RNA, but testing would be more streamlined if they were allowed to use automated RNA extraction platforms. He said the automatic extraction devices would cost each lab about $200,000.

Joanne Barkus, PhD, the director of the Public Health Laboratory at the Minnesota Department of Health, said she is frustrated by the delay.

AMERICAN OVERSIGHT

"We are trying to prepare for what I feel will be inevitable—a case in Minnesota—and we will want to expand testing," she told CIDRAP News. Right now, Barkus said the CDC was keeping up with test demands. But that could easily be changed if multiple community detections occur across the country and state epidemiologists begin testing case contacts en masse.

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/25/2020 4:43:15 AM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject**: Fwd: APHL Letter for FDA
**Attachments**: enforcement discretion request for COVID-19 for PHLs final.pdf

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**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 24, 2020 at 8:34:10 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: APHL Letter for FDA

FYI

---

**From:** Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS) <yyw2@cdc.gov>
**Date:** February 24, 2020 at 8:20:42 PM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Fwd: APHL Letter for FDA

FYI

---

**From:** Becker, Scott | APHL <Scott.Becker@aphl.org>
**Sent:** Monday, February 24, 2020 11:22 AM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD); Salerno, Reynolds (CDC/DDPHSS/CSELS/DLS)
**Subject:** APHL Letter for FDA

Dear Wendi and Ren:

I am writing to let you know that the APHL Board of Directors approved sending a letter urging the FDA Commissioner to consider enforcement discretion to allow governmental public health laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). In the letter we state that to the extent possible, public health laboratories could work together to:

- Utilize a standard protocol or use a limited set of protocols
- Purchase reagents including primers and probes from a common source
- Utilize a standard validation panel
- Recommend a minimum standard validation approach
- Enable confirmation at another PHL while cases remain sporadic. It is also possible to consider the use of LRN advanced labs to serve as a confirmatory lab if resources are available to do so.

We recognize that not all PHL's will develop and implement an LDT. If PHL's decided against the use of an LDT for whatever reason, they could: 1) wait for the availability of the new CDC replacement kit, 2) coordinate with a PHL that has developed an LDT (this is not uncommon for PHLs to work together), or 3) use a commercially available assay once approved by FDA under an EUA.

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We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request.

We will let you know the outcome of our communication with FDA, which is attached. The letter was sent to the FDA Commissioner, copy to his chief of staff; Dr. Redfield, copy to Dr. Jernigan.

Sincerely,

Scott Becker

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Scott Becker MS
Executive Director
Association of Public Health Laboratories
Silver Spring MD
240.485.2747

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**Scott J. Becker** (he/him)
Chief Executive Officer
**P** +1 240.485.2747 | **M** +1 301.526.5704
scott.becker@aphl.org | @scottjbecker

Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
www.aphl.org | APHL Blog
Facebook | Twitter | LinkedIn | Instagram

ID Lab Con 2020 | APHL 2020 Why Attend? (video)

AMERICAN OVERSIGHT

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

February 24, 2020

Stephen M. Hahn, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn,

On behalf of our nation's state and local public health laboratories (PHLs), we are writing to urge you to consider enforcement discretion to allow this select group of governmental laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request.

While we appreciate the many efforts underway at CDC to provide a diagnostic assay to our member labs under the Emergency Use Authorization (EUA), this has proven challenging and we find ourselves in a situation that requires a quicker local response. We are now many weeks into the response with still no diagnostic or surveillance test available outside of CDC for the vast majority of our member laboratories. While we understand that the EUA process is open to PHLs, we believe a more expeditious route is needed at this time.

To the extent possible, public health laboratories could work together to:

- Utilize a standard protocol or use a limited set of protocols
- Purchase reagents including primers and probes from a common source
- Utilize a standard validation panel
- Recommend a minimum standard validation approach
- Enable confirmation at another PHL while cases remain sporadic. It is also possible to consider the use of LRN advanced labs to serve as a confirmatory lab if resources are available to do so.

We recognize that not all PHL's will develop and implement an LDT. If PHL's decided against the use of an LDT for whatever reason, they could: 1) wait for the availability of the new CDC replacement kit, 2) coordinate with a PHL that has developed an LDT (this is not uncommon for PHLs to work together), or 3) use a commercially available assay once approved by FDA under an EUA.

We look forward to discussing this request with you and your staff as soon as possible. If you have questions, please contact Scott Becker at 301-526-5704 or via email at scott.becker@aphl.org.

Sincerely,

Grace Kubin

Scott J. Becker

Grace Kubin, Ph.D.
Director, Laboratory Services Section
Texas Department of State Health Services

Scott J. Becker, MS
Chief Executive Officer
Association of Public Health Laboratories

cc: Robert Redfield, MD, Director, Centers for Disease Control and Prevention

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/25/2020 11:33:42 PM
**To**: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]
**Subject**: RE: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

Thank you.

Jeff

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 11:31 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** RE: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

Jeff,
Heather and I will make sure that this gets shepherded expeditiously through the IMG and Office of Commissioner to meet the deadline noted.

Suzanne

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov




*Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.*

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 10:45 PM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** FW: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

I don't know how to submit to the IMG so adding Heather and Suzanne.

Heather, Suzanne – the drop dead deadline is to have IMG and the Commissioner's Office clear the attached letter and then send the letter to APHL before we have a teleconference with them tomorrow (Wednesday) at 4:30 PM. Can you please shepherd it through?

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Jeff

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**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 10:32 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

Jeff,

Attached is the draft response and APHL letter.

I don't know how to submit to IMG. Do you?

Thanks,
Ellen

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 10:12 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

Has IMG reviewed?

If so, OC.

Sent from my iPhone

On Feb 25, 2020, at 10:10 PM, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov> wrote:

(b) (5)

I will clean it up. Who should get it next?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 25, 2020 at 10:08:05 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** Re: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

Thx all.

Sent from my iPhone

AMERICAN OVERSIGHT

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---

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**Sent:** Tuesday, February 25, 2020 9:53 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** Re: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests

CDRH working to respond to that letter.

Sent from my iPhone

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http://www.cidrap.umn.edu/news-perspective/2020/02/cdc-warns-us-covid-19-spread-labs-frustrated-over-lack-tests

just FYI – realize u r responding to APHL

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 3:32:28 PM
**To:** Tomasello, Jennifer (Jennifer.Tomasello@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=Jennifer.Tomasello]

**Subject:** FW: Call with Approps Subcommittee Staff on COVID-19 Funding Needs
**Location:** Webex Dial-In: 1-210-795-0506; 900 407 044

**Start:** 2/27/2020 4:00:00 PM
**End:** 2/27/2020 5:00:00 PM
**Show Time As:** Tentative

-----Original Appointment-----
**From:** Price, William
**Sent:** Thursday, February 27, 2020 2:18 PM
**To:** Price, William; McBride, Maren; Lenihan, Keagan; Tyler, James; Tootle, William; Woodcock, Janet; Shuren, Jeff; Marks, Peter; Hinton, Denise; McMeekin, Judith; Cavazzoni, Patrizia; Solomon, Steven M; Klimczak, Katherine; Van Pool, Kendall; Stone, Eric; Tierney, Julia; Forfa, Tracey; Leary, Mary; Hussey, Deirdre; Earley, Rosemary; Trivedi, Aalap
**Subject:** Call with Approps Subcommittee Staff on COVID-19 Funding Needs
**When:** Thursday, February 27, 2020 4:00 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** Webex Dial-In: 1-210-795-0506; (b) (6)

-- Do not delete or change any of the following text. --

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Meeting password: (b) (6)

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Need help? Go to http://help.webex.com

Folks—Our call with Approps is today at 4:00. William Price will send an invite for an internal 3:30 call and then the 4:00 call with the Hill. Rough agenda for us to follow is below. I don't want to tick through each Q the Hill had but will rather suggest we just try to cover them in better explaining our request. Jay and Bill will also share a simple table soon that answers the Hill's Q of how this money is spread in each category and any FTEs. I will also share that with the Hill when they have it done. Thanks!

**Agenda**

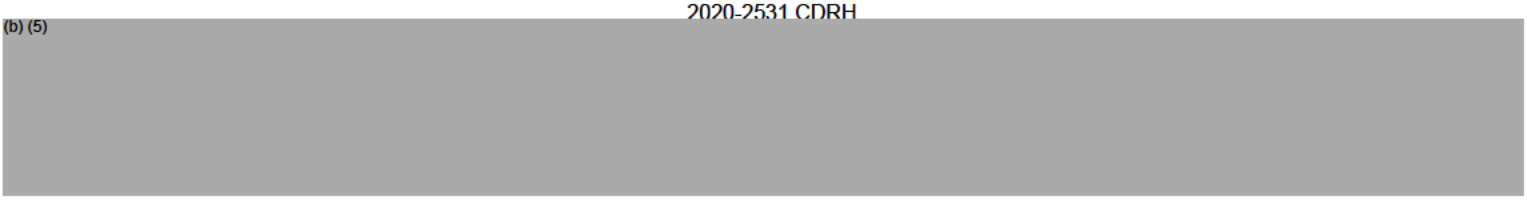
1. **Opening (Denise)**

(b) (5)



AMERICAN OVERSIGHT

(b) (5)



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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/28/2020 6:01:46 PM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject**: FW: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 5:51 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** Re: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Talked to Kat. She thinks she is getting guidance no later than 6:30, and HHS will send comments/clearance by 7:30. OIRA will have it until 9:00.

Adding Joni to this chain as FYI

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 28, 2020 at 5:09:10 PM EST
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** Re: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Hopefully 6ish

Sent from my iPhone

On Feb 28, 2020, at 4:50 PM, Roth, Lauren <Lauren.Roth@fda.hhs.gov> wrote:

I'll send it to her. Does anyone have a sense of what time? Before 6? closer to midnight?

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Date:** February 28, 2020 at 4:44:45 PM EST
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

AMERICAN OVERSIGHT

I won't be able to reliably do that b/c my phone battery keeps dying and I have to leave for a DOJ event.

(Keagar[(b) (5)] I've been saving the phone one.)

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 4:42 PM
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** Re: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Once the guidance is FDA cleared, can someone send to Kat or do I need to?

Sent from my iPhone

On Feb 28, 2020, at 4:40 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

+ Keagan. Lauren I'm not sure who should be coordinating with Kat. Keagan could you do that or should it be Lauren?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 4:31 PM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

My responses are in bold in your email below.

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 4:07 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Stacy and Jeff –

(b) (5)

Thanks,
Lauren

AMERICAN OVERSIGHT

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 2:29 PM
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

(b) (5), (b) (4)

[redacted]

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 2:10 PM
**To:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
**Subject:** FW: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Removing the Department, adding Jeff and Marcy

**From:** Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
**Sent:** Friday, February 28, 2020 2:08 PM
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>
**Subject:** OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories

Please find attached OMB edits on the plan.

OMB want to know: (b) (5)
[redacted]

May I please ask whether it is possible to email me the guidance by 3pm?

Thank you.

**********

Lowell and Lauren, update on the process, below for your information:

WH Clearance: (b) (5)
[redacted]

Olivia Troy from the Vice President's office is the point of contact, and she is working closely with OIRA.
Olivia is also running the National Security Council (NSC) process for coronavirus.
OIRA will include Olivia, and other staff from VP and EOP Offices for the 1 hour WH clearance.

HHS Clearance: (b) (5)
[redacted]

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**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:03 PM
**To:** Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>; Schiller, Lowell (FDA/OC) <Lowell.Schiller@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>
**Subject:** RE: Heads up: FDA guidance on clinical laboratories

Kat can you give me a call? I can explain. I just spoke to Judy. (b) (6)

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:01 PM
**To:** Malliou, Ekaterini (OS) <Ekaterini.Malliou@hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: Heads up: FDA guidance on clinical laboratories

Adding Stacy, deleting RPMS.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/28/2020 2:03:39 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**CC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** FW: DIAGNOSTIC TESTING DOCUMENT
**Attachments:** Plan to Increase COVID-19 Testing in the US 2-28-20 FINAL JVL_JB.docx; ATT00001.htm; UNMC CLEAN - Plan to Increase COVID-19 Testing in the US 2-28-20 FINAL JVL_JB.docx; ATT00002.htm

Adding some other folks.

The edits would allow (b) (5) [redacted]

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 1:53 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: DIAGNOSTIC TESTING DOCUMENT

---

**From:** Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
**Sent:** Friday, February 28, 2020 1:08 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>
**Subject:** Fwd: DIAGNOSTIC TESTING DOCUMENT

Comments and suggested edits from UNMC. I have not reviewed personally
Sent from my iPhone

Begin forwarded message:

**From:** "Lawler, James V" <james.lawler@unmc.edu>
**Date:** February 28, 2020 at 1:04:43 PM EST
**To:** "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>
**Cc:** "Hinrichs, Steven H" <shinrich@unmc.edu>, "Iwen, Peter C" <piwen@unmc.edu>, "Kratochvil, Christopher J" <ckratoch@unmc.edu>, "Broadhurst, Mara J" <jana.broadhurst@unmc.edu>
**Subject: DIAGNOSTIC TESTING DOCUMENT**

Bob,
Please find attached tracked and clean versions of our edits on FDA document on rapid test network.
james

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**James Lawler, MD, MPH, FIDSA**

Executive Director, International Programs & Innovation
Global Center for Health Security, and
Associate Professor of Medicine
Division of Infectious Diseases
University of Nebraska Medical Center
m: (b) (6)
james.lawler@unmc.edu

The information in this e-mail may be privileged and confidential, intended only for the use of the addressee(s) above. Any unauthorized use or disclosure of this information is prohibited. If you have received this e-mail by mistake, please delete it and immediately contact the sender.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/25/2020 11:32:25 PM
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**CC:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Mitchell, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=715a1fb727db4c3b9a2fa223cacec85d-Diane.Mitch]; Kannan, Lakshmi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8efc4e7e0adb4246a67ca3e110e46bd6-Lakshmi.Kan]
**Subject:** Re: COVID Congressional Engagement

Will do.

Jeff

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 25, 2020 at 10:45:50 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Mitchell, Diane <Diane.Mitchell@fda.hhs.gov>, Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>
**Subject:** FW: COVID Congressional Engagement

Jeff,

OL just sent additional intel and suggestions for tomorrow's briefing, below. As noted, all Senate HELP Health LAs will be invited. OL is asking that in addition to walking through the responses to the bipar HELP Qs (attached), you and Janet each provide an overview including the state of play, our outreach efforts, what we know (and don't know) to date, discussion of reporting authorities (or in our case – the lack thereof), and correcting the record (for Janet it will be addressing the Axios piece; for us, you could take the opportunity to discuss our record on EUAs and the importance of those authorities in emergency situations). I do concur with OL that you should be prepared for COVID-19 questions outside the Senate bipar list.

I've also highlighted the point from staff below that they will appreciate context for the numbers.

Please note, (b) (5)

(b) (5)

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(b) (5)

[redacted]

Please do let me know if you have any questions or concerns on the overall plan for tomorrow, and if there is anything else you want to be sure we cover during tomorrow's 9 am prep.

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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---

**From:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 10:19 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Ken and Jennifer,

The committee staff is planning to invite all HELP LA's to the briefing, and we should expect additional questions in the drug and device space, outside of the QA doc to come up. Margaret did state that walking through the questions sounds good, and providing a general update would be nice for folks on the phone that haven't heard one from FDA. She also stated "In general, all the numbers you all shared, while they are very helpful, it would be also great to have in context – for example, where we have the number of facilities in China, do we also have the number of facilities globally? Recognizing there is a volume component there too."

(b) (5)

[redacted]

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(b) (5)

[redacted]

Thanks,
Prakash

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:43 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Same!

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

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---

**From:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:42 PM
**To:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

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Phone works for us.

**From:** Rath, Prakash (FDA)
**Sent:** Tuesday, February 25, 2020 4:41 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Thank you, and about to send.

For the briefing, we secured the EOC exec conference room, 32-1337, and center directors should have access from what I'm told. For the prep, it may be easier to do it by the phone, but please let us know otherwise.

**From:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:40 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

I'm getting the 100% from JW, but if 9:00 – 9:30 still works lets lock it in and get out the invites.

Please also invite per her request:

Cindy Buhse (Lucinda)
Val Jenson; and
John Farley

**From:** Van Pool, Kendall
**Sent:** Tuesday, February 25, 2020 4:04 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Thanks so much.

We are still holding both windows so lock in and please send through the invite.

I'll check in on the prep time.

Can you include:

Janet Woodcock
Kendall Van Pool
Patrizia Cavazzoni (OPTIONAL if she can make it)

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**From:** Tomasello, Jennifer
**Sent:** Tuesday, February 25, 2020 4:00 PM
**To:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Prakash,

Thank you for confirming! Let me check on prep as we need to rearrange a couple things here. Will circle back.

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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**From:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:57 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Hi all,

Just heard from HELP and 12-1 works for them. We'll find a room and send an invite shortly. Regarding a prep, I mentioned below that maybe we could look for times today, but it seems pretty late now.

Do you think Drs. Woodcock and Shuren would like/need a prep, and if so, could we use 15-30 min from 9-10 tomorrow? Please let us know.

Thanks,
Prakash

**From:** Rath, Prakash (FDA)
**Sent:** Tuesday, February 25, 2020 8:47 AM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black,

AMERICAN OVERSIGHT

Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

We inquired about these times and will circle back once we hear from the committee. Please 'hold' for now. If you feel it's necessary (and time permits), we can look for a quick prep time this afternoon.

Thanks,
Prakash

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 5:52 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

No worries and thank you! OL – please see if one of those two windows will work for staff.

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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**From:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 4:59 PM
**To:** Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** FW: COVID Congressional Engagement

These windows will work for JW on Wednesday. Sorry for the back and forth on this!

Ken

AMERICAN OVERSIGHT

**From:** Thomas, Ashley
**Sent:** Monday, February 24, 2020 4:57 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

9-10 am and 12-1 pm will work.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 3:31:41 PM
**To:** Tomasello, Jennifer (Jennifer.Tomasello@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=Jennifer.Tomasello]

**Subject:** FW: Pre-Briefing Meeting for Call with Approps Subcommittee Staff on COVID-19 Funding Needs
**Location:** Dial In: 1-877-465-7975; 15596991#

**Start:** 2/27/2020 3:30:00 PM
**End:** 2/27/2020 4:00:00 PM
**Show Time As:** Tentative

-----Original Appointment-----
**From:** Price, William
**Sent:** Thursday, February 27, 2020 2:06 PM
**To:** Price, William; McBride, Maren; Lenihan, Keagan; Tyler, James; Tootle, William; Woodcock, Janet; Shuren, Jeff; Marks, Peter; Hinton, Denise; McMeekin, Judith; Cavazzoni, Patrizia; Solomon, Steven M; Klimczak, Katherine; Van Pool, Kendall; Stone, Eric; Tierney, Julia; Forfa, Tracey; Leary, Mary; Hussey, Deirdre
**Cc:** Anderson, Lori (Henry); Trivedi, Aalap
**Subject:** Pre-Briefing Meeting for Call with Approps Subcommittee Staff on COVID-19 Funding Needs
**When:** Thursday, February 27, 2020 3:30 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** Dial In: 1-877-465-7975; 15596991#

Folks—Our call with Approps is today at 4:00. William Price will send an invite for an internal 3:30 call and then the 4:00 call with the Hill. Rough agenda for us to follow is below. (b) (5) [redacted] I will also share that with the Hill when they have it done. Thanks!

## Agenda

1. **Opening (Denise)**

(b) (5) [redacted]

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 10:34:00 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: (b) (5)

Tim,

(b) (5)

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 27, 2020 at 10:10:26 AM EST
**To:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: (b) (5)

I am in the (b) (5) Might not take an hour but need to focus on that key meeting.
Tim

---

**From:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>
**Date:** February 27, 2020 at 10:05:28 AM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** RE: (b) (5)

Hi Elizabeth, Tim now has a 11 – 12pm meeting on schedule from the CDC that may conflict with this 1130 call.

I'm sure he will chime in if can still make this call.

Jennifer

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 8:50 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Cc:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>
**Subject:** RE: (b) (5)

Thanks Tim

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Heather can you try for a call at 11:30 and Tim and I will do it together.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 27, 2020 at 8:44:36 AM EST
**To:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Cc:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>
**Subject:** RE: (b) (5) [redacted]

I am available at 11:30 am to noon today and I am free following a 3 pm with CBER on their efforts (b) (5) [redacted]

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 8:26 AM
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>
**Subject:** RE: (b) (5) [redacted]

Looping in Jennifer for Tim's calendar.

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 8:17 AM
**To:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: (b) (5) [redacted]

Yes. I can offer 11:30-noon and after 3. Adding Tim to see if he is interested and what his availability may be.

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**From:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Date:** February 27, 2020 at 8:04:04 AM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** RE: (b) (5) [redacted]

Sorry, today isn't good for Jeff. There is really nothing he can miss and is back to back all day.

Can we try and let you and/or Tim handle this one for him?

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 5:51 AM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Subject:** Fwd: (b) (5) [redacted]

Heather,
See below. Jeff will do a call today if Lindsay can make it work. If not, I can do it or we can reach out to Tim who is at CDC this week.
Elizabeth

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 27, 2020 at 4:27:54 AM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** Re: (b) (5) [redacted]

Elizabeth,

I'm happy to talk with Tremel today, if Lindsay can make it work; if not, then you or Tim. I agree we should clarify for them now.

Jeff

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Date:** February 26, 2020 at 11:03:58 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: (b) (5) [redacted]

(b) (5) [redacted]

Elizabeth

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Date:** February 26, 2020 at 9:31:33 PM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** FW: (b) (5) [redacted]

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Hi Elizabeth,

(b) (5)

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: 240-507-3139
Email: Heather.Agler@fda.hhs.gov

---

**From:** Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
**Sent:** Wednesday, February 26, 2020 10:37 AM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Subject:** FW: (b) (5)

I just sent this to Jennifer and then realized I should have sent to you too. Any thoughts?

---

**From:** Faison, Tremel (OS/ASPR/BARDA)
**Sent:** Wednesday, February 26, 2020 10:37 AM
**To:** Ross, Jennifer (FDA/OC) <Jennifer.Ross@fda.hhs.gov>
**Subject:** (b) (5)

Hi Jennifer,

(b) (5)

Have you guys thought about this?

Thanks, Tremel

*Tremel A. Faison, MS, RAC, SCT(ASCP)*
Director (Acting)
Regulatory and Quality Affairs Division (RQA)
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Emergency Response and Preparedness (ASPR)
U.S. Department of Health and Human Services (HHS)

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330 Independence Avenue, SW
Room G644
Washington, DC 20201

Phone: (202) 692-4764
Cell: (b) (6)
tremel.faison@hhs.gov

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 10:03:12 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** FW: Pre-EUA IVD template request
**Attachments:** Draft cover letter for Sponsor 01212020.docx; EUA Review Template_NAT_Novel Coronavirus 1.19.2020.doc

Additional communication — as of February 25th Wadsworth hadn't finished validating their test.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 27, 2020 at 10:01:33 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Pre-EUA IVD template request

FYI

---

**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:03 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Pre-EUA IVD template request

FYI – see information in red in the email below and:

Wadsworth:

(b) (5), (b) (4)

[redacted]

Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:50 PM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** RE: Pre-EUA IVD template request

Dear Jill,

Thank you very much for reaching out to us about the test you have validated at Wadsworth Center, NYS Department of Health it was very nice to chat with you. As discussed please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [formally - 2019-novel coronavirus (2019-nCoV)]. I suggest the first step is to populate this draft template with the validation information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center). The Pre-EUA review is an interactive process, so we will provide feedback after receiving and reviewing the information provided. The draft review template is a shared "work-in-progress" document which you will populate with information and data as obtained and which we will review and provide feedback to you. **Please make sure to capture in the EUA review template that you** (b) (4) [redacted]

I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of SARS-CoV-2 to FDA (it includes the address for the Document Control Center). Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under Section A (type of submission) please check "other" and specify Pre-EUA; please also complete Sections B, C, F and G. For G please use the information provided in this link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=3669.

One hard copy of the signed EUA Cover Letter and one electronic copy (CD or thumb drive) of you Pre-EUA submission package should be enclosed in your Pre-EUA submission package mailed to FDA (recommend FedEx). In addition to mailing your Pre-EUA package to FDA we also request that you submit the package to the review division via electronic mail (including the EUA Review Template in MS word) to myself Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;
- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please let me know if you have ANY questions I am happy to assist if you are not sure about certain sections in the template.
Best regards
Kim

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

---

**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Tuesday, February 25, 2020 1:08 PM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** Pre-EUA IVD template request

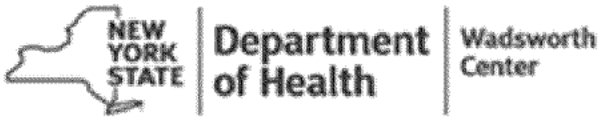
At your earliest convenience, I wish to request a copy of the most recent EUA review template relevant to an assay for the SARS-CoV-2 pathogen.

(b) (4)

Thank you,

**Jill Taylor, Ph.D.**
Director

Wadsworth Center, NYS Department of Health
Room E-260, Biggs Laboratory
(518) 474-3157 | jill.taylor@health.ny.gov
www.wadsworth.org




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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/24/2020 7:51:59 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** Re: (b) (5)

(b) (5)

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 24, 2020 at 7:37:19 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: Public health labs press FDA to allow homegrown coronavirus tests

Thoughts?

Sent from my iPhone

Begin forwarded message:

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>
**Date:** February 24, 2020 at 7:16:33 PM EST
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
**Subject: Public health labs press FDA to allow homegrown coronavirus tests**
**Reply-To:** "POLITICO subscriptions" <reply-fe971c727160017c75-553241_HTML-924728035-1376319-258397@politicoemail.com>

**Public health labs press FDA to allow homegrown coronavirus tests**

By David Lim

02/24/2020 07:15 PM EST

Public health laboratories urged the FDA on Monday to permit them to create their own tests for the coronavirus, after problems with a diagnostic developed by CDC prevented its widespread rollout.

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FDA typically allows "laboratory developed tests" — which are designed, manufactured and used within a single lab — to be used without close regulatory scrutiny. But the agency requires labs to submit such tests for review during health emergencies to prevent harm from false or misleading results from compounding a crisis. The coronavirus does not appear to be an exception.

"No test should be used without being validated," FDA spokesperson Stephanie Caccomo said. "In the context of a public health emergency, false results can lead to significant adverse public health consequences."

The FDA has traditionally shied away from allowing the use of LDTs in emergency situations. In 2016, the agency sent a letter to two Houston hospitals that created an LDT to rapidly detect the Zika virus, expressing concern that the agency had not reviewed the "high-risk" test.

But Association of Public Health Laboratories Executive Director Scott Becker said that the coronavirus requires a different approach. The virus is spreading in multiple countries, and the CDC's efforts to expand testing capability beyond its labs have run into trouble.

Only five state and local public health labs — in California, Nebraska, Illinois, Nevada and Tennessee — have verified the CDC diagnostic for use since the FDA approved it on an emergency basis on Feb. 4, he said.

APHL hopes to work with FDA to develop a policy that allows some labs to market a LDT without submitting it for FDA review, Becker told POLITICO — adding that it doesn't make sense for more than 100 labs to file individual emergency use authority applications.

**"**We believe a more expeditious route is needed at this time," Becker and Grace Kubin, director of the Laboratory Services Section at the Texas Department of State Health Services, wrote to FDA Commissioner Stephen Hahn on Monday.

**"** What we're suggesting is that public health labs be viewed as a group to do this," Becker told POLITICO. "It isn't every lab on their own — we would want to do this in a network sort of fashion. We could also enable confirmation at another public health laboratory to ensure confidence."

The letter says that labs could work together towards a standard protocol, purchase reagents and supplies from a common source and recommend a minimum standard approach for validating test results.

Caccomo says that the FDA is working with more than 70 test developers on products for the virus. The agency can complete reviews for such tests in as little as one day, she added — ensuring that it is effective and meets the minimum standards for emergency use.

Some major hospitals are also starting to develop LDTs for coronavirus screening, but are concerned that FDA rules do not permit them to actually start testing patients, according to Michael Mina, associate medical director of molecular diagnostics at Brigham and Women's Hospital.

"We're actually trying to get our test up and running, even though we don't know if we'll be able to use it," Mina said. "I know that Mass General Hospital is also thinking about doing something very similar. I presume all the major academic hospitals are at least considering it."

The American Clinical Laboratory Association, which represents large commercial labs like LabCorp and Quest Diagnostics, declined to comment on whether LDTs should be used to help increase the country's capacity to screen for the coronavirus. Historically, the lab industry trade lobby has maintained LDTs are not medical devices and subject to FDA regulation.

*To view online*:
https://subscriber.politicopro.com/health-care/article/2020/02/public-health-labs-press-fda-to-allow-homegrown-coronavirus-tests-1884096

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USA.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/25/2020 11:16:47 PM
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject:** FW: COVID Congressional Engagement
**Attachments:** Senate HELP Bipar followup questions 2.24.20.pdf

We also have been speaking with distributors, hospitals, hospitals associations, and industry trade associations, as well as working with HHS, CDC and other government bodies

(b) (5) [redacted]

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 25, 2020 at 10:45:50 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Mitchell, Diane <Diane.Mitchell@fda.hhs.gov>, Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>
**Subject:** FW: COVID Congressional Engagement

Jeff,

OL just sent additional intel and suggestions for tomorrow's briefing, below. As noted, all Senate HELP Health LAs will be invited. OL is asking that (b) (5) [redacted] I do concur with OL that you should be prepared for COVID-19 questions outside the Senate bipar list.

I've also highlighted the point from staff below that they will appreciate context for the numbers.

Please note, I did flag for (b) (5) [redacted]

(b) (5) [redacted]

Please do let me know if you have any questions or concerns on the overall plan for tomorrow, and if there is anything else you want to be sure we cover during tomorrow's 9 am prep.

Best,

Jennifer

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**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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---

**From:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 10:19 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Ken and Jennifer,

The committee staff is planning to invite all HELP LA's to the briefing, and we should expect additional questions in the drug and device space, outside of the QA doc to come up. Margaret did state that walking through the questions sounds good, and providing a general update would be nice for folks on the phone that haven't heard one from FDA. She also stated "In general, all the numbers you all shared, while they are very helpful, it would be also great to have in context – for example, where we have the number of facilities in China, do we also have the number of facilities globally? Recognizing there is a volume component there too."

(b) (5)



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Thanks,
Prakash

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:43 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Same!

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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---

**From:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:42 PM
**To:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Phone works for us.

---

**From:** Rath, Prakash (FDA)
**Sent:** Tuesday, February 25, 2020 4:41 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Thank you, and about to send.

AMERICAN OVERSIGHT

For the briefing, we secured the EOC exec conference room, 32-1337, and center directors should have access from what I'm told. For the prep, it may be easier to do it by the phone, but please let us know otherwise.

---

**From:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:40 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

I'm getting the 100% from JW, but if 9:00 – 9:30 still works lets lock it in and get out the invites.

Please also invite per her request:

Cindy Buhse (Lucinda)
Val Jenson; and
John Farley

---

**From:** Van Pool, Kendall
**Sent:** Tuesday, February 25, 2020 4:04 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Cc:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Thanks so much.

We are still holding both windows so lock in and please send through the invite.

I'll check in on the prep time.

Can you include:

Janet Woodcock
Kendall Van Pool
Patrizia Cavazzoni (OPTIONAL if she can make it)

---

**From:** Tomasello, Jennifer
**Sent:** Tuesday, February 25, 2020 4:00 PM
**To:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Prakash,

Thank you for confirming! Let me check on prep as we need to rearrange a couple things here. Will circle back.

Jennifer

AMERICAN OVERSIGHT

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

---

**From:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:57 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

Hi all,

Just heard from HELP and 12-1 works for them. We'll find a room and send an invite shortly. Regarding a prep, I mentioned below that maybe we could look for times today, but it seems pretty late now.

Do you think Drs. Woodcock and Shuren would like/need a prep, and if so, could we use 15-30 min from 9-10 tomorrow? Please let us know.

Thanks,
Prakash

---

**From:** Rath, Prakash (FDA)
**Sent:** Tuesday, February 25, 2020 8:47 AM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

We inquired about these times and will circle back once we hear from the committee. Please 'hold' for now. If you feel it's necessary (and time permits), we can look for a quick prep time this afternoon.

Thanks,
Prakash

---

AMERICAN OVERSIGHT

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 5:52 PM

**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

No worries and thank you! OL – please see if one of those two windows will work for staff.

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

---

**From:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 4:59 PM
**To:** Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** FW: COVID Congressional Engagement

These windows will work for JW on Wednesday. Sorry for the back and forth on this!

Ken

---

**From:** Thomas, Ashley
**Sent:** Monday, February 24, 2020 4:57 PM
**To:** Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>
**Subject:** RE: COVID Congressional Engagement

9-10 am and 12-1 pm will work.

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/27/2020 4:41:41 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: RE: UC Testkit information.

Thank you. Please let me know what you learn.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 4:41 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** RE: UC Testkit information.

I am calling her now. Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 4:40 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: UC Testkit information.

Uwe,

Can you or one of your folks reach out to (b) (5) [redacted]

Jeff

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>
**Sent:** Thursday, February 27, 2020 4:33 PM
**To:** Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: UC Testkit information.

AM OVERSIGHT

Thanks much Bob.

I am copying Keagan and Jeff.
Steve

Sent from my iPad

On Feb 27, 2020, at 3:37 PM, Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov> wrote:

Here is the information that was just forwarded to me. B

---

**From:** Rachel Nosowsky <Rachel.Nosowsky@ucop.edu>
**Sent:** Thursday, February 27, 2020 3:17 PM
**To:** Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
**Subject:** RE: Testkit
**Importance:** High

OK, just got clarification, here's where we are:

1. We have one lab at the Chan-Zuckerberg Biohub run by Joe Derisi (https://profiles.ucsf.edu/joe.derisi) that has been working with the Bill & Melinda Gates Foundation. I understand this lab played a role in the index case in Cambodia and have been helping folks in multiple countries. They believe they can rapidly turn the Biohub into a testing facility capable running several thousand tests/day, using what sounds like the same test that CDC is using. They have the necessary space, infrastructure, molecular biology, and data science teams at the ready. I'm expecting a brief bulleted write-up in the next 20 minutes or so that I can send you to introduce you to this lab. They already work with public health departments and health facilities around the country and would be able and willing to accept kits from throughout California and beyond. They already have BUA to receive inactivated human samples.

2. Derisi's lab and a separate lab run by Charles Chiu are also working on rapid assays using CRISPR technology. Here are a couple of articles. I will have more information for you on the Chiu option later today (he's unavailable before 2pm Pacific).

https://www.sfchronicle.com/bayarea/article/Coronavirus-UCSF-expert-working-on-quicker-15014490.php
https://www.nytimes.com/2020/02/24/health/genomic-diagnostic-tests.html
https://profiles.ucsf.edu/charles.chiu

I'm on cell 24/7 if you need anything in the meantime. Cell is (b) (6)
- R

**Rachel Nosowsky**
University of California
(510) 987-9407

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/24/2020 11:29:53 PM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** Fwd: PREP Act liability coverage

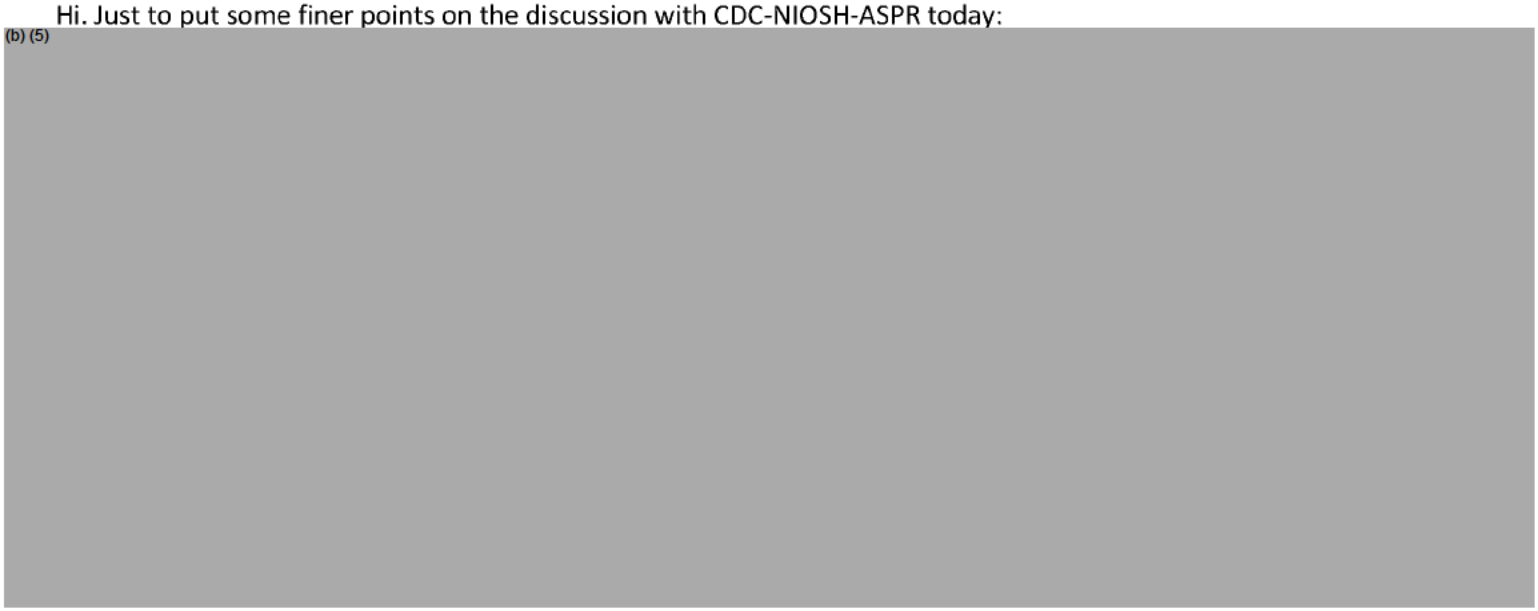
FYI

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Date:** February 24, 2020 at 11:09:57 PM EST
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: PREP Act liability coverage

Hi. Just to put some finer points on the discussion with CDC-NIOSH-ASPR today:

(b) (5)



**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 7:04 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** RE: PREP Act liability coverage

Great - adding Michael so he's also engaged as we discuss options/next steps.

Thanks!

Denise

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 24, 2020 at 6:54:20 PM EST
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Amin, Stacy

AMERICAN OVERSIGHT

<Stacy.Amin@fda.hhs.gov>
**Subject:** RE: PREP Act liability coverage

I think we can talk tomorrow. Not sure this will come up with the Senators tomorrow and he can be more generic on steps we are taking. Thanks.

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:44 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: PREP Act liability coverage

Would you like to discuss this evening or in the morning as the information may be useful for Dr. Hahn tomorrow?

Thanks,

Denise

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:25 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** RE: PREP Act liability coverage

+Stacy

WE should discuss how we want to handle this and the proactive comms piece. Would be nice to couple.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:23 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Subject:** FW: PREP Act liability coverage

(b) (5) [redacted]

Happy to discuss.

Jeff

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 6:06 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** PREP Act liability coverage

Jeff,
I wanted to update you on (b) (5) [redacted]

As we've discussed, (b) (5) [redacted]
Suzanne

AMERICAN OVERSIGHT

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov




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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/24/2020 4:15:44 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: COVID-19 Diagnostics Validation materials (update Feb 24, 2020)

Deliberative/Predecisional

I agree

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 24, 2020 at 4:12:10 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: COVID-19 Diagnostics Validation materials (update Feb 24, 2020)

Deliberative / Pre-decisional

Hi Jeff and Uwe,

(b) (5)

[redacted]

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

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**From:** Huynh, Chuong (OS/ASPR/BARDA) <Chuong.Huynh@hhs.gov>
**Sent:** Monday, February 24, 2020 3:22 PM

**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Smith, Lia H (CDC) <loh5@cdc.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Humes, Rosemary (OS) <Rosemary.Humes@hhs.gov>
**Subject:** COVID-19 Diagnostics Validation materials (update Feb 24, 2020)

Hi,

- **Diagnostics validation materials:**

(b) (5)

Chuong Huynh
Currently assigned to COVID-19 response - ASPR/BARDA liaison to CDC-Atlanta
HHS/OS/ASPR/BARDA/IEID
Mobile: (b) (6)
Email: Chuong.Huynh@hhs.gov
https://www.medicalcountermeasures.gov/

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 7:52:04 AM
**To:** Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** FW: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

(b) (5) [redacted]

Jeff

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 7:19 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

(b) (5) [redacted]

Sent from my iPhone

On Feb 26, 2020, at 7:18 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thoughts? (b) (5) [redacted]

Sent from my iPhone

Begin forwarded message:

**From:** Julie Khani <jkhani@acla.com>
**Date:** February 26, 2020 at 7:16:24 PM EST
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
**Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing**

It's a hotel ballroom. I could look into videoconferencing?

Also, just FYI, I reached out to Danielle Steele on this as well, re both FDA and CDC participation.

Sent from my iPhone

On Feb 26, 2020, at 5:41 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Not sure we could get anyone to do it in person. Could the FDA person participate by phone?

---

**From:** Julie Khani <jkhani@acla.com>
**Sent:** Wednesday, February 26, 2020 2:52 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

AMERICAN OVERSIGHT

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available here.

I am reaching out because in addition to Commissioner Hahn's remarks, I think the ACLA meeting would provide an excellent opportunity for the FDA to address the diagnostics community about the Coronavirus. I've extended the same invitation to the CDC. There will be approximately 200 people in attendance at the meeting, including CEOs and senior leadership from companies such as LabCorp, Quest, Mayo Clinic Laboratories, Hologic, and Siemens. ACLA and several member companies have a weekly call with the CDC, and the FDA has participated on some of the calls. We have shared information with the CDC about lab capacity and other information, in the event that public health labs are unable to handle testing needs, and surge capacity is necessary.

While these calls have been helpful, numerous questions remain about the availability of the CDC assay to commercial labs, the FDA EUA process, and other issues. I'd be happy to modify the agenda to allow time for a representative from the FDA, CDC, or both, to provide an update an answer questions.

I know the situation is changing quickly, and I can only imagine how busy it is at the FDA. But, as a lot of the key players in the diagnostics community will be together at our meeting next week, I wanted to extend the opportunity.

My office and mobile numbers are below if you have questions or if you would like to discuss.

Thanks.

Julie

**Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) ** (b) (6) **(m)**

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/26/2020 9:11:17 PM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**CC:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**Subject:** Re: N95 EUA for COVID19

Yep

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 26, 2020 at 9:05:38 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Re: N95 EUA for COVID19

Actually I was just thinking the same thing. (b) (5) [redacted]

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: 202-841-9996

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 26, 2020 at 9:03:47 PM EST
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Re: N95 EUA for COVID19

(b) (5) [redacted]

Jeff

---

AMERICAN OVERSIGHT

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>

**Date:** February 26, 2020 at 8:51:44 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Fwd: N95 EUA for COVID19

(b) (5)

[redacted]

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: 202-841-9996

---

**From:** D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
**Date:** February 26, 2020 at 8:46:43 PM EST
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Pillai, Satish K (CDC) <vig8@cdc.gov>, Yu, Yon C (CDC) <fkb8@cdc.gov>, Patel, Anita (CDC) <bop1@cdc.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Delaney, Lisa (CDC) <lkd2@cdc.gov>, Dowell, Chad (CDC) <crd7@cdc.gov>
**Cc:** Miller, Colleen S (CDC) <hku6@cdc.gov>, Peterson, Jeffrey A (CDC) <jap3@cdc.gov>
**Subject:** RE: N95 EUA for COVID19

Dear FDA Colleagues,

CDC/NIOSH appreciates the opportunity to discuss the Emergency Use Authorization to permit the use of NIOSH-approved filtering facepiece respirators currently not cleared by the FDA in healthcare settings.

(b) (5)

[redacted]

Please copy all CDC folks on this message when submitting the draft to us for review.

AMERICAN OVERSIGHT

Thank you,

Maryann

**Maryann M. D'Alessandro, PhD**
Director
HHS/Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety & Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
626 Cochrans Mill Rd
Building 141, Rm 105
Pittsburgh, PA 15236

Office: (412) 386-4033
Mobile: (412) 760-3449
bpj5@cdc.gov




-----Original Appointment-----
**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 7:45 AM
**To:** Schwartz, Suzanne; Flannery, Ellen (FDA/CDRH); Ross, Aftin (FDA/CDRH); Tomasello, Jennifer (FDA/CDRH); Pillai, Satish K. (CDC/DDID/NCEZID/DPEI); Yu, Yon C. (CDC/DDID/NCEZID/DPEI); D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL); Patel, Anita (CDC/DDID/NCIRD/OD); Courtney, Brooke (FDA/OC); Delaney, Lisa (CDC/NIOSH/OD); Dowell, Chad (CDC/NIOSH/OD)
**Subject:** N95 EUA for COVID19
**When:** Wednesday, February 26, 2020 2:30 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** Suzanne's Office/ WebEx below

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**From:** D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
**Date:** February 26, 2020 at 7:08:46 AM EST
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Patel, Anita (CDC) <bop1@cdc.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Pillai, Satish K (CDC) <vig8@cdc.gov>, Yu, Yon C (CDC) <fkb8@cdc.gov>, Delaney, Lisa (CDC) <lkd2@cdc.gov>, Dowell, Chad (CDC) <crd7@cdc.gov>
**Subject:** RE: N95 EUA

+ Lisa Delaney
+ Chad Dowell

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 12:13 AM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Cc:** Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Ross, Aftin (FDA/CDRH) <Aftin.Ross@fda.hhs.gov>; Tomasello, Jennifer (FDA/CDRH) <Jennifer.Tomasello@fda.hhs.gov>; Pillai, Satish K. (CDC/DDID/NCEZID/DPEI) <vig8@cdc.gov>; Yu, Yon C. (CDC/DDID/NCEZID/DPEI) <fkb8@cdc.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
**Subject:** RE: N95 EUA

That works on our end. We'll provide an invite with a call-in.
TY! get some rest…

Suzanne

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov




AMERICAN OVERSIGHT

*Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.*

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Sent:** Wednesday, February 26, 2020 12:12 AM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Pillai, Satish K (CDC) <vig8@cdc.gov>; Yu, Yon C (CDC) <fkb8@cdc.gov>; D'alessandro, Maryann M (CDC) <bpj5@cdc.gov>
**Subject:** RE: N95 EUA

How about 2:30?
+ Yon from CDC reg affairs

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 11:52 PM
**To:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
**Cc:** Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Ross, Aftin (FDA/CDRH) <Aftin.Ross@fda.hhs.gov>; Tomasello, Jennifer (FDA/CDRH) <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** N95 EUA
**Importance:** High

Anita,

(b) (5)

Can you spare 30 minutes tomorrow for us to discuss?
I will do my best to accommodate to your availability as I'm sure your time is overcommitted.
The only times I absolutely cannot get on a call tomorrow (Wednesday) is 9-9:30 and noon to 1pm.

Suzanne

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
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-- Do not delete or change any of the following text. --

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/29/2020 8:50:52 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: NYS Wadsworth Center COVID-19

Yes, I believe Redfield spoke with him after speaking with Steve.

(b) (5) [redacted]

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:49 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: NYS Wadsworth Center COVID-19

Sorry, didn't realize you weren't copied. Just spoke to Dan. Sounds like to today the CDC is willing to have (b) (4) [redacted] under their EUA and they are willing to do lot release testing. Stay tuned.

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Saturday, February 29, 2020 8:10 AM
**To:** Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
**Subject:** RE: NYS Wadsworth Center COVID-19

Thank you Dan! We will follow up with similar requests for (b) (4) [redacted] which have built kits on the CDC design.

AMERICAN OVERSIGHT

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

---

**From:** Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
**Sent:** Saturday, February 29, 2020 8:06 AM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
**Subject:** NYS Wadsworth Center COVID-19

Dr Hahn:
Yes, The New York State Wadsworth Center can reference the data in the CDC's 2019 nCoV EUA application.
Dan

Daniel B. Jernigan, MD MPH
Director, Influenza Division
Captain, USPHS (RET)
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Atlanta, GA 30329
Phone 404-639-2621, Cell 404-375-7508
djernigan@cdc.gov, www.cdc.gov/flu

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Friday, February 28, 2020 7:50 PM
**To:** Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Rose, Laura E. (CDC/DDPHSS/OLSS/OLS) <zey9@cdc.gov>
**Cc:** Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
**Subject:** NYS Wadsworth Center COVID-19 Test
**Importance:** High

Wendi, Dan, Laura,

AMERICAN OVERSIGHT

NYS Wadsworth Center submitted an EUA request to us this afternoon for a test that uses the CDC protocol but only for N1/N2 (consistent with the CDC test currently subject to enforcement discretion). To support their EUA, Wadsworth conducted a bridging study that demonstrates performance similar to CDC's N1/N2 test. We know their performance is comparable because we have seen CDC's data but Wadsworth has not. **Would CDC allow Wadsworth to have a right of reference to its data, under which does not get access to the data but can reference it in support of their EUA?** Wadsworth has one more test to perform, which if it looks good, we would otherwise grant the EUA.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/27/2020 7:30:21 AM
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]
**Subject:** Re: Hill call tomorrow after 1:00

Yes, just wanted to keep folks in the loop.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 27, 2020 at 7:11:23 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Subject:** Re: Hill call tomorrow after 1:00

Thank you. (b) (5) [redacted]

Best,

Jennifer

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 27, 2020 at 4:31:50 AM EST
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Subject:** Fwd: Hill call tomorrow after 1:00

Here is initial material from Maren. She is requesting (b) (5) [redacted]

Jeff

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>
**Date:** February 26, 2020 at 11:14:38 PM EST
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Tyler, James <James.Tyler@fda.hhs.gov>, Tootle, William <William.Tootle@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>, Price, William <William.Price@fda.hhs.gov>, Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>, Stone, Eric <Eric.Stone@fda.hhs.gov>, Tierney, Julia <Julia.Tierney@fda.hhs.gov>
**Subject:** RE: Hill call tomorrow after 1:00

AMERICAN OVERSIGHT

Folks-

I am still working with the Hill to find a time or us to all chat tomorrow afternoon but it will be after 2:00. Once I nail down a time from the Hill, I will also schedule a short, internal prep call for us all to talk through a good game plan for the call.

For awareness, below (the notes in red are mine) and attached are some of the questions I got from the committee earlier that I think we will need to cover on the call.

Again, thank you in advance for your help. I know there are a lot of moving pieces right now but hopefully this will be time well spent for the Agency's current and ongoing efforts.

**Funding:**

- Provide a breakdown by center and field for all funding (b) (5)

- Which activities are currently being undertaken out of FY 2020 funds and how much has been spent to date? (b) (5)

- For all lines, explain why these activities cannot be funded out of the base. Some potential items are noted on the attachment. Can walk through on call

- What the cost drivers behind the estimates, (i.e., lab work, people, IT)?
  - Please share data/numbers on how the estimates were built and include an FTE estimate for each of the four COVID Response Activities ok

- Are any of these activities brand-new to FDA and if so, which ones and how was the cost estimate derived? Believe this answer is no but will confirm on call tomorrow

- Why is the funding proposed for two years? Would potential new FTEs become wrapped into the baseline S&E account in future years? Can walk through on call

AMERICAN OVERSIGHT

**Overarching themes:**

- How does FDA envision managing this long-term? We can walk though ebola or zika in how we managed those to give you a sense of long term picture of efforts

- Does FDA need any new legislative authority to carry out these activities? Is so, please provide the language. We can discuss on call (CDRH/CDER)

- Do any of these activities implicate other HHS op-div activities? Yes—working with several. Can walk through tomorrow on which ones

**Centers:**

- Are any of these activities eligible for user fee funding? Some potential items are noted on the attachment. (b) (5) [redacted]

- For the planned hires, how many and how would the hires be completed (special authorities, contract…)? All

- What is the timeframe for a potential coronavirus vaccine? Can walk through on call (CBER/OC)

- Please explain in greater detail the potential for drug shortages should coronavirus continue to spread. Can walk through on call (CDER)

---

**From:** McBride, Maren
**Sent:** Wednesday, February 26, 2020 6:09 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Price, William <William.Price@fda.hhs.gov>
**Subject:** RE: Hill call tomorrow after 1:00

AMERICAN OVERSIGHT

Thank you Keagan. Adding Judy bc I forgot earlier (sorry!)

Attached is what was sent to the Hill earlier based on info your teams shared with OB for your reference.

The preliminary feedback I just got from the Hill was they need to understand the big picture/message here—in very simple terms. They are working under a VERY expedited timeline here (will have the bill drafted by Friday) so they are looking for basic facts/needs in plain English.

The specific cost-drivers for our needs is what they need to better understand—and why that work can't be done with our base funds (say for example on MCMs—we get funding for that work so why is more needed?) Are we hiring staff? If not, what are the funds specifically for?

As I mentioned earlier, I am supposed to get some questions later tonight but wanted to relay the preliminary feedback I got. They are supportive—we just need to arm them with the details and justification so they can get members on board.

I will also try to set up a quick pre-call tomorrow for us to touch base prior to speaking with the Hill so we can all get on the same page.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 5:36 PM
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Price, William <William.Price@fda.hhs.gov>
**Subject:** RE: Hill call tomorrow after 1:00

(b) (5)

Thank you!

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 4:38 PM
**To:** Tyler, James <James.Tyler@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Price, William <William.Price@fda.hhs.gov>
**Subject:** Hill call tomorrow after 1:00

AMERICAN OVERSIGHT

Folks—the Approps staff would like to speak with us tomorrow (sometime after 1:00) related to the supplemental for coronavirus and FDA's needs. I am supposed to get some specific questions/areas they would like to discuss with us and can circulate tonight. Just wanted to put on everyone's radar. I'll keep you posted.

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/26/2020 2:15:59 PM
**To**: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]
**CC**: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
**Subject**: Re: TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

Many thanks.

Jeff

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 26, 2020 at 2:11:30 PM EST
**To:** Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
**Subject:** Re: TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

Thanks all.

Sent from my iPhone

On Feb 26, 2020, at 2:09 PM, Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov> wrote:

Response attached.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 8:53 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
**Subject:** Re: TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

Lindsay- can you make sure you format the letter when it comes back and get to Frank for a signature and he can scan and send it to you Jeff?

Sent from my iPhone

On Feb 26, 2020, at 4:48 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

AMERICAN OVERSIGHT

Keagan,

Once Michael has the letter cleared, we would need the letter put on FDA letterhead, signed by Dr. Hahn, and then a scanned copy emailed to CDRH (me) so I can email it to APHL before 4:30 PM. Is that enough time and is there someone on your end who can take the hand off from Michael?

Jeff

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Date:** February 26, 2020 at 12:52:00 AM EST
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Fisher, Robert <Robert.Fisher@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

Will do thx

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Wednesday, February 26, 2020 12:31 AM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs

Hi Michael,

CDRH is submitting a response to the letter received by Dr. Hahn regarding a request from the Association of Public Health Laboratories (APHL) regarding enforcement discretion of LDTs for the coronavirus. We wanted to raise this to the IMG and obtain clearance. The deadline is to have clearance by **4 pm Wednesday (2/26/2020)** before a teleconference meeting with APHL at 4:30 pm. Please let us know if you have any questions.

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: 240-507-3139
Email: Heather.Agler@fda.hhs.gov

<APHL Final Response Letter.pdf>
<EUA Review Template_NAT_Novel Coronavirus 1.19.2020.doc>

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/24/2020 9:17:14 PM
**To**: Wilkerson, Jessica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=584d09c8b36143839192c7e90e7aa84d-Jessica.Wil]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Kyprianou, Iacovos [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d9bfcd0b50847f18dbf63c27cfda580-ISK]; Simone, Lisa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bef29ca2bf64bbd90a60c7cfc45176b-LKS]; Hazelett, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9806d6b1350d4b1693d1d1f0f6cd52a9-Matthew.Haz]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Hoshi, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e381bd6e59d045da953e80dbe3499a2e-Ryan.Hoshi]
**Subject**: Re: Monday, February 24 Update on Response to Cybersecurity Signal (SweynTooth)

TY

---

**From:** Wilkerson, Jessica <Jessica.Wilkerson@fda.hhs.gov>
**Date:** February 24, 2020 at 9:15:22 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Kyprianou, Iacovos <Iacovos.Kyprianou@fda.hhs.gov>, Simone, Lisa <Lisa.Simone@fda.hhs.gov>, Hazelett, Matthew <Matthew.Hazelett@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Hoshi, Ryan <Ryan.Hoshi@fda.hhs.gov>
**Subject:** Re: Monday, February 24 Update on Response to Cybersecurity Signal (SweynTooth)

Jeff —

I'll work with the team tomorrow to get a contact for Singapore HSA so we—or they—can reach out to the researchers and ensure they are aware of the potential safety risks, given that the vulnerabilities impact medical devices.

JLW

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 24, 2020 at 20:45:42 EST
**To:** Wilkerson, Jessica <Jessica.Wilkerson@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Ricci, Linda J

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<Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Kyprianou, Iacovos <Iacovos.Kyprianou@fda.hhs.gov>, Simone, Lisa <Lisa.Simone@fda.hhs.gov>, Hazelett, Matthew <Matthew.Hazelett@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Hoshi, Ryan <Ryan.Hoshi@fda.hhs.gov>
**Subject:** Re: Monday, February 24 Update on Response to Cybersecurity Signal (SweynTooth)

Jessica,

Since the researchers are in Singapore is (b) (5)
(b) (5)

Jeff

---

**From:** Wilkerson, Jessica <Jessica.Wilkerson@fda.hhs.gov>
**Date:** February 24, 2020 at 8:22:22 PM EST
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Kyprianou, Iacovos <Iacovos.Kyprianou@fda.hhs.gov>, Simone, Lisa <Lisa.Simone@fda.hhs.gov>, Hazelett, Matthew <Matthew.Hazelett@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>
**Subject:** Monday, February 24 Update on Response to Cybersecurity Signal (SweynTooth)

Good evening –

**Bottom Line Up Front:** CDRH continues to respond to the "SweynTooth" vulnerabilities. As indicated in our update on Friday (the 21st), CDRH's concern regarding the "SweynTooth" vulnerabilities are increasing as we have learned about the possibility that this vulnerability may be remotely executed or leveraged as part of a pivot attack (i.e. from a network to a device). Concern is further heightened as we heard from an ISAO partner that the researchers may release additional exploit code (the timing of this potential release is unknown).

As detailed in our initial communication below, on Tuesday, February 18th, CDRH was made aware of a suite of vulnerabilities collectively termed "SweynTooth." CDRH has continued to work expeditiously with internal and external stakeholders to respond to these vulnerabilities. Updated details regarding these activities are provided below:

- Impact Assessment

(b) (5)

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(b) (5)

- FDA Internal Communications/Coordination

(b) (5)

- External Partners Communications/Coordination

(b) (5)

**Jessica Wilkerson**
*Cyber Policy Advisor*
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-837-7440
Cell: (b) (6)

---

**From:** Wilkerson, Jessica
**Sent:** Friday, February 21, 2020 7:51 PM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Kyprianou, Iacovos <Iacovos.Kyprianou@fda.hhs.gov>; Simone, Lisa <Lisa.Simone@fda.hhs.gov>; Hazelett, Matthew <Matthew.Hazelett@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>
**Subject:** Friday, February 21 Update on Response to New Cybersecurity Signal (SweynTooth)

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Good evening –

**Bottom Line Up Front:** CDRH's concern regarding the "SweynTooth" vulnerability is increasing as we have learned about the possibility that this vulnerability may be remotely executed or leveraged as part of a pivot attack (i.e. from a network to a device). Concern is further heightened as we are aware that the researchers may release additional exploit code (the timing of this potential release is unknown).

As detailed in our initial communication below, on Tuesday, February 18th, CDRH was made aware of a suite of vulnerabilities collectively termed "SweynTooth." CDRH has continued to work expeditiously with internal and external stakeholders to respond to these vulnerabilities. Details regarding these activities are provided below:

- Impact Assessment

(b) (5)



- FDA Internal Communications/Coordination

(b) (5)



- Government Partners Communications/Coordination

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(b) (5)

- External Partners Communications/Coordination

(b) (5)

Please let me know if there are any questions, thank you.

**Jessica Wilkerson**
*Cyber Policy Advisor*
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-837-7440
Cell: (b) (6)

---

**From:** Wilkerson, Jessica
**Sent:** Thursday, February 20, 2020 10:33 AM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen

AMERICAN OVERSIGHT

<Ellen.Flannery@fda.hhs.gov>
**Cc:** Kyprianou, Iacovos <Iacovos.Kyprianou@fda.hhs.gov>; Simone, Lisa <Lisa.Simone@fda.hhs.gov>; Hazelett, Matthew <Matthew.Hazelett@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>
**Subject:** Update on Response to New Cybersecurity Signal (SweynTooth)

Good morning –

Two days ago, CDRH was made aware from a press inquiry of a suite of vulnerabilities related to the Bluetooth Low Energy (BLE) protocol that may impact certain medical devices that contain the affected chipsets. According to the researchers that disclosed the vulnerabilities, the "SweynTooth" vulnerabilities may allow actors to crash devices, to force them into a "deadlocked" state where the device becomes nonresponsive or may automatically restart, or to bypass security features. The research team has also posted Proof-of-Concept code on GitHub. Preliminary analysis of FDA databases identified more than 800 different medical devices that might be susceptible to these vulnerabilities.

Based on the information we have so far, including the nature and significance of these vulnerabilities, the possible impacts to patient health and the number of devices impacted, (b) (5)
(b) (5)

Planned response:
(b) (5)

Impact on operations:

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(b) (5)

**Jessica Wilkerson**

*Cyber Policy Advisor*

**Office of Strategic Partnerships and Technology Innovation (OST)**

**Center for Devices and Radiological Health**

**U.S. Food and Drug Administration**

**Tel: 301-837-7440**

**Cell:** (b) (6)

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/25/2020 1:20:40 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Uwe – can you/someone on your team please reach out to IDT now to see if the kits are available?

Tim – can you please talk with CDC that we would have the public health labs that received CDC's test obtain new primers/probes from IDT and verify their use with the material already provided in their CDC kit and make sure we are all on the same page. CDC should communicate this to the labs unless you think it should come from us. We can contact APHL now to let them know and include this in the response letter we send to them.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 1:05 PM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

If the kits of the company are available, the labs could use the verification material they already have from their CDC kit.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 12:51 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Deliberative/PreDecisional

The CDC has not received kits from IDT yet, doesn't expect them for 2-3 weeks. CDC says they may be advertising kits but may not be able to ship. I or someone else can call IDT to find out for sure. I'm going into my last lab manufacture tour now.

If IDT can ship kits today, the question is (b) (5)
(b) (5)

---

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

**Date:** February 25, 2020 at 12:11:07 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

If CDC has verified these probes (b) (5)
(b) (5)

Also, (b) (5)
(b) (5)

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 25, 2020 at 11:24:51 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

Tim, Ellen, Jeff,

Based on the attached information it looks like that the CDC primer is commercially available at IDT Integrated Technology:

# 2019-nCoV CDC qPCR Probe Assays

IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes. Three of the primer/probe sets in this panel target different locations on the 2019-nCoV/SARS-CoV-2 Nucleocapsid gene (N-gene). These 3 primer/probe sets must be run concurrently with the internal control (4th assay), which targets the human RNase P gene. Altogether, there are 4 qPCR assays per patient sample.

Components are premixed to the CDC recommended working concentration and delivered in IDTE, pH 7.5. Stocked kits are available in 3 reaction sizes of 50, 100, and 500 reactions, with custom sizes available (see section below. Kits are shipped within 1–2 business days at ambient temperature.

https://www.idtdna.com/pages/education/decoded/article/assays-and-sequences-for-2019-ncov-detection-and-vaccine-development

Uwe

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/19/2020 10:34:30 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** Re: N95 EUA Approach

Okay. Let's also touch base in the morning when we get in.

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 19, 2020 at 10:32:56 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: N95 EUA Approach

I can try a call with them tomorrow. But I expect you will need to elevate it so wanted you to see their position.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 19, 2020 at 10:11:52 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 EUA Approach

Do you want me to elevate this?

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 19, 2020 at 9:50:40 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: N95 EUA Approach

OCET ....

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** February 19, 2020 at 8:05:02 PM EST
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: N95 EUA Approach

Thanks very much Claire. We will put a meeting on the calendar. We would welcome a conversation to understand the
(b) (5) [redacted]

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(b) (5)

[redacted]

AM OVERSIGHT

**From:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 4:06 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

**Cc:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** N95 EUA Approach

Hi all,

(b) (5)

[redacted]

Thank you,
Claire

**Claire Dennis**
Office of the Chief Counsel | FDA
Food and Drug Division, OGC | HHS
Tel: 301-796-0415
Claire.Dennis@fda.hhs.gov

This e-mail is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, dis tributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at Claire.Dennis@fda.hhs.gov.

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(b) (5) Draft

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/19/2020 12:28:22 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** Fwd: N95 Respirators
**Attachments:** EUA for Non-Surgical N95 Respirators for Use in Healthcare during Public Health Emergencies 20200218_v2.docx; EUA for Non-Surgical N95 Respirators for Use in Healthcare during Public Health Emergencies 20200218v2_redlined.docx; EUA for Surgical N95 Respirators 20200219.docx; EUA for Surgical N95 Respirators 20200219_redlined.docx

Ellen,

Can you please have the EUA templates cleared by OCC (very quickly)? I understand from Stacey that we may be able to do an "umbrella EUA"?

Jeff

---

**From:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Date:** February 19, 2020 at 10:56:54 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Jeff,

We discussed internally and we believe we could (b) (5)
(b) (5)

I am attaching the current EUA documents for the following N95 respirator devices:
1. Non-surgical (same documents as those provided at 6:42pm 2/18/2020)
2. Surgical (revised, redlined and clean)

Best regards,
Cynthia

**Cynthia J. Chang, Ph.D.**
*Director*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4646 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6970 | (301) 796-6891
Cynthia.Chang@fda.hhs.gov

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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1624&S=E

U.S. FOOD & DRUG ADMINISTRATION

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 7:09 PM
**To:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Cynthia,

Great. Thank you. Also, I forgot to ask, for surgical use, (b) (5)
(b) (5)

Jeff

**From:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 6:42 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Jeff,

Following our discussion and after conferring with Liz, we concur that the fluid resistance testing can be waived for non-surgical use. This is because, (b) (5)
(b) (5)
(b) (5) We have revised the Non-Surgical documents (redlined and clean), accordingly.

For surgical use, fluid resistance testing continues to be appropriate.

We also discussed that the EUAs will be focused on use by healthcare providers. Therefore, the General Public Use documents do not need to be considered further.

I am attaching the current EUA documents for the following N95 respirator devices:
1. Non-surgical (revised with "v2" in file name, redlined and clean)
2. Surgical (same documents as those provided at 5:45pm)

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OHT4 has not reviewed these yet, but I wanted to provide this based on our discussion.

Best regards,
Cynthia

**Cynthia J. Chang, Ph.D.**
*Director*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4646 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6970 | (301) 796-6891
Cynthia.Chang@fda.hhs.gov

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FDA U.S. FOOD & DRUG ADMINISTRATION

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 5:48 PM
**To:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Cynthia,

Thank you. I'm on a call right now that should end shortly. Can I give you a call in about 5 minutes?

Jeff

---

**From:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 5:45 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Dear Dr. Shuren,

(b) (5)

AMERICAN OVERSIGHT

(b) (5)

The team additionally removed (b) (5) as recommended by Binita.

Please let us know of additional questions or requests.

Best regards,
Cynthia

**Cynthia J. Chang, Ph.D.**
*Director*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4646 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6970 | (301) 796-6891
Cynthia.Chang@fda.hhs.gov

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---

**From:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 8:34 AM
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 Respirators

AMERICAN OVERSIGHT

Good morning, All,

I am in receipt of the emails and will work with Cynthia and the team to respond soonest today.

Respectfully,
Liz

**Elizabeth F. Claverie-Williams, MS**
*CAPT, USPHS-CC, Microbiologist*
*Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Elizabeth.Claverie@fda.hhs.gov






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https://www.research.net/s/cdrhcustomerservice?ID=1622&S=E

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 7:38 AM
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: N95 Respirators

Good Morning Liz and Cynthia,

Resensding this email during normal business hours –

When possible, please see attached EUAs for Surgical N95s (particle and fluid barrier) and Non-surgical N95s (particle barrier only) and let us know if you have edits or if you concur for the Team or Division.

I am on leave today so if you could reply all, that would be helpful.

Thank you.
Binita

**Binita S. Ashar, MD, MBA, FACS**
*Director*

OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

AMERICAN OVERSIGHT

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G408 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6970
Binita.Ashar@fda.hhs.gov

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---

**From:** Ashar, Binita S
**Sent:** Saturday, February 15, 2020 9:30 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Dear All,

Please see attached:

- EUA for Surgical N95 respirators – slightly modified from the one sent forward yesterday (tracked and clean)
- EU for Non-Surgical N95 respirators – modified from the surgical N95 respirator document (tracked and clean)

I modified these without conferring with the OHT4 team since I am not sure that they are checking email today. Hopefully this serves to keep things moving until they have an opportunity to review.

Binita

**Binita S. Ashar, MD, MBA, FACS**
*Director*

OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G408 |10903 New Hampshire Avenue | Silver Spring, MD 20993
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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 6:45 PM
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Binita,

Sorry for taking so long to get back to you. (b) (5)
(b) (5)

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 10:13:56 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Okay - so modifying the one sent forward. Is that correct?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 10:06:59 AM EST
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

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Thank you. Adding Ellen.

I think we could also do a (b) (5)
(b) (5)

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 9:42:30 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Good Morning,

Yes, a second EUA for situations where there is low risk for fluid exposure will make these protective against particle penetration N95s more readily available.

I am including Cynthia Chang on this note as well since she was working closely with Liz on this so they can help coordinate this second particle barrier only EUA provided others agree.

FYI I was on leave yesterday and will be returning on Wed. All credit for the quick response goes to the team.

Binita

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 8:15:38 AM EST
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** N95 Respirators

Thank you and your team for the quick work on an EUA for N95 respirators and your flexibility. My understanding is that for NIOSH certified N95 respirators (standard respirators), the only additional testing we would need to grant an EUA is for fluid resistance. Given the current environment, we would expect healthcare workers to use N95 respirators in two types of situations – one in non-surgical/non-emergency settings with known or possible coronavirus patients (or patients with another serious, highly contagious infection) and one in surgical/emergency settings with the same patient population where they may be exposed to high pressure bodily fluids.

Could/should we create two EUAs – one for non-surgical/non-emergency settings where NIOSH certification would be sufficient and one for surgical/emergency settings where we would need NIOSH certification plus fluid resistance testing? The labeling would be different, as well, reflecting the different uses and known performance.

Jeff

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/20/2020 8:06:13 AM
**To**: Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]
**CC**: Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**Subject**: RE: COVID-19 Hearings

Heather,

Great. For Q8, (b) (5)
(b) (5)

Jeff

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:09 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** RE: COVID-19 Hearings

HI Jeff,

Jennifer and I are starting to populate the questions that we received from the HELP Committee. Please see the initial draft of responses. Please note that we are still working on responses to 13, 15, and 16. While that does not provide the type of numbers that we will be preparing for you today, it provides information on how we intend to respond.

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: (b) (6)
Email: Heather.Agler@fda.hhs.gov

---

**From:** Shuren, Jeff
**Sent:** Thursday, February 20, 2020 4:36 AM
**To:** O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>

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**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** COVID-19 Hearings

Dr. Hahn now has three congressional hearings on COVID-19. There is a prep session at 3:30 PM today for the E&C hearing that I am attending. As you've seen from Jennifer's updates on Hill briefings (Heather, I believe you have been participating), (b) (5)
(b) (5)
(b) (5) All the things the team has been working on.

In light of today's prep, I'll need the latest information on what we know for when we meet later today, including the chart on who makes PPE, production numbers, etc.

There also may be other questions E&C staff or members have raised during briefings that Jennifer/Heather can provide more details on.

Jeff

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 19, 2020 at 7:24:53 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Cc:** CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>
**Subject:** COVID-19 Congressional Update - 2.19.2020

Good evening all,

Below are some updates on FDA's Congressional engagement with respect to COVID-19 response efforts. Please do let me know if anyone has questions.

Best,

Jennifer

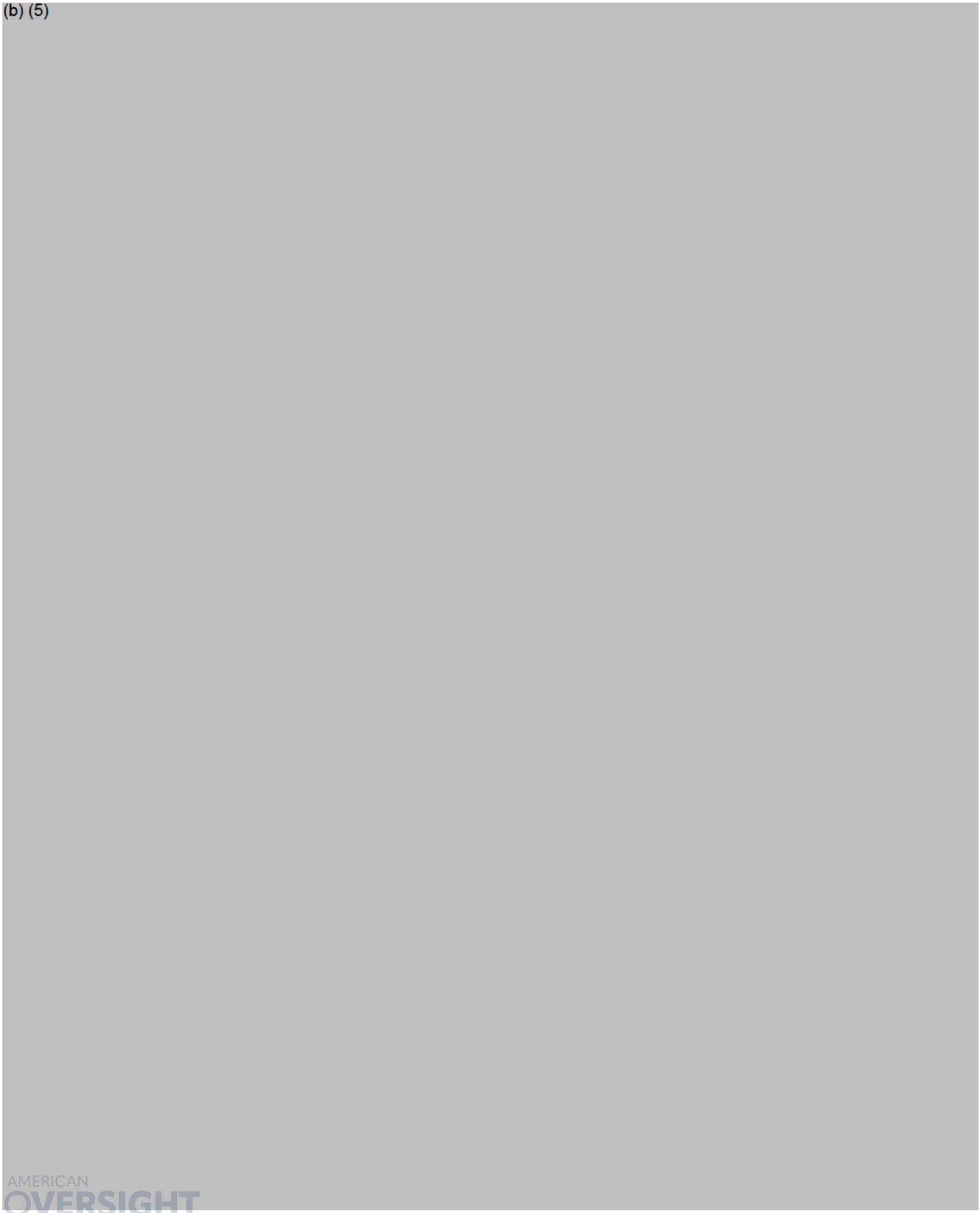
(b) (5)

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(b) (5)

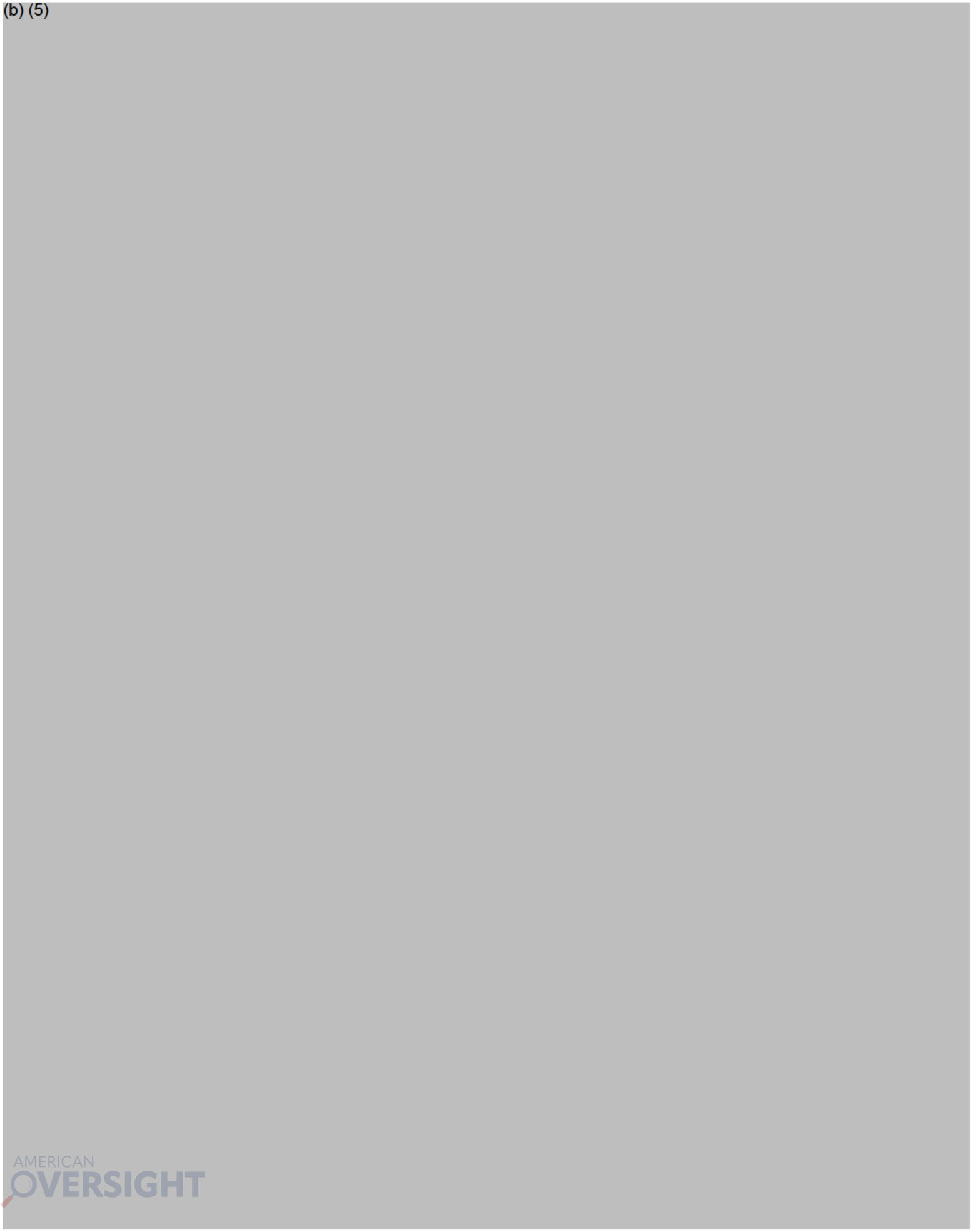
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(b) (5)



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(b) (5)



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(b) (5)

[redacted]

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: (b) (6)
jennifer.tomasello@fda.hhs.gov






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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/16/2020 9:33:49 AM
**To**: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**CC**: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
**Subject**: Re: CDC 2019-nCoV Test

Thank you. Latest update is (b) (5) [redacted]

Regarding Princess Diamond cruise ship traveler testing, (b) (5) [redacted]
However, in the interim, we told CDC to proceed with their plans so as not to create any delay.

Jeff

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Date:** February 16, 2020 at 9:16:31 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Hahn, Stephen (b) (6) [redacted] @fda.hhs.gov>
**Subject:** Re: CDC 2019-nCoV Test

I'll be standing by for the call later today and will alert OCET that a new EUA may be submitted for review.

Thank you,

Denise

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 7:10:11 PM EST
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Hahn, Stephen (b) (6) [redacted] @fda.hhs.gov>
**Subject:** Re: CDC 2019-nCoV Test

Unless I hear more tonight, this should be my last update for today.

We notified CDC by email that we have no objection to their use of the test on asymptomatic individuals from the Diamond Princess cruise ship if the test is performed at CDC headquarters, they report to us the number of asymptomatic patients who test positive, and they expeditiously submit a new EUA or a supplement to modify the current EUA to include the new use.

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We are still awaiting the email from CDC with the details of their request for enforcement discretion for a change in the cut-off level.

Jeff

Internal confidential

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**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 15, 2020 at 6:15:28 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Hahn, Stephen (b) (6) @fda.hhs.gov>
**Subject:** Re: CDC 2019-nCoV Test

I(b) (5) Thanks for keeping us in the loop as this works it's way through the process Jeff.

Sent from my iPhone

On Feb 15, 2020, at 5:55 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

Here is the latest update. As of 4 PM (b) (5) . My team needs to see the proposal before we can agree on any cut-off change. The team discussed a (b) (5) and working out the details tonight. They will need to have a conference call with CDC to come to an agreement which, at this point, will realistically happen tomorrow. I will keep all of you posted as things develop.

Jeff

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 5:34 PM
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen (b) (6) @fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC 2019-nCoV Test

Just connected with Jeff. (b) (5)

Keagan (b) (5)

Internal confidential

---

AMERICAN OVERSIGHT

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Date:** February 15, 2020 at 4:32:42 PM EST

**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hahn, Stephen (b) (6) @fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC 2019-nCoV Test

Thank you for the update.

Denise

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 4:03:13 PM EST
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Hahn, Stephen (b) (6) @fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Subject:** RE: CDC 2019-nCoV Test

The Commissioner and Redfield already spoke.

I just signed off on the no objection language for the testing of asymptomatic patients. That will be sent to CDC soon. We are awaiting an email from CDC with details on the ask for a new cut off. Once we have it we have folks standing by to review and make a decision. We are already working on no objection language, assuming we and CDC are on the same page for a cut off. Given that tested individuals would still be under quarantine, I anticipate we'll be in a good place. If we receive the email within the next few hours it's our hope to wrap this up and inform CDC that we have no objection tonight. If not, it would be tomorrow.

Jeff

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 3:55 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen (b) (6) @fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Subject:** Re: CDC 2019-nCoV Test

Jeff, thank you for the timely update.

(b) (5)

+ Denise

Internal confidential

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 2:53:33 PM EST
**To:** Hahn, Stephen (b) (6) @fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan

AMERICAN OVERSIGHT

<Keagan.Lenihan@fda.hhs.gov>
**Subject:** CDC 2019-nCoV Test

We have become aware of (b) (5) as well as a request by the Secretary for expanded use of the test. As you know, (b) (5) of the (b) (5) public health labs who received the CDC test reported false positive results with the N3 component. (The test has three components – N1, N2, and N3.) CDC determined that there was a problem in the manufacturing of the N3 component. (b) (5)

As of now, the (b) (5) This means there will be a (b) (5). Our team is currently reviewing. If supportable, we would inform CDC that we do not object and, subsequently, modify the EUA. (b) (5) We would be happy to facilitate those discussions.

Lastly, CDC has sent us the following request in response to a request from the Secretary: "CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC respectfully requests enforcement discretion from FDA for the testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Testing will be conducted at CDC's headquarters in Atlanta, GA. Specimens are expected to arrive at CDC for testing during this holiday weekend."

We believe it is appropriate to use the test at CDC headquarters for testing these asymptomatic individuals. (This is the test that we know works.) We will work with OCC on language informing CDC that we do not object to such use of the test and, subsequently, modify the EUA.

Jeff

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/21/2020 7:43:10 AM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: 2/21/20 6 AM update

Do you have a minute to discuss the plans for CDC?

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 21, 2020 at 7:01:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** 2/21/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/21/20 6 AM update:

**Status of activities on diagnostics:**

Association of Public Health Laboratories announced yesterday that only three of the more than 100 public health labs across the country have verified the CDC test for use.

(b) (5)

DMD has received a and is reviewing 4 new pre-EUA submission: (b) (4), (b) (5)
(b) (4), (b) (5) 3 are from small companies, several abroad.

Uwe

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**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/15/2020 8:15:37 AM
**To**: Claverie, Elizabeth F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=316a6efc030f403398c138d318dc487d-EFC]; Krause, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43e466e978c844dc83be09a25e972eca-dxk]; Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]
**CC**: Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]
**Subject**: N95 Respirators

Thank you and your team for the quick work on an EUA for N95 respirators and your flexibility. My understanding is that for NIOSH certified N95 respirators (standard respirators), the only additional testing we would need to grant an EUA is for fluid resistance. Given the current environment, we would expect healthcare workers to use N95 respirators in two types of situations – one in non-surgical/non-emergency settings with known or possible coronavirus patients (or patients with another serious, highly contagious infection) and one in surgical/emergency settings with the same patient population where they may be exposed to high pressure bodily fluids.

Could/should we create two EUAs – one for non-surgical/non-emergency settings where NIOSH certification would be sufficient and one for surgical/emergency settings where we would need NIOSH certification plus fluid resistance testing? The labeling would be different, as well, reflecting the different uses and known performance.

Jeff

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/19/2020 12:12:32 PM
**To:** Chang, Cynthia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dcd7bfbdbd3401b8092b3f4cd157208-Cynthia.Cha]
**CC:** Krause, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43e466e978c844dc83be09a25e972eca-dxk]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Claverie, Elizabeth F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=316a6efc030f403398c138d318dc487d-EFC]; Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]
**Subject:** RE: N95 Respirators

Thank you very much.

Jeff

---

**From:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Date:** February 19, 2020 at 10:56:54 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Jeff,

We discussed internally and we believe we could (b) (5)
(b) (5)

I am attaching the current EUA documents for the following N95 respirator devices:
1. Non-surgical (same documents as those provided at 6:42pm 2/18/2020)
2. Surgical (revised, redlined and clean)

Best regards,
Cynthia

**Cynthia J. Chang, Ph.D.**
*Director*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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CDRH | Food and Drug Administration
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Cynthia.Chang@fda.hhs.gov

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 7:09 PM
**To:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Cynthia,

Great. Thank you. Also, I forgot to ask, for surgical use, (b) (5)
(b) (5)

Jeff

**From:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 6:42 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Jeff,

Following our discussion and after conferring with Liz, we concur that the fluid resistance testing can be waived for non-surgical use. This is because, (b) (5)
(b) (5)

For surgical use, fluid resistance testing continues to be appropriate.

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We also discussed that the EUAs will be focused on use by healthcare providers. Therefore, the General Public Use documents do not need to be considered further.

I am attaching the current EUA documents for the following N95 respirator devices:

1. Non-surgical (revised with "v2" in file name, redlined and clean)
2. Surgical (same documents as those provided at 5:45pm)

OHT4 has not reviewed these yet, but I wanted to provide this based on our discussion.

Best regards,
Cynthia

**Cynthia J. Chang, Ph.D.**
*Director*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Cynthia.Chang@fda.hhs.gov

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 5:48 PM
**To:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Cynthia,

Thank you. I'm on a call right now that should end shortly. Can I give you a call in about 5 minutes?

Jeff

---

**From:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 5:45 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>;

AMERICAN OVERSIGHT

Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Dear Dr. Shuren,

We have revised the EUA documents for 3 types of N95 respirators:
1. Surgical
2. Non-surgical for Healthcare Use
3. General Public Use.

Redlined and clean documents are provided for each of the 3 devices above.

(b) (5)

The team additionally removed (b) (5) as recommended by Binita.

Please let us know of additional questions or requests.

Best regards,
Cynthia

**Cynthia J. Chang, Ph.D.**
*Director*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak, Bldg. 66, Rm. 4646 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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Cynthia.Chang@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

---

**From:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 8:34 AM
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>

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**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Good morning, All,

I am in receipt of the emails and will work with Cynthia and the team to respond soonest today.

Respectfully,
Liz

**Elizabeth F. Claverie-Williams, MS**
*CAPT, USPHS-CC, Microbiologist*
*Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 7:38 AM
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: N95 Respirators

Good Morning Liz and Cynthia,

Resensding this email during normal business hours –

When possible, please see attached EUAs for Surgical N95s (particle and fluid barrier) and Non-surgical N95s (particle barrier only) and let us know if you have edits or if you concur for the Team or Division.

I am on leave today so if you could reply all, that would be helpful.

Thank you.

AMERICAN OVERSIGHT

Binita

**Binita S. Ashar, MD, MBA, FACS**
*Director*

OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
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**From:** Ashar, Binita S
**Sent:** Saturday, February 15, 2020 9:30 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Dear All,

Please see attached:

- EUA for Surgical N95 respirators – slightly modified from the one sent forward yesterday (tracked and clean)
- EU for Non-Surgical N95 respirators – modified from the surgical N95 respirator document (tracked and clean)

I modified these without conferring with the OHT4 team since I am not sure that they are checking email today. Hopefully this serves to keep things moving until they have an opportunity to review.

Binita

**Binita S. Ashar, MD, MBA, FACS**
*Director*

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Office of Product Evaluation and Quality

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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 6:45 PM
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Binita,

Sorry for taking so long to get back to you. Ellen has been talking with OCC with the hope of resolving issues today but we are now not expecting a response on whether or not we can issue a bulk EUA and related questions until Tuesday. Therefore, (b) (5)
(b) (5)

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 10:13:56 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Okay - so modifying the one sent forward. Is that correct?

---

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

**Date:** February 15, 2020 at 10:06:59 AM EST
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Thank you. Adding Ellen.

I think we could also do a "bulk EUA", particularly for low risk (?high pressure) fluid exposure that are NIOSH certified. Optimal if we could a bulk EUA for both uses.

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 9:42:30 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Good Morning,

Yes, a second EUA for situations where there is low risk for fluid exposure will make these protective against particle penetration N95s more readily available.

I am including Cynthia Chang on this note as well since she was working closely with Liz on this so they can help coordinate this second particle barrier only EUA provided others agree.

FYI I was on leave yesterday and will be returning on Wed. All credit for the quick response goes to the team.

Binita

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 8:15:38 AM EST
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** N95 Respirators

Thank you and your team for the quick work on an EUA for N95 respirators and your flexibility. My understanding is that for NIOSH certified N95 respirators (standard respirators), the only additional testing we would need to grant an EUA is for fluid resistance. Given the current environment, we would expect healthcare workers to use N95 respirators in two types of situations – one in non-surgical/non-emergency settings with known or possible coronavirus patients (or patients with another serious, highly contagious infection) and one in surgical/emergency settings with the same patient population where they may be exposed to high pressure bodily fluids.

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Could/should we create two EUAs – one for non-surgical/non-emergency settings where NIOSH certification would be sufficient and one for surgical/emergency settings where we would need NIOSH certification plus fluid resistance testing? The labeling would be different, as well, reflecting the different uses and known performance.

Jeff

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/21/2020 6:50:10 AM
**To:** Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**CC:** Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: N95 Framework Documents for EUAs

Thank you all. Adding Ellen, as well.

Jeff

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Date:** February 21, 2020 at 6:30:11 AM EST
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Raza, Mark <Mark.Raza@fda.hhs.gov>
**Subject:** RE: N95 Framework Documents for EUAs

+ Mark (b) (5) [redacted] anything else I missed.

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Date:** February 20, 2020 at 11:24:36 PM EST
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: N95 Framework Documents for EUAs

Thanks Jeff and Stacy. (b) (5) [redacted]

Thanks,

Denise

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Date:** February 20, 2020 at 9:45:41 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Lenihan, Keagan

AMERICAN OVERSIGHT

<Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: N95 Framework Documents for EUAs

(b) (5)

[redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 9:24 PM
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** Fwd: N95 Framework Documents for EUAs

Deliberative/Predecisional

I could use your help. (b) (5)

(b) (5)

[redacted]

Happy to discuss.

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 20, 2020 at 8:48:52 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: N95 Framework Documents for EUAs

Update from OCET

---

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**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** February 20, 2020 at 8:21:42 PM EST

**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Cc:** Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>, O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** RE: N95 Framework Documents for EUAs

Hi- (b) (5) [redacted]

(b) (5) [redacted]

Thanks, Liz

-----Original Appointment-----
**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 12:05 PM
**To:** Flannery, Ellen; Ross, Jennifer; Busch, Marcy; Dennis, Claire; Sadove, Elizabeth; Agler, Heather L; Ross, Aftin; Marders, Julia A
**Cc:** Kannan, Lakshmi; O'Callaghan, Kathryn; Ricci, Linda J; Tomasello, Jennifer
**Subject:** N95 Framework Documents for EUAs
**When:** Friday, February 21, 2020 3:00 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** 5425

-- Do not delete or change any of the following text. --

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Meeting number (access code): (b) (6) [redacted]

Meeting password: (b) (6)

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/20/2020 4:00:29 PM
**To:** Kannan, Lakshmi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8efc4e7e0adb4246a67ca3e110e46bd6-Lakshmi.Kan]
**CC:** O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; CDRH All Hazards Readiness Response and Cybersecurity [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af150d41dbea48c2b898c3431c24a132-CDRHEMCM]
**Subject:** Re: COVID-19 updates: For today's 3:30 briefing

Thank you. One question for the team — according to the email below, (b) (5)
(b) (5)
(b) (5) Can we please reconcile?

Jeff

---

**From:** Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>
**Date:** February 20, 2020 at 2:59:55 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>
**Subject:** COVID-19 updates: For today's 3:30 briefing

Good afternoon.

I'm sending you today's updates on COVID-19 for your afternoon briefing. Please let us know if you have any questions.

(b) (5)

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(b) (5)

AMERICAN OVERSIGHT

(b) (5)

AMERICAN OVERSIGHT

Lakshmi

**Lakshmi Kannan, Ph.D.**
*Senior Project Manager*
*Staff Fellow*
**Team: All-Hazards Readiness Response and Cybersecurity (ARC)**
**Division: All hazards Response, Science and Strategic Partnerships (DARSS)**
**Office of Strategic Partnership and Technology Innovation (OST)**
**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
---
WO 66, Room 5561
10903 New Hampshire Ave, Silver Spring, MD 20993
Office: 240-402-7735; Cell: (b) (6)
lakshmi.kannan@fda.hhs.gov

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/20/2020 7:01:32 AM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: 2/20/20 6 AM update

Uwe,

Thank you. What's the relevance of the last item regarding the (b) (5) ? Is it to allow for (b) (5)

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 20, 2020 at 6:53:50 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** 2/20/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

2/20/20 6 AM update:

AMERICAN OVERSIGHT

**Status of activities on diagnostics:**

(b) (5)

[redacted]

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/23/2020 11:55:11 AM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Re: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Uwe,

Thank you and your team for the quick turnaround.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 23, 2020 at 11:53:55 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities
**Importance:** High

Jeff,

The draft edits for the document for the surveillance study just went out to CDC.

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:13 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

AMERICAN OVERSIGHT

The following email just went out to CDC. Thank you all for the fast turnabout to get this done.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:09 AM
**To:** Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear Laura,

Attached please find the following documents you submitted on February 21, 2020 to support the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in surveillance activities. These documents have been reviewed and edited by FDA's OCET and OCC.

1. Draft COVID-19 sentinel surveillance
2. Draft SARS-CoV-2 surveillance risk benefit
3. Draft CDC Surveillance EUA Request Cover letter

Please do not hesitate to reach out to me with questions.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/18/2020 12:34:37 PM
**To**: Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]
**CC**: Stevenson, Jennifer R [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=befef4f26f53481fb0dc791c2a00bce3-JRS2]; Krause, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43e466e978c844dc83be09a25e972eca-dxk]; Saltman, Adam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=941424473c4e4cfeb01594032f253e91-Adam.Saltma]; Faris, Owen P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d919c42856449589d2d24454b2f774e-OPF]; Brockman, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0dbb293045cd4e9393e8bc6385d86194-RGB]
**Subject**: RE: Seeking help from FDA [ ref:_00Dd0fegA._500t0SCkbJ:ref ]

An EUA should not be needed. These are FDA cleared gowns that have not been distributed due to concerns about possible contamination. It's up to FDA to decide whether under the circumstances the benefits outweigh the risks to allow the product to be used in the US with or without mitigations, such as changed labeling.

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 12:28 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Cc:** Stevenson, Jennifer R <Jennifer.Stevenson@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Saltman, Adam <Adam.Saltman@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>; Brockman, Randall <Randall.Brockman@fda.hhs.gov>
**Subject:** RE: Seeking help from FDA [ ref:_00Dd0fegA._500t0SCkbJ:ref ]

Thank you.

Please let OHT4 know if an EUA or something else from us is needed.

Binita

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 18, 2020 at 12:15:16 PM EST
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Cc:** Stevenson, Jennifer R <Jennifer.Stevenson@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Saltman, Adam <Adam.Saltman@fda.hhs.gov>, Faris, Owen P <Owen.Faris@fda.hhs.gov>, Brockman, Randall

AMERICAN OVERSIGHT

<Randall.Brockman@fda.hhs.gov>
**Subject:** RE: Seeking help from FDA [ ref:_00Dd0fegA._500t0SCkbJ:ref ]

Adding ARC team. They should be included in the discussions on what to do. We need to consider whether, under the current circumstances, we would allow use of the gowns In the US rather than use in Hong Kong.

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 11:37 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Stevenson, Jennifer R <Jennifer.Stevenson@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Saltman, Adam <Adam.Saltman@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>; Brockman, Randall <Randall.Brockman@fda.hhs.gov>
**Subject:** FW: Seeking help from FDA [ ref:_00Dd0fegA._500t0SCkbJ:ref ]
**Importance:** High

Forwarding the first letter from Hong Kong on the quarantined gowns which provides more info than the other one I sent accompanying my note

Binita

---

**From:** Stevenson, Jennifer R <Jennifer.Stevenson@fda.hhs.gov>
**Date:** February 18, 2020 at 10:21:47 AM EST
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Korz, Dorian <Dorian.Korz@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Subject:** FW: Seeking help from FDA [ ref:_00Dd0fegA._500t0SCkbJ:ref ]
**Importance:** High

Please see below.

**CDR Jennifer Stevenson, MBE, RAC**
*Deputy Office Director*

OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4682 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-5615
Jennifer.Stevenson@fda.hhs.gov






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**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 9:57 AM

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**To:** CDRH Small Manu. Assistance <DSMA@CDRH.FDA.GOV>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Eakle, Melissa <Melissa.Eakle@fda.hhs.gov>; Stevenson, Jennifer R <Jennifer.Stevenson@fda.hhs.gov>; Saltman, Adam <Adam.Saltman@fda.hhs.gov>; Deviceshortages <Deviceshortages@fda.hhs.gov>
**Cc:** Welch, Jan <Jan.Welch@fda.hhs.gov>; Brackett, Gina M <Gina.Brackett@fda.hhs.gov>; Wilbon, Tonya <Tonya.Wilbon@fda.hhs.gov>; Freeman, Anike <Anike.Freeman@fda.hhs.gov>; Lang, Andrew <Andrew.Lang@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>
**Subject:** RE: Seeking help from FDA [ ref:_00Dd0fegA._500t0SCkbJ:ref ]

Hey folks-
Can you keep OMA looped in to how your proceed with this request? Thx.

---

**From:** noreply@salesforce.com <noreply@salesforce.com> **On Behalf Of** DICE
**Sent:** Tuesday, February 18, 2020 9:42 AM
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Eakle, Melissa <Melissa.Eakle@fda.hhs.gov>; Stevenson, Jennifer R <Jennifer.Stevenson@fda.hhs.gov>; Saltman, Adam <Adam.Saltman@fda.hhs.gov>; Deviceshortages <Deviceshortages@fda.hhs.gov>
**Cc:** Welch, Jan <Jan.Welch@fda.hhs.gov>; Brackett, Gina M <Gina.Brackett@fda.hhs.gov>; Wilbon, Tonya <Tonya.Wilbon@fda.hhs.gov>; Freeman, Anike <Anike.Freeman@fda.hhs.gov>; Lang, Andrew <Andrew.Lang@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
**Subject:** FW: Seeking help from FDA [ ref:_00Dd0fegA._500t0SCkbJ:ref ]

Good Morning All,

DICE received the following email on the Cardinal Health gown recall that connects with another hot issue, please follow up immediately with ORA and eventually the stakeholder.

I have copied multiple staff here to keep everyone in the loop.

Thank You,
Joe

Joseph Tartal, Deputy Director DICE
FDA/CDRH/OCE/DICE

---------- Forwarded Message ----------
**From:** David CHAN (b) (6)
**Sent:** 2/17/2020 5:57 AM
**To:** jan.welch@fda.hhs.gov
**Cc:** dice@fda.hhs.gov
**Subject:** Seeking help from FDA

VERY URGENT
Dear Jan,
I am the Quality Assurance Manager of Hospital Authority HA), Hong Kong – Mr. David CHAN.

It is noted that around 9 million surgical gowns are involved in the recall which have been quarantined by Cardinal Health since the manufacturing sites of the gowns concerned were not registered with U.S. Food and Drug Administration (FDA) and were not qualified by Cardinal Health.

I write on behalf of Hospital Authority to seek your kind assistance to explore the possibility for Hospital Authority to take over some affected lots of surgical gowns which are currently placed on hold as a result of a voluntary recall announced by Cardinal Health.

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In view of the current situation in Hong Kong with increasing trend in confirmed coronavirus cases locally, increasing demand for isolation gowns is expected. HA is trying the best to arrange sufficient PPEs for front line staff who are committed in providing quality patient services in fighting against Coronavirus.

We assure that the intended purpose of the affected surgical gowns will only be used as AAMI Level 3 isolation gowns for front line staff in hospitals/clinics as long as Level 3 Surgical Gowns meet our product specifications and are acceptable from infection control point of view.

Thank you for your kind coordination and reflect our request to the concerned party of FDA.

Yours sincerely,

Best regards,

David CHAN
Manager (Quality Assurance),
Business Support Services Dept.,
Hospital Authority Head Office,
Direct Line : +852 2300 6852
Mobile : (b) (6)
e-mail :(b) (6)
Fax : +852 2194 6813

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**********



ref:_00Dd0fegA._500t0SCkbJ:ref

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/17/2020 7:26:45 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: 2019-nCoV RT-PCR Test EUA

Thank you.

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 17, 2020 at 7:23:46 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: 2019-nCoV RT-PCR Test EUA

Predecisional / Deliberative,

Jeff,

Brief response:

I don't see anything in the EUA Guidance addressing contract manufacturers specifically. The Guidance uses "manufacturing site(s)" and "manufacturing processes" (not manufacturer alone) as the focus of attention for the contents of an EUA application and FDA's review.

From my review of the EUA authorization letter, (b) (5) (b) (5) but maybe you understand something that I do not -- see page 6 of 8 of the attached letter pdf (also available at this website https://www.fda.gov/media/134919/download )

Analysis:

1. The EUA Guidance (pages 12, 13 and 15) states that an EUA application must include:

"Information on chemistry (as applicable), manufacturing, and controls; a list of each site where the product, if authorized, is or would be manufactured, and the current CGMP status of the manufacturing site(s);"

"Any right of reference, as applicable."

"For IVDs, device performance data to support the intended use such as analytical sensitivity and analytical specificity, and data from testing fresh, contrived, banked or archived specimens."

2. In granting the EUA for this CDC test, FDA waived cGMP compliance, as provided in the statute and noted in the EUA Guidance (page 27):

"FDA generally expects that EUA products will be produced, stored, and distributed in compliance with CGMPs; however, limits or waivers may be granted in an EUA on a case-by-case basis, after consideration of the circumstances and of any alternative proposed approach (section 564(e)(3))."

At the time the waiver was granted, the two additional contract manufacturers were not considered in the circumstances.

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3. In determining whether to revise an EUA, FDA can consider whether "the manufacturing site and processes has raised significant questions regarding the purity, potency, or safety of the EUA product that materially affect the risk/benefit assessment upon which the EUA was based."

The EUA Guidance references "manufacturing site(s)" and not "manufacturers." (b) (5)
(b) (5)

I think that (b) (5)
(b) (5)

Ellen

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 5:40 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** 2019-nCoV RT-PCR Test EUA

Predecisional/Deliberative

Ellen,

CDC plans to contract with (b) (5) contract manufacturers to make components for the test, in addition to CDC. When they add the (b) (5) contract manufacturers do we need to update the EUA? (b) (5)
(b) (5)

Jeff

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/22/2020 11:22:05 AM
**To:** Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: [Time Sensitive Leadership Policy Question] Insertion of Section on FDA Regulated Products into SNS: Dear HCP letter for expired SNS PPE Letter

Thank you

---

**From:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>
**Date:** February 22, 2020 at 11:14:08 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: [Time Sensitive Leadership Policy Question] Insertion of Section on FDA Regulated Products into SNS: Dear HCP letter for expired SNS PPE Letter

Good morning. (b) (5) [redacted]

Best,

Aftin

**Aftin Ross, Ph.D.**
*Senior Project Manager*
*Senior Science Health Advisor*
**Team: All-Hazards Readiness Response and Cybersecurity (ARC)**
**Division: All hazards Response, Science and Strategic Partnerships (DARSS)**
**Office of Strategic Partnerships and Technology Innovation (OST)**
**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
---
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10903 New Hampshire Ave, Silver Spring, MD 20993
Office: 301-796-5679; Cell: 202-870-0517
aftin.ross@fda.hhs.gov
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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 11:10 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>
**Subject:** RE: [Time Sensitive Leadership Policy Question] Insertion of Section on FDA Regulated Products into SNS: Dear HCP letter for expired SNS PPE Letter

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(b) (5) [redacted]

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 22, 2020 at 11:06:32 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>
**Subject:** RE: [Time Sensitive Leadership Policy Question] Insertion of Section on FDA Regulated Products into SNS: Dear HCP letter for expired SNS PPE Letter

(b) (5) [redacted]

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 10:48 AM
**To:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Mitchell, Diane <Diane.Mitchell@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Re: [Time Sensitive Leadership Policy Question] Insertion of Section on FDA Regulated Products into SNS: Dear HCP letter for expired SNS PPE Letter

Yes, I do think we should include a statement as well as additional clarity on the recommendations pending SMEs' feedback.

Of note, though, (b) (5) [redacted], which we are still working out.

Jeff

---

**From:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>
**Date:** February 22, 2020 at 10:26:28 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Mitchell, Diane <Diane.Mitchell@fda.hhs.gov>, CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** [Time Sensitive Leadership Policy Question] Insertion of Section on FDA Regulated Products into SNS: Dear HCP letter for expired SNS PPE Letter
**Importance:** High

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Good morning. We received the request below from the SNS regarding the review and insertion of an FDA statement concerning FDA regulated product into a letter that would accompany any of the product that would be released from

the SNS. We are reaching out to the SMEs to get their product specific thoughts on what CDC is proposing. We had already reached out to our SMEs this week regarding the use of expired N95s (see second attachment for their full analysis) and in their opinion the hierarchy for use was as follows: (b) (5) [redacted] We are in agreement with NIOSH that expired products should only be used in the event of a shortage and also identified characteristics that should be considered when deciding whether to use expired product so I think we could say something high-level about this. We just wanted to get insight from leadership on whether you were ok with us adding a specific paragraph on FDA regulated products vs, just providing commentary on the information CDC has posed regarding FDA regulated products. We recognize that any final language would need to be cleared through the center.

Best,

Aftin

**Aftin Ross, Ph.D.**
*Senior Project Manager*
*Senior Science Health Advisor*
**Team: All-Hazards Readiness Response and Cybersecurity (ARC)**
**Division: All hazards Response, Science and Strategic Partnerships (DARSS)**
**Office of Strategic Partnerships and Technology Innovation (OST)**
**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
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Office: 301-796-5679; Cell: 202-870-0517
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U.S. FOOD & DRUG ADMINISTRATION

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Saturday, February 22, 2020 9:45 AM
**To:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Mitchell, Diane <Diane.Mitchell@fda.hhs.gov>
**Cc:** CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>
**Subject:** TIME SENSITIVE REVIEW REQUEST SNS: Dear HCP letter for expired SNS PPE
**Importance:** High

Hi Aftin and team,

The SNS is developing a letter to accompany the use of any PPE that comes from the SNS. This ties into the use of expired product that we are working on. They want to know if we would like to insert a statement for FDA-regulated products. Please review the letter and provide suggestions by **Sunday 9 pm**. That will give me time to put the suggestions together and get it back to OCET by Monday morning. I have asked OCET to provide the type of statement

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that they have provided in the past for these types of letters. We don't want to over edit, but focus on the parts that are directly related to CDRH regulated product and determine if our comments can be included in one added paragraph.

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: 240-507-3139
Email: Heather.Agler@fda.hhs.gov

---

**From:** Courtney, Brooke
**Sent:** Saturday, February 22, 2020 7:01 AM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Subject:** SNS: Dear HCP letter for expired SNS PPE

Hi Heather,

I'm so sorry to email you on a Saturday morning! (b) (5) [redacted]

(b) (5) [redacted]

Thanks,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) / 240-328-5589 (cell)
brooke.courtney@fda.hhs.gov

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/18/2020 5:47:42 PM
**To**: Chang, Cynthia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dcd7bfbdbd3401b8092b3f4cd157208-Cynthia.Cha]
**CC**: Krause, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43e466e978c844dc83be09a25e972eca-dxk]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Claverie, Elizabeth F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=316a6efc030f403398c138d318dc487d-EFC]; Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]
**Subject**: RE: N95 Respirators

Cynthia,

Thank you. I'm on a call right now that should end shortly. Can I give you a call in about 5 minutes?

Jeff

---

**From:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 5:45 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Dear Dr. Shuren,

We have revised the EUA documents for 3 types of N95 respirators:
1) Surgical
2) Non-surgical for Healthcare Use
3) General Public Use.

Redlined and clean documents are provided for each of the 3 devices above.

(b) (5)

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The team additionally removed (b) (5) 020-2531 CDRH as recommended by Binita.

Please let us know of additional questions or requests.

Best regards,
Cynthia

**Cynthia J. Chang, Ph.D.**
*Director*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4646 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6970 | (301) 796-6891
Cynthia.Chang@fda.hhs.gov

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**From:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 8:34 AM
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Good morning, All,

I am in receipt of the emails and will work with Cynthia and the team to respond soonest today.

Respectfully,
Liz

**Elizabeth F. Claverie-Williams, MS**
*CAPT, USPHS-CC, Microbiologist*
*Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Elizabeth.Claverie@fda.hhs.gov






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---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 7:38 AM
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: N95 Respirators

Good Morning Liz and Cynthia,

Resensding this email during normal business hours –

When possible, please see attached EUAs for Surgical N95s (particle and fluid barrier) and Non-surgical N95s (particle barrier only) and let us know if you have edits or if you concur for the Team or Division.

I am on leave today so if you could reply all, that would be helpful.

Thank you.
Binita

**Binita S. Ashar, MD, MBA, FACS**
*Director*

OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G408 |10903 New Hampshire Avenue | Silver Spring, MD 20993
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**From:** Ashar, Binita S
**Sent:** Saturday, February 15, 2020 9:30 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Dear All,

Please see attached:

- EUA for Surgical N95 respirators – slightly modified from the one sent forward yesterday (tracked and clean)
- EU for Non-Surgical N95 respirators – modified from the surgical N95 respirator document (tracked and clean)

I modified these without conferring with the OHT4 team since I am not sure that they are checking email today. Hopefully this serves to keep things moving until they have an opportunity to review.

Binita

**Binita S. Ashar, MD, MBA, FACS**
*Director*

OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
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Binita.Ashar@fda.hhs.gov

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AMERICAN OVERSIGHT

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 6:45 PM
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Binita,

Sorry for taking so long to get back to you. Ellen has been talking with OCC with the hope of resolving issues today but we are now not expecting a response on whether or not we can issue a bulk EUA and related questions until Tuesday. Therefore, (b) (5)
(b) (5)

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 10:13:56 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Okay - so modifying the one sent forward. Is that correct?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 10:06:59 AM EST
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Thank you. Adding Ellen.

I think we could also do a "bulk EUA", particularly for low risk (?high pressure) fluid exposure that are NIOSH certified. Optimal if we could a bulk EUA for both uses.

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 9:42:30 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J

AMERICAN OVERSIGHT

<Linda.Ricci@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Good Morning,

Yes, a second EUA for situations where there is low risk for fluid exposure will make these protective against particle penetration N95s more readily available.

I am including Cynthia Chang on this note as well since she was working closely with Liz on this so they can help coordinate this second particle barrier only EUA provided others agree.

FYI I was on leave yesterday and will be returning on Wed. All credit for the quick response goes to the team.

Binita

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 8:15:38 AM EST
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** N95 Respirators

Thank you and your team for the quick work on an EUA for N95 respirators and your flexibility. My understanding is that for NIOSH certified N95 respirators (standard respirators), the only additional testing we would need to grant an EUA is for fluid resistance. Given the current environment, we would expect healthcare workers to use N95 respirators in two types of situations – one in non-surgical/non-emergency settings with known or possible coronavirus patients (or patients with another serious, highly contagious infection) and one in surgical/emergency settings with the same patient population where they may be exposed to high pressure bodily fluids.

Could/should we create two EUAs – one for non-surgical/non-emergency settings where NIOSH certification would be sufficient and one for surgical/emergency settings where we would need NIOSH certification plus fluid resistance testing? The labeling would be different, as well, reflecting the different uses and known performance.

Jeff

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/15/2020 2:53:31 PM
**To:** 'Hahn, Stephen' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Abram, Anna (Anna.Abram@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Anna.Abram3ba]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** CDC 2019-nCoV Test

We have become aware of two new issues regarding the CDC's test as well as a request by the Secretary for expanded use of the test. As you know, ~26 of the ~100 public health labs who received the CDC test reported false positive results with the N3 component. (The test has three components – N1, N2, and N3.) CDC determined that there was a problem in the manufacturing of the N3 component. Today they informed us that some of the labs have identified what may be false positives with the N1 component. In addition, and particularly concerning, CDC informed us that the test they validated for purposes of the EUA used a different lot of components than the test that was manufactured for the public health labs, i.e., they were made by two different entities (and they clearly perform differently). (b) (5)
(b) (5)

As of now, the contract manufacturer CDC is using has not been able to solve their quality control problem; the latest batch still has problems. (b) (5) Therefore, CDC is requesting that the public health labs be able to use a different cut off – essentially raise the cut off so that it excludes the false positives that have occurred with the N3 and now possibly the N1 components. (b) (5)
(b) (5) Our team is currently reviewing. If supportable, we would inform CDC that we do not object and, subsequently, modify the EUA. CDC would need to issue new instructions to the public health labs. In addition, we plan to suggest to CDC that, (b) (5)
(b) (5)

Lastly, CDC has sent us the following request in response to a request from the Secretary: "CDC has been instructed to test all U. S. passengers returning to the United States from the Diamond Princess cruise ship, currently docked in Japan. These passengers are asymptomatic, thus they do not meet CDC's current Person Under Investigation (PUI) definition or testing criteria. CDC respectfully requests enforcement discretion from FDA for the testing of asymptomatic U.S. citizens from the Diamond Princess cruise ship using the FDA-authorized 2019-nCoV Real-Time RT-PCR Diagnostic Panel. (b) (5)
(b) (5)

(b) (5)
(b) (5) We will work with OCC on language informing CDC that we do not object to such use of the test and, subsequently, modify the EUA.

Jeff

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/21/2020 5:01:53 AM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** Fwd: N95 Framework Documents for EUAs

FYI

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Date:** February 20, 2020 at 11:24:36 PM EST
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: N95 Framework Documents for EUAs

Thanks Jeff and Stacy. (b) (5) [redacted].

Thanks,

Denise

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Date:** February 20, 2020 at 9:45:41 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: N95 Framework Documents for EUAs

(b) (5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 9:24 PM
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** Fwd: N95 Framework Documents for EUAs

Deliberative/Predecisional

I could use your help. (b) (5) [redacted]

(b) (5) [redacted]

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(b) (5)

Happy to discuss.

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 20, 2020 at 8:48:52 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: N95 Framework Documents for EUAs

Update from OCET

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** February 20, 2020 at 8:21:42 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Cc:** Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>, O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** RE: N95 Framework Documents for EUAs

Hi- (b) (5)

(b) (5)

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(b) (5)

[redacted]

Thanks, Liz

-----Original Appointment-----
**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 12:05 PM
**To:** Flannery, Ellen; Ross, Jennifer; Busch, Marcy; Dennis, Claire; Sadove, Elizabeth; Agler, Heather L; Ross, Aftin; Marders, Julia A
**Cc:** Kannan, Lakshmi; O'Callaghan, Kathryn; Ricci, Linda J; Tomasello, Jennifer
**Subject:** N95 Framework Documents for EUAs
**When:** Friday, February 21, 2020 3:00 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** 5425

-- Do not delete or change any of the following text. --

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/23/2020 11:40:09 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Re: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Thank you. And as you saw, CDC got the green light to proceed under enforcement discretion while we work to finalize an EUA.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 23, 2020 at 11:29:32 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

FYI

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 23, 2020 at 11:12:57 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

The following email just went out to CDC. Thank you all for the fast turnabout to get this done.

Thanks,
Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov
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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Sunday, February 23, 2020 11:09 AM
**To:** Rose, Laura E (CDC) <zey9@cdc.gov>
**Cc:** Spies, Stacey (CDC) <khq7@cdc.gov>; Langley, Gayle E (CDC) <fez7@cdc.gov>; Kuhnert-Tallman, Wendi L (CDC)

AMERICAN OVERSIGHT

<wdk1@cdc.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities

Dear Laura,

Attached please find the following documents you submitted on February 21, 2020 to support the use of the FDA-authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in surveillance activities. These documents have been reviewed and edited by FDA's OCET and OCC.

1. Draft COVID-19 sentinel surveillance
2. Draft SARS-CoV-2 surveillance risk benefit
3. Draft CDC Surveillance EUA Request Cover letter

Please do not hesitate to reach out to me with questions.

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/22/2020 9:57:16 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** Re: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

TY!!

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 22, 2020 at 9:45:55 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Dear Wendi,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

Today, February 22, 2020, CDRH/FDA was informed that CDC would need enforcement discretion from FDA, until approval of a new EUA, for certain public health surveillance testing activities that do not fall within the currently authorized intended use of the assay (EUA200001) – namely, CDC has identified an urgent need to partner with designated jurisdictions and surveillance sites across the United States to perform testing to identify possible transmission of SARS-CoV-2 among individuals without a clear epidemiologic link (contact with known cases or history of recent travel to mainland China).

At this time, there are no adequate, approved, and available alternative tools that can detect SARS-CoV-2 during the acute phase of infection in the United States in symptomatic individuals without the epidemiological risk factors. In addition, unlike typical surveillance activities, individuals who test positive or inconclusive for SARS-CoV-2 using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel will be notified of their test result and followed up accordingly.

Our understanding of the facts and the public health concerns at issue here are that there is currently no other test available to respond to this emergency, significant public health concerns are presented by the infectious disease, the proposed testing may help to prevent the spread of the infectious disease, and the testing activity will help to support situational awareness and guide the public health response to COVID-19. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the following conditions: that all patients must be adequately informed about the status of this testing and the potential implications of agreeing to this testing, and that CDC will act promptly to submit an application for a new EUA to authorize the testing described above.

If you have any questions, please contact Uwe Scherf or me.

AMERICAN OVERSIGHT

Sincerely,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov






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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/17/2020 5:39:38 PM
**To**: Ellen Flannery (Ellen.Flannery@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: 2019-nCoV RT-PCR Test EUA

Predecisional/Deliberative

Ellen,

CDC plans to contract with (b) contract manufacturers to make components for the test, in addition to CDC. When they add the (b) contract manufacturers do we need to update the EUA? My understanding is that (b) (5) [redacted]

Jeff

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/18/2020 7:53:41 AM
**To:** Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]; Claverie, Elizabeth F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=316a6efc030f403398c138d318dc487d-EFC]; Chang, Cynthia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dcd7bfbdbd3401b8092b3f4cd157208-Cynthia.Cha]
**CC:** Krause, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43e466e978c844dc83be09a25e972eca-dxk]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: N95 Respirators

Thank you. I would ask, as well (b) (5) [redacted]

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 7:38 AM
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: N95 Respirators

Good Morning Liz and Cynthia,

Resensding this email during normal business hours –

(b) (5) [redacted]

I am on leave today so if you could reply all, that would be helpful.

Thank you.
Binita

**Binita S. Ashar, MD, MBA, FACS**
*Director*

OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G408 |10903 New Hampshire Avenue | Silver Spring, MD 20993

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Ph: (301) 796-6970
Binita.Ashar@fda.hhs.gov

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**From:** Ashar, Binita S
**Sent:** Saturday, February 15, 2020 9:30 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Dear All,

Please see attached:

(b) (5)

I modified these without conferring with the OHT4 team since I am not sure that they are checking email today. Hopefully this serves to keep things moving until they have an opportunity to review.

Binita

**Binita S. Ashar, MD, MBA, FACS**
*Director*

OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G408 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6970
Binita.Ashar@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

AMERICAN OVERSIGHT



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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 6:45 PM
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Binita,

Sorry for taking so long to get back to you. Ellen has been talking with OCC with the hope of resolving issues today but we are now not expecting a response on whether or not we (b) (5) [redacted]

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 10:13:56 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Okay - so modifying the one sent forward. Is that correct?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 10:06:59 AM EST
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
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**Subject:** Re: N95 Respirators

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Thank you. Adding Ellen.

I think we could also (b) (5) [redacted]

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 9:42:30 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
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**Subject:** Re: N95 Respirators

Good Morning,

(b) (5) [redacted]

FYI I was on leave yesterday and will be returning on Wed. All credit for the quick response goes to the team.

Binita

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 8:15:38 AM EST
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
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Thank you and your team for the quick work on an EUA for N95 respirators and your flexibility. My understanding is (b) (5) [redacted]. Given the current environment, we would expect healthcare workers to use N95 respirators in two types of situations – one in non-surgical/non-emergency settings with known or possible coronavirus patients (or patients with another serious, highly contagious infection) and one in surgical/emergency settings with the same patient population where they may be exposed to high pressure bodily fluids.

Could/should we (b) (5) [redacted]

Jeff

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/15/2020 9:43:11 PM
**To**: Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]; Claverie, Elizabeth F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=316a6efc030f403398c138d318dc487d-EFC]; Krause, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43e466e978c844dc83be09a25e972eca-dxk]; Chang, Cynthia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dcd7bfbdbd3401b8092b3f4cd157208-Cynthia.Cha]
**CC**: Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: N95 Respirators

Thank you, Binita. I greatly appreciate it.

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 9:29:42 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
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**Subject:** RE: N95 Respirators

Dear All,

Please see attached:

(b) (5)

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Binita

**Binita S. Ashar, MD, MBA, FACS**
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AMERICAN OVERSIGHT

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FDA U.S. FOOD & DRUG ADMINISTRATION

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**Subject:** Re: N95 Respirators

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AMERICAN OVERSIGHT

Could/should we (b) (5) [redacted]

Jeff

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/15/2020 12:52:35 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: Urgent - Action needed

Understood. Then we may have to grant temporary enforcement discretion today while working towards expansion of the EUA. We should not hold up testing these individuals, particularly when we believe the use of the test for these individuals is appropriate.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 15, 2020 at 12:36:47 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: Urgent - Action needed

Not in a day.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 12:35 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: Urgent - Action needed

Thank you for the heads up. How quickly can we expand the EUA?

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 15, 2020 at 12:15:36 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Urgent - Action needed
**Importance:** High

Jeff and Ellen,

I want you to give you a heads up on this. I received a call from CDC to let me know that they (b) (5) test all U.S. citizens being evacuated from the Diamond Princess cruise ship in Yokohama, regardless of having signs or symptoms of respiratory infection or not. CDC is preparing a formal email to request our concurrence.

As you know, the currently issued EUA for the CDC's test is not authorized for testing asymptomatic individuals. Based on our knowledge of the device, DMD would not have objections allowing CDC to test asymptomatic individuals using the 2019-nCoV Real-Time RT-PCR Diagnostic Panel kit.

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I will let you know as soon as I receive CDC's formal request. I can be reached at (b) (6) .

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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AMERICAN OVERSIGHT

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**Sent**: 2/15/2020 12:50:20 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: EUA Questions

Thank you. Is it typical for us to waive GMP requirements in an EUA?

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 15, 2020 at 12:41:47 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: EUA Questions

Jeff,

The authorization letter waives certain requirement as cited below:

I am waiving the following requirements for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel during the duration of this EUA:
· Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

However, certain conditions of authorization in the letter mitigate these risks. These conditions include:

G. Through a process of inventory control, CDC will maintain records of test usage.
H. CDC will collect information on the performance of the test. CDC will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which CDC becomes aware.

Here the link to the complete authorization letter: https://www.fda.gov/media/134919/download

Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 9:49 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: EUA Questions

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Yes, thank you!

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 15, 2020 at 9:33:37 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: EUA Questions

The statute's provisions are focused on allowing deviations from GMP requirements.

Do you want me to do check guidance etc. and give you some bullet points?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 9:05:29 AM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** EUA Questions

I have two questions and no rush in responding. I prepping for an upcoming press roundtable on CoV.

Under our EUA authority, do we have oversight over the CDC's (or other makers') manufacturing of their CoV test? Can we require manufacturing data or inspect before or after granting an EUA?

Jeff

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/18/2020 10:00:33 AM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: BARDA Coronavirus support

What support are they seeking from FDA?

Adding Keagan, Anna, and Denise for awareness.

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 18, 2020 at 9:08:13 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** BARDA Coronavirus support

Hi Jeff,

(b) (5)

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

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OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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**Sent:** 2/24/2020 11:35:56 AM
**To:** Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**CC:** Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: enforcement discretion request for COVID-19 for PHLs final.pdf

Stacy,

Thank you. We would have the same conversations with them as we have had with other developers.

Adding Tim and Ellen for awareness.

Jeff

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Date:** February 24, 2020 at 11:20:22 AM EST
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>
**Subject:** RE: enforcement discretion request for COVID-19 for PHLs final.pdf

Jeff -- Marcy Busch can work on this for us. (b) (5) [redacted]

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Monday, February 24, 2020 11:11 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** Fwd: enforcement discretion request for COVID-19 for PHLs final.pdf

(b) (5) [redacted]

Sent from my iPhone

Begin forwarded message:

**From:** "Becker, Scott | APHL" <Scott.Becker@aphl.org>
**Date:** February 24, 2020 at 10:39:18 AM EST
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
**Cc:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Redfield, Robert R (CDC)" <olx1@cdc.gov>, "Kubin, Grace" <Grace.Kubin@dshs.texas.gov>, "Jernigan, Daniel B (CDC)" <dbj0@cdc.gov>
**Subject: enforcement discretion request for COVID-19 for PHLs final.pdf**

AMERICAN OVERSIGHT

Dear Commissioner Hahn,

On behalf of our nation's state and local public health laboratories (PHLs), we are writing to urge you to consider enforcement discretion to allow this select group of governmental laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request. The letter attached details our request.

Please contact me for any follow up or questions you may have at 301-526-5704 or scott.becke@aphl.org

Sincerely,

Scott Becker

**Scott J. Becker** (he/him)
Chief Executive Officer
**P** +1 240.485.2747 | **M** +1 301.526.5704
scott.becker@aphl.org | @scottjbecker

Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
www.aphl.org | APHL Blog
Facebook | Twitter | LinkedIn | Instagram

ID Lab Con 2020 | APHL 2020 Why Attend? (video)

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/14/2020 1:12:00 PM
**To:** Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]
**Subject:** Re: (b) (4)

Thank you.

Jeff

---

**From:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Date:** February 14, 2020 at 12:39:30 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Subject:** (b) (4)

Good morning,

(b) (4) has reached out to us (Adam Saltman in OPEQ shortages) to give us a heads up on what is going on. They did (b) (4) their plant due to a test that they (b) (4) ran that showed the amount of EtO that they were releasing exceeded allowable limits. They are updating equipment to fix this. They have (b) (4) of inventory and do not expect to have any shortages. They will be providing us the information on the products that would be impacted should the fix take longer to implement than the 4 weeks. Also, they will update us with additional information if the situation changes.

--Linda

Linda Ricci, MME MPH
*Director*

**Division of All Hazard Response, Science and Strategic Partnerships (DARSS)**
**Office of Strategic Partnerships and Technology Innovation (OST)**
**CDRH | Food and Drug Administration**
Tel: 301-796-6325
Cell: 240-506-4356
Linda.Ricci@fda.hhs.gov
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AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/19/2020 3:10:33 PM
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** RE: what do I need to know for AMA check in at 3:30 today? thanks.

(b) (5)

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 19, 2020 at 3:08:09 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: what do I need to know for AMA check in at 3:30 today? thanks.

(b) (5)

Just anticipating the questions we may get asked. Dr. Hahn will join this check in too.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 3:07 PM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: what do I need to know for AMA check in at 3:30 today? thanks.

Anna,

(b) (5)
More details to come.

No word yet on (b) (5)

Jeff

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 19, 2020 at 2:58:33 PM EST
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: what do I need to know for AMA check in at 3:30 today? thanks.

AMERICA OVERSIGHT

Plus Jeff – Jeff any update on the CDC test? Want to be prepared if asked.

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 2:50 PM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: what do I need to know for AMA check in at 3:30 today? thanks.

Safe to proceed letter for NIAID's coronavirus trial has been signed. Kudos CDER

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Sent:** Wednesday, February 19, 2020 2:44 PM
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** what do I need to know for AMA check in at 3:30 today? thanks.

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/15/2020 11:22:17 AM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: N95 Respirators

I appreciate the creativity!

(b) (5) [redacted]

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 11:12 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 Respirators

(b) (5), (b) (4) [redacted]

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 11:09 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: N95 Respirators

That would be good, although (b) (5) [redacted]

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 11:02 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 Respirators

(b) (5) [redacted]

I was thinking that (b) (5) [redacted]

AMERICAN OVERSIGHT

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 10:59 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: N95 Respirators

(b) (5) [redacted]

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 10:53 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 Respirators

(b) (5) [redacted]

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 10:32 AM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Thank you. Yes, please discuss.

I was thinking we would (b) (5) [redacted]

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 15, 2020 at 10:21:07 AM EST
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Predecisional / Deliberative

AMERICAN OVERSIGHT

(b) (5) [redacted]

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 10:14 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Okay - so modifying the one sent forward. Is that correct?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 10:06:59 AM EST
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Thank you. Adding Ellen.

I think we could also (b) (5) [redacted]

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 9:42:30 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Good Morning,

(b) (5) [redacted]

AMERICAN OVERSIGHT

FYI I was on leave yesterday and will be returning on Wed. All credit for the quick response goes to the team.

Binita

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 8:15:38 AM EST
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** N95 Respirators

Thank you and your team for the quick work on an EUA for N95 respirators and your flexibility. My understanding is (b) (5) [redacted] Given the current environment, we would expect healthcare workers to use N95 respirators in two types of situations – one in non-surgical/non-emergency settings with known or possible coronavirus patients (or patients with another serious, highly contagious infection) and one in surgical/emergency settings with the same patient population where they may be exposed to high pressure bodily fluids.

Could/should we (b) (5) [redacted]

Jeff

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/20/2020 5:27:25 PM
**To:** Tim Stenzel (Timothy.Stenzel@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** FW: Problems with CDC coronavirus test delay expanded US screening

**Importance:** High

Please see the story in POLITICO Pro below. According to the article, APHL is saying that only 3 of the public health labs have been able to verify use of the CDC test. (b) (5) (b) (5). Can OHT7 follow up with CDC on the veracity of what APHL is reporting?

The article also states that CDC will distribute a second test and will need it approved by the FDA first, according to CDC.

Jeff

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 5:19 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** FW: Problems with CDC coronavirus test delay expanded US screening

FYI

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: (b) (6)
jennifer.tomasello@fda.hhs.gov






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---

**From:** POLITICO Pro <politicoemail@politicopro.com>
**Sent:** Thursday, February 20, 2020 5:04 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Problems with CDC coronavirus test delay expanded US screening

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# Problems with CDC coronavirus test delay expanded US screening

By David Lim

02/20/2020 05:03 PM EST

Problems with a coronavirus test developed by the CDC have delayed the Trump administration's efforts to expand screening to state and local public health labs, more than two weeks after the FDA granted permission to distribute the CDC test nationwide.

Only three of the more than 100 public health labs across the country have verified the CDC test for use, according to the Association of Public Health Laboratories.

The delay has also hampered CDC's plan to screen samples collected by its national flu-surveillance network for the coronavirus, according to Peter Kyriacopoulos, APHL's senior director of public policy. CDC hopes to use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples that test negative for the flu and other common respiratory viruses for the coronavirus.

CDC confirmed the problems with the coronavirus test, and with using its flu-surveillance network to screen for the virus. But the agency declined to answer further questions on the matter.

The delay in establishing additional screening capacity could impede the U.S. government's ability to detect scattered cases before they snowball into larger outbreaks, former FDA Commissioner Scott Gottlieb told POLITICO.

"By that point, it may be harder to contain spread, and we'll be forced to rely on mitigation tactics to just limit the impact of the virus," he said.

More than 75,000 cases of coronavirus infection have been confirmed globally as of Thursday, and more than 2,100 people have died, according to the World Health Organization. The vast majority of cases are in China, where the virus first emerged, although countries such as Japan, South Korea and Iran are also battling local outbreaks.

In the United States, efforts to expand use of the CDC test have struggled after one of the three reagents upon which the test depends delivered inconclusive results during quality checks, said Kelly Wroblewski, APHL's director of infectious diseases. Samples that test positive at any of the three labs are still being sent to CDC for retesting.

CDC has not told public health labs when it will distribute a second version of the diagnostic test, Wroblewski said. That has left many labs struggling to decide if it is worth continuing to pursue verification of the current version, because they will have to go through the process again once the CDC revises its testing procedure, she added.

Nancy Messonnier, director of the CDC's National Center for Immunization and Respiratory Diseases, told reporters on Feb. 14 that the public health agency is reformulating the original test and is moving quickly to get the revised version to labs. FDA would have to authorize any changes to the coronavirus test before the CDC could distribute a new one.

But concerns about money also threaten the rollout of state and local coronavirus testing. Over the weekend, more than 20 Senate Democrats called for additional cash after Trump administration officials told senators during a Feb. 12 briefing that HHS would soon exhaust existing funding for its response to the virus.

"We strongly urge the administration to transmit an emergency supplemental request that ensures it can and will fully reimburse states for the costs they are incurring as part of this response," the senators wrote in a letter to HHS Secretary Alex Azar and OMB Director Mick Mulvaney.

The diagnostic test can cost up to $250 to run, depending on procedures and volume of tests a lab performs, according to Wroblewski. But it is unclear who is paying for personnel costs and other items such as personal protective gear, machines to extract RNA and sample transportation, according to APHL.

"This is a national-level response, so we would hope the federal government would have an interest in

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supporting a national-level response," Kyriacopoulos said. "Labs are much more interested in beginning to get the work done. But figuring out how to pay for it is not far behind."

*To view online*:
https://subscriber.politicopro.com/ehealth/article/2020/02/problems-with-cdc-coronavirus-test-delay-expanded-us-screening-1882473

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/20/2020 10:34:14 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** Fwd: N95 Framework Documents for EUAs

FYI

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Date:** February 20, 2020 at 9:45:41 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: N95 Framework Documents for EUAs

(b) (5) [redacted]

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 9:24 PM
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** Fwd: N95 Framework Documents for EUAs

Deliberative/Predecisional

I could use your help. (b) (5) [redacted]

(b) (5) [redacted]

Happy to discuss.

AMERICAN OVERSIGHT

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 20, 2020 at 8:48:52 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: N95 Framework Documents for EUAs

Update from OCET

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** February 20, 2020 at 8:21:42 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Cc:** Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>, O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** RE: N95 Framework Documents for EUAs

Hi- (b) (5) [redacted]

(b) (5) [redacted]

Thanks, Liz

-----Original Appointment-----
**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 12:05 PM

AMERICAN OVERSIGHT

**To:** Flannery, Ellen; Ross, Jennifer; Busch, Marcy; Dennis, Claire; Sadove, Elizabeth; Agler, Heather L; Ross, Aftin; Marders, Julia A
**Cc:** Kannan, Lakshmi; O'Callaghan, Kathryn; Ricci, Linda J; Tomasello, Jennifer
**Subject:** N95 Framework Documents for EUAs
**When:** Friday, February 21, 2020 3:00 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** 5425

-- Do not delete or change any of the following text. --

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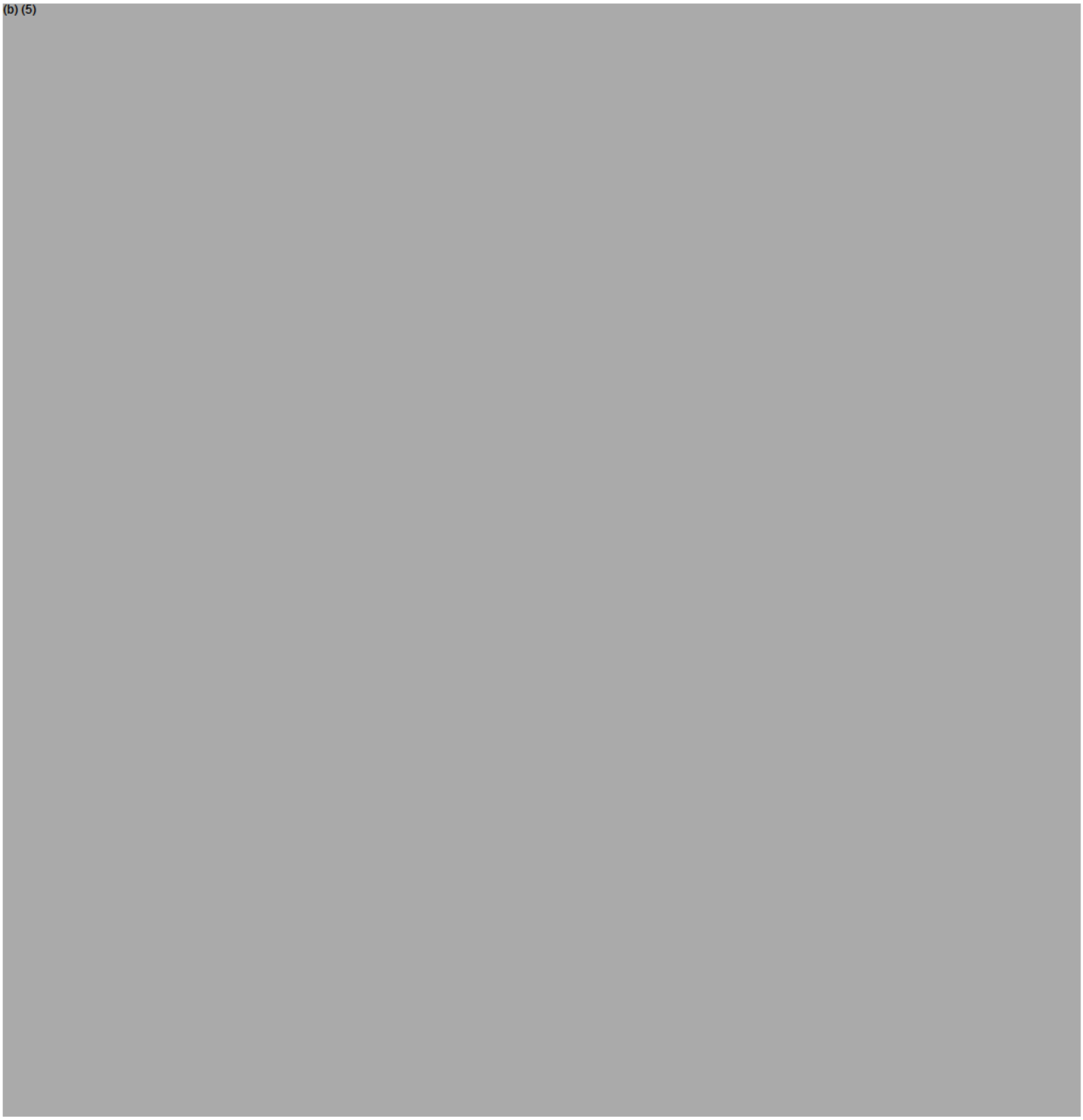
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## Senate HELP Bipartisan Staff Briefing on Supply Chain: Follow-up Questions

*Note: There may be some data we are not able to provide. If that is the case please explain why we can't (e.g.: it's CCI; the data is not provided in a useable format; we track specific products, ingredients, processes, etc. so we would not have data that speaks to this). This will provide important context to the Committee.*

(b) (5)



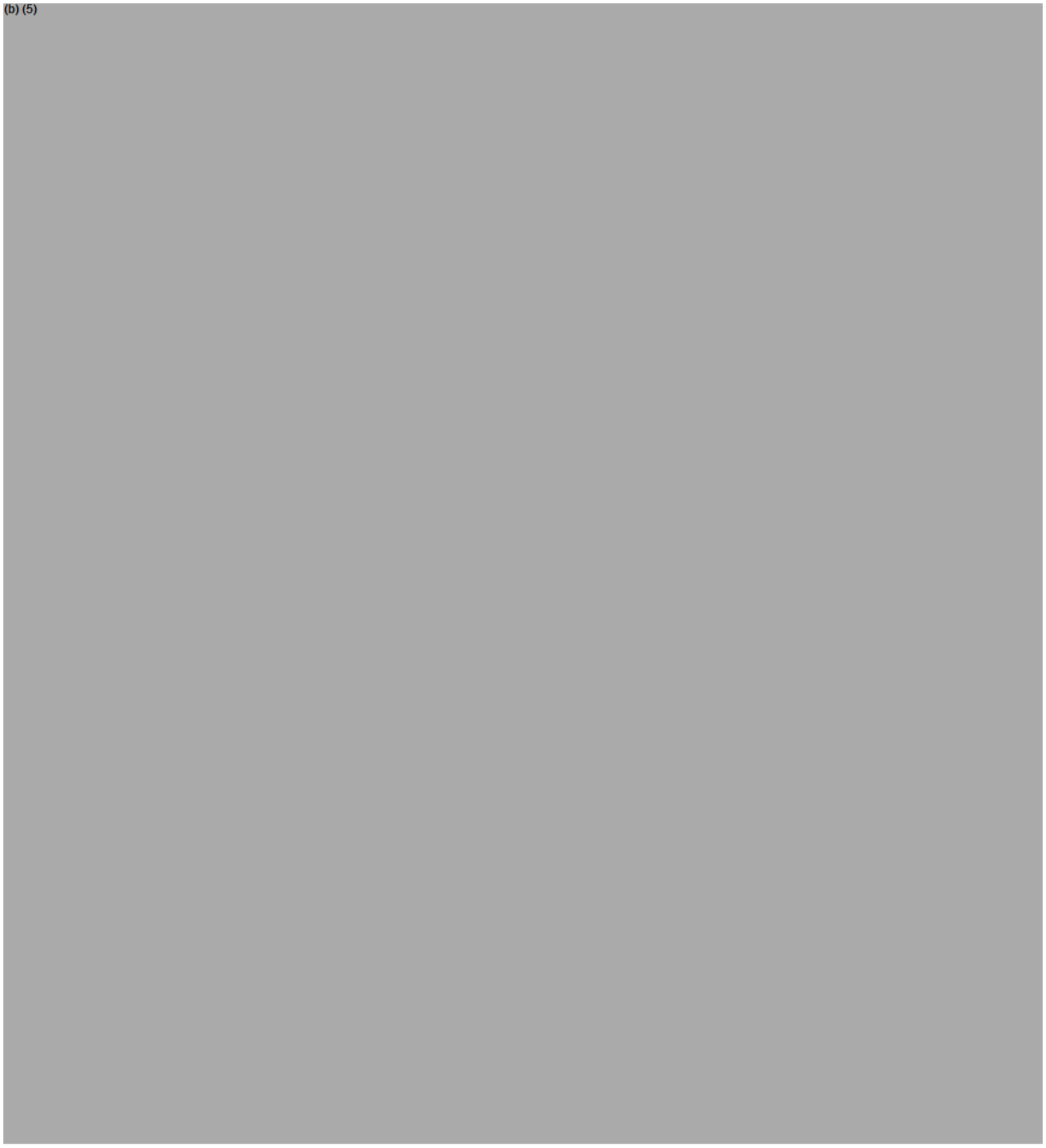
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(b) (5)



AMERICAN OVERSIGHT

(b) (5)



AMERICAN OVERSIGHT

(b) (5)



AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/20/2020 4:35:33 AM
**To:** O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]
**CC:** Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**Subject:** COVID-19 Hearings
**Attachments:** Senate HELP Bipar followup questions 2.18.20.docx

Dr. Hahn now has three congressional hearings on COVID-19. There is a prep session at 3:30 PM today for the E&C hearing that I am attending. As you've seen from Jennifer's updates on Hill briefings (Heather, I believe you have been participating), much of the focus for devices is (b) (5) [redacted] All the things the team has been working on.

In light of today's prep, I'll need the latest information on what we know for when we meet later today, including the chart on (b) (5) [redacted]

There also may be other questions E&C staff or members have raised during briefings that Jennifer/Heather can provide more details on.

Jeff

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 19, 2020 at 7:24:53 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Cc:** CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>
**Subject:** COVID-19 Congressional Update - 2.19.2020

Good evening all,

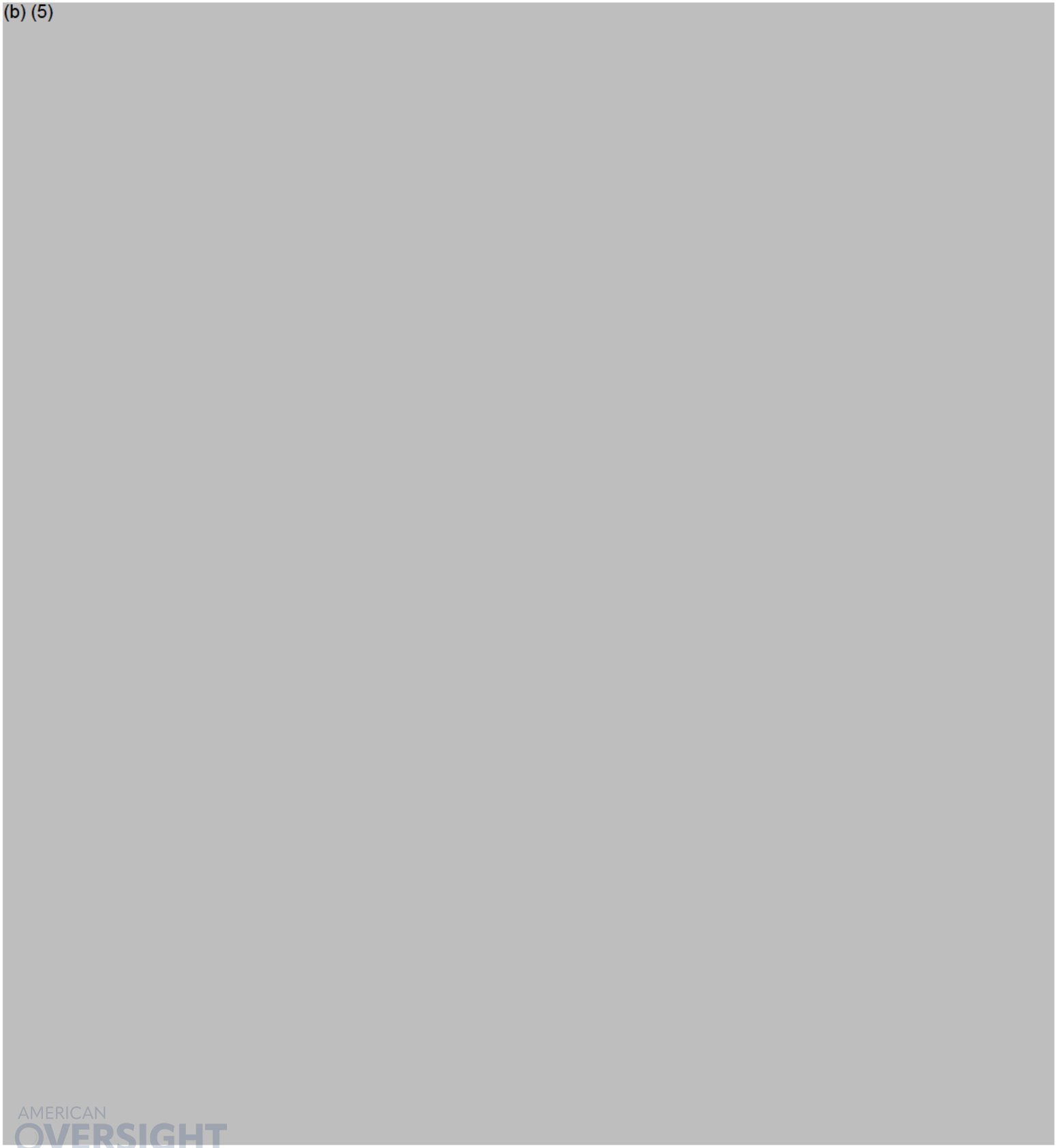
Below are some updates on FDA's Congressional engagement with respect to COVID-19 response efforts. Please do let me know if anyone has questions.

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Best,

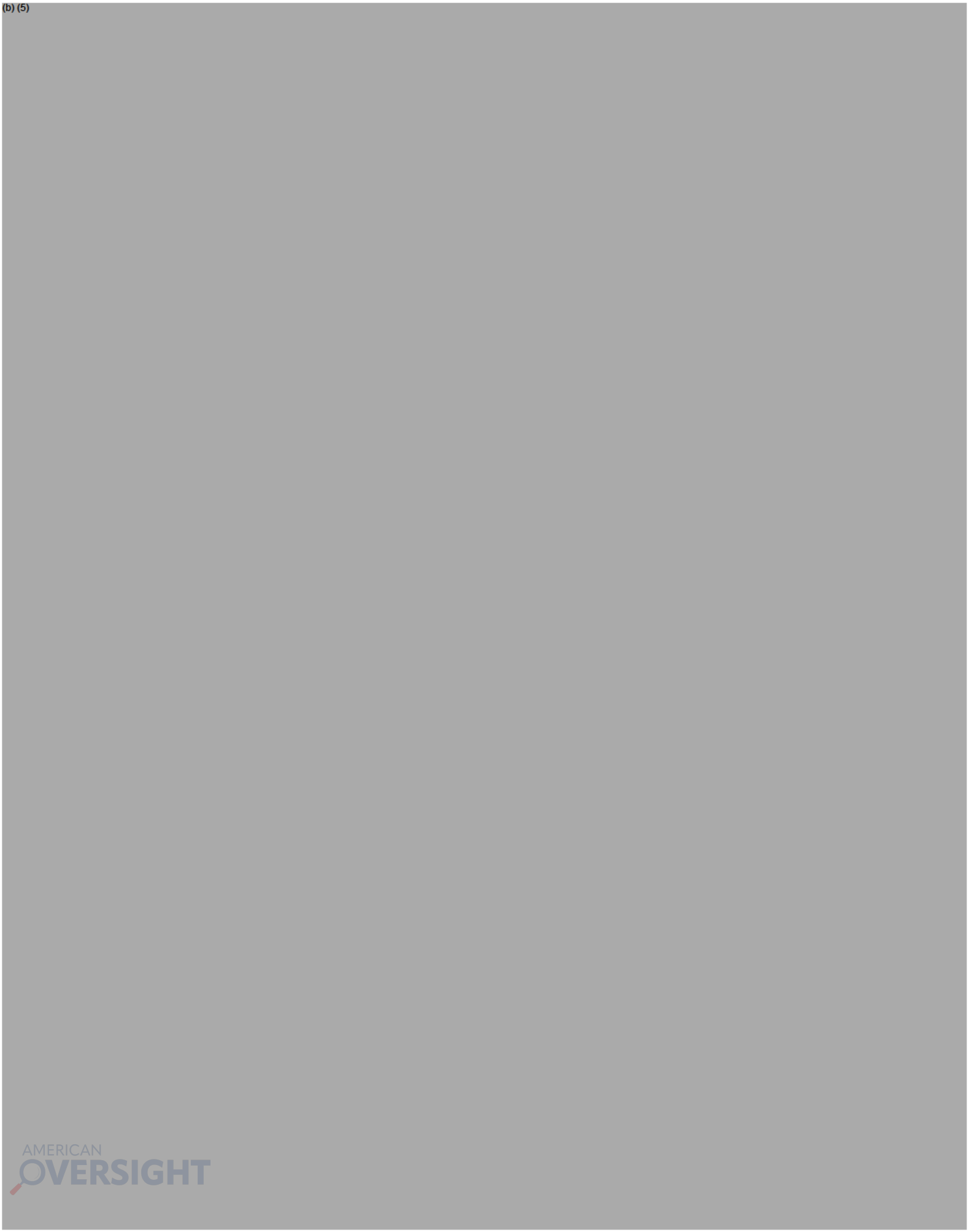
Jennifer

(b) (5)

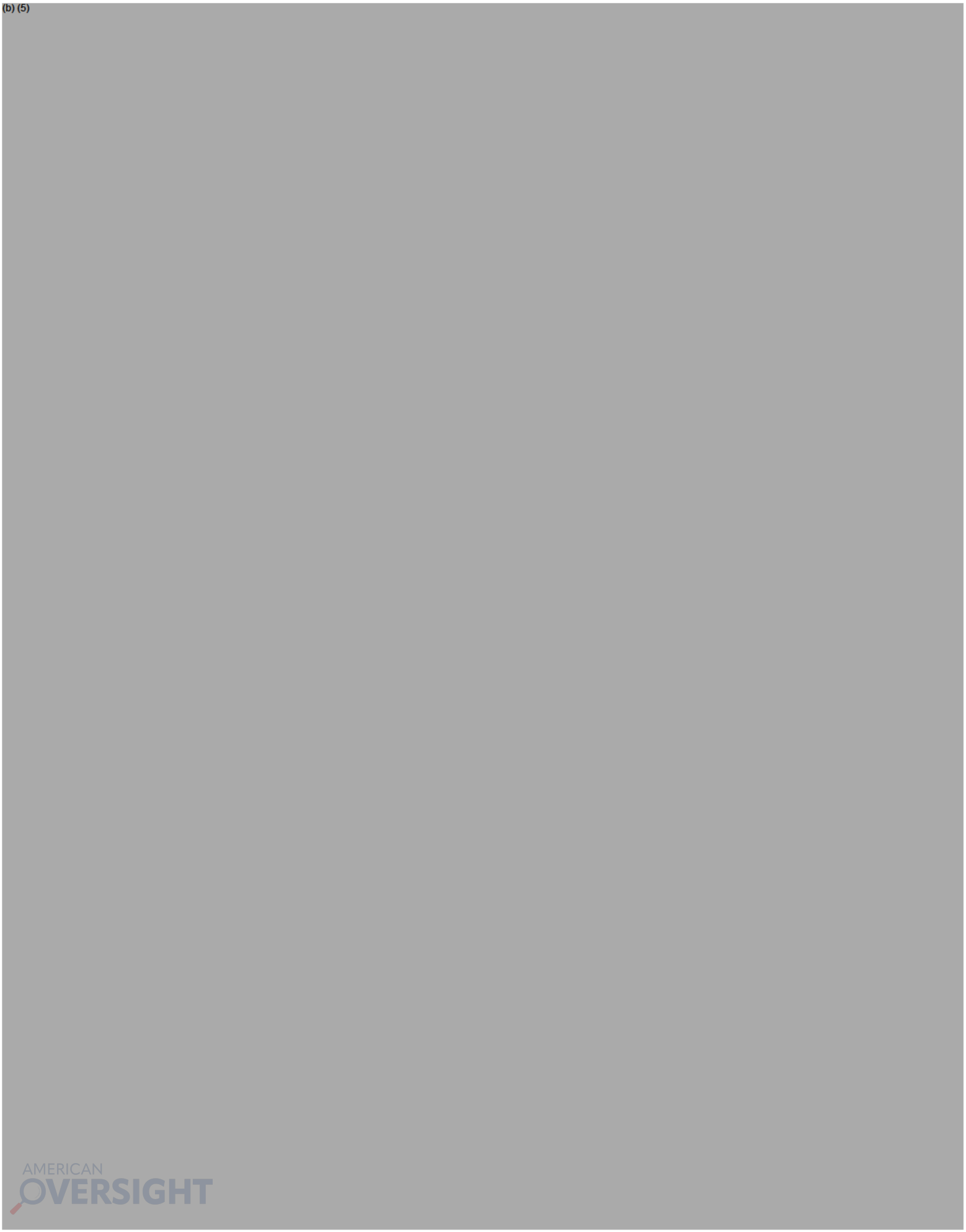


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(b) (5)



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(b) (5)

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(b) (5)

[redacted]

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov






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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/23/2020 10:44:13 AM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** Re: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Thank you

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 23, 2020 at 10:38:35 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

The EUA-related draft documents will be going back to CDC with our comments today, probably this morning.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 22, 2020 at 9:57:18 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

TY!!

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 22, 2020 at 9:45:55 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Dear Wendi,

On February 4, 2020, the Centers for Disease Control and Prevention (CDC) received an Emergency Use Authorization (EUA) for the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing.

Today, February 22, 2020, CDRH/FDA was informed that CDC would need enforcement discretion from FDA, until approval of a new EUA, for certain public health surveillance testing activities that do not fall within the currently authorized intended use of the assay (EUA200001) – namely, CDC has identified an urgent need to partner with designated jurisdictions and surveillance sites across the United States to perform testing to

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identify possible transmission of SARS-CoV-2 among individuals without a clear epidemiologic link (contact with known cases or history of recent travel to mainland China).

At this time, there are no adequate, approved, and available alternative tools that can detect SARS-CoV-2 during the acute phase of infection in the United States in symptomatic individuals without the epidemiological risk factors. In addition, unlike typical surveillance activities, individuals who test positive or inconclusive for SARS-CoV-2 using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel will be notified of their test result and followed up accordingly.

Our understanding of the facts and the public health concerns at issue here are that there is currently no other test available to respond to this emergency, significant public health concerns are presented by the infectious disease, the proposed testing may help to prevent the spread of the infectious disease, and the testing activity will help to support situational awareness and guide the public health response to COVID-19. Based on this understanding, at this time, FDA does not intend to object to the use of this test as described above, with the following conditions: that all patients must be adequately informed about the status of this testing and the potential implications of agreeing to this testing, and that CDC will act promptly to submit an application for a new EUA to authorize the testing described above.

If you have any questions, please contact Uwe Scherf or me.

Sincerely,
Ellen

**Ellen J. Flannery, J.D.**
*Deputy Center Director for Policy*
*Director, Office of Policy*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Ellen.Flannery@fda.hhs.gov






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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/19/2020 6:11:20 PM
**To:** Tim Stenzel (b) (6)
**CC:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** RE: [idsd] - CDC LOCS communication: Reminder: COVID-19 Diagnostic Testing

Thanks

---

**From:** Tim Stenzel (b) (6)
**Sent:** Wednesday, February 19, 2020 6:03 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Subject:** Fwd: [idsd] - CDC LOCS communication: Reminder: COVID-19 Diagnostic Testing

Hi Jeff, Thought you might be interested in this AMP communication that the CDC asked them to share. AMP has a webinar scheduled on Coronavirus testing and Uwe and his team are scheduled to be listening in to the AMP webinar. Best, Tim

Sent from my iPad

Begin forwarded message:

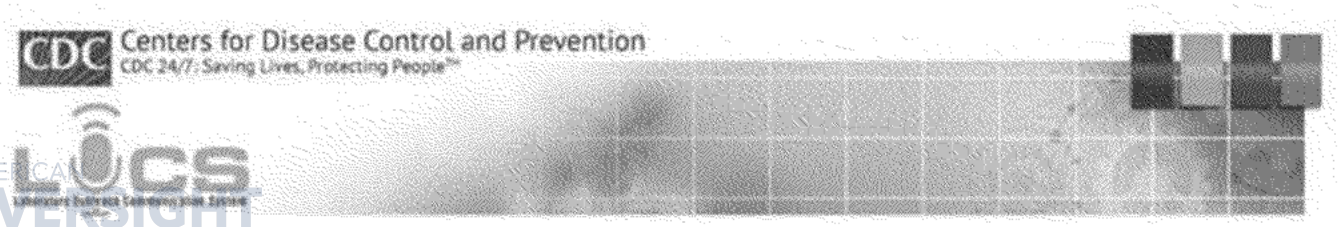
**From:** "Infectious Diseases Subdivision Discussion; on behalf of Robyn Temple Smolkin" <idsd@lists.amp.org>
**Date:** February 19, 2020 at 4:24:02 PM EST
**To:** "idsd@lists.amp.org" <idsd@lists.amp.org>
**Subject: [idsd] - CDC LOCS communication: Reminder: COVID-19 Diagnostic Testing**
**Reply-To:** idsd@lists.amp.org

Hello AMP ID Subdivision members –

The message below was received Tuesday, February 18, 2020 as part of AMP's participation in the CDC Clinical Lab Partners group. We will pass along information to our membership when requested by government agencies or AMP leadership.

***REMINDER:* The AMP Training & Education Committee will host a FREE webinar "The 2019 Novel Coronavirus Outbreak: What Laboratories Need to Know about the Virus, Epidemiology, and Diagnostic Testing" TOMORROW Thursday, February 20, 1:00 PM ET.**

CLICK HERE for registration and additional information. ***This webinar is free for ALL attendees***, so please share the link with your interested colleagues.




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**Audience:** Clinical Laboratory Professionals

**Subject:** Reminder: COVID-19 Diagnostic Testing

**Level:** Laboratory Advisory

The Food and Drug Administration (FDA) granted an Emergency Use Authorization (EUA) for the CDC 2019-Novel Coronavirus (COVID-19) Real-Time RT-PCR Diagnostic Panel which is to be used in qualified laboratories for testing patient respiratory specimens that meet CDC criteria for COVID-19 testing. **This message is to remind clinical laboratories that this is currently the only EUA assay for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19. Any laboratory that is not designated by CDC as a qualified laboratory and is implementing a COVID-19 diagnostic test other than the CDC EUA assay must contact the FDA to obtain an EUA before any COVID-19 diagnostic testing may be performed in their facilities.**

The Secretary of Health and Human Services issued an emergency declaration that justifies the authorization of emergency use of in vitro diagnostics for the detection of SARS-CoV-2 and the diagnosis of COVID-19. All tests for SARS-CoV-2, including laboratory developed tests (LDTs), must be reviewed and cleared or authorized by the FDA for emergency use, or they cannot be used for diagnostic testing. The FDA requests that developers of such LDTs submit information about their tests to help FDA better understand their design, validation, and performance characteristics. For more details, please refer to FDA: Information for Laboratories Implementing IVD Tests Under EUA.

Qualified laboratories for use of the CDC-distributed 2019-nCoV Real-Time RT-PCR Diagnostic Panel, as defined by the EUA, include select U.S. state and local public health laboratories and Department of Defense laboratories. Diagnostic testing with this assay can only be done at CDC and by these qualified laboratories. The state and local public health laboratories are in the process of implementing the CDC EUA assay.

Clinical laboratories should contact their state health departments for guidance if they have a suspected COVID-19 case specimen. Clinical laboratories that need a diagnostic test for COVID-19 performed should contact their local health department, which will either provide testing or facilitate referral of the specimen to the CDC for testing.

Clinical laboratories should NOT attempt viral isolation from specimens collected from COVID-19 persons under investigation (PUIs). For interim guidelines for collecting, handling, and testing clinical specimens from PUIs for COVID-19, please see the CDC Coronavirus Disease 2019 (COVID-19) website.

**Additional Resources:**

- CDC 2019 Novel Coronavirus Laboratory Biosafety
- CDC Information for Laboratories: COVID-19
- CDC 2019 Novel Coronavirus
- International Air Transport Association (IATA) Dangerous Goods Regulation
- IATA Packing Instructions 650
- Register for CDC Health Alert Network (HAN) notifications, including updates about the 2019 Novel Coronavirus. Enter your email address, search for HAN, and sign-up.
- Add CDC's 2019 Novel Coronavirus Microsite to your website for real-time content updates

If you have any questions, please contact us at LOCS@cdc.gov.

Thank you,

The Laboratory Outreach and Communications System
**Laboratory Outreach Communication System (LOCS)** | Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Centers for Disease Control and Prevention (CDC)
LOCS@cdc.gov

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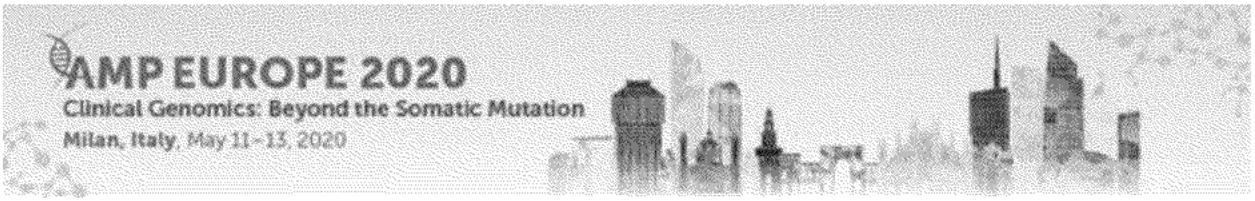
www.cdc.gov/csels/dls/locs

Thanks, Robyn

**Robyn Temple-Smolkin, MBA, PhD, HCLD**
Director, Clinical & Scientific Affairs
Association for Molecular Pathology (AMP)
6120 Executive Blvd., Suite 700
Rockville, MD 20852

Tel: (b) (6)
Email: rtemple@amp.org | Web: www.amp.org
Follow AMP on Twitter: @AMPath

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Posted By: Robyn Temple-Smolkin, Director, Clinical and Scientific Affairs at Association for Molecular Pathology
Email Address: rtemple@amp.org

**Attachment Links:** image001.jpg (11 k) image002.jpg (10 k)
**Site Links:** View post in thread online View community discussion online Start new thread via email Unsubscribe from this mailing list Manage your subscription

This email has been sent by the Association for Molecular Pathology (AMP) to: ttstenzel@gmail.com

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/19/2020 6:59:36 AM
**To:** Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; MacLennan, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e3684d6a36e4002bc07015b7506b803-Lori.MacLen]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]
**CC:** O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: N95 EUA Template

Thank you.

Jeff

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Date:** February 19, 2020 at 6:53:01 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Cc:** O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: N95 EUA Template

Thank you, Jeff. I will work with Lori on developing the messaging quickly.

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: 240-507-3139
Email: Heather.Agler@fda.hhs.gov

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**From:** Shuren, Jeff
**Sent:** Wednesday, February 19, 2020 5:03 AM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Cc:** O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** N95 EUA Template

Heather, Lori — As you know, we will make available two EUA templates for makers of standard N95 respirators to seek an EUA for surgical and non-surgical uses in healthcare settings as well as offer to work with them through pre-EUAs, as we've been doing with diagnostic test makers. While we work with OCC on whether we can grant EUAs in a more streamlined fashion, e.g., bulk EUAs, can you please raise this to the JIC to develop a communication plan? We could have the templates ready to go this week, depending on OCC clearance.

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Heather, Linda — I would give IMG and CDC a heads up of what we plan to do. I would also reach out to makers of standard N95s once OCC clears the templates to encourage them to request an EUA and offer to work with them.

Jeff

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/13/2020 12:39:00 PM
**To:** Hahn, Stephen (b) (6) Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** Re: N95 Respirators

(b) (4), (b) (5)

---

**From:** Hahn, Stephen (b) (6) @fda.hhs.gov>
**Date:** February 13, 2020 at 12:33:06 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Thanks, Jeff. (b) (5)
Steve

---

**From:** Jeffrey Shuren <Jeff.Shuren@fda.hhs.gov>
**Date:** Thursday, February 13, 2020 at 12:32 PM
**To:** Stephen Hahn (b) (6) @fda.hhs.gov>, Anna Abram <Anna.Abram@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** N95 Respirators

Confidential/Deliberative/Privileged

(b) (5)

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/19/2020 12:44:14 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: Today's CDC Call

Thank you.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 19, 2020 at 12:42:30 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Today's CDC Call

Hi Jeff,

Uwe and I just got off the call for the new Sentinel Surveillance proposal. They answered all our questions and we will start working on the draft proposal that arrived today. They anticipate finalizing the proposal with the sites in the next day or two and submitting it to us for a new EUA approval. They understood the importance of separating this approval from the previous diagnostic approval. In discussion with the sites, they will do some more work on what it means to notify patients of the Coronavirus testing and understand the importance of documenting that notification in some way.

Separately, we asked the status of the (b) (5) [redacted]

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*
OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

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CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/20/2020 9:24:19 PM
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
**Subject:** Fwd: N95 Framework Documents for EUAs

Deliberative/Predecisional

I could use your help. As you know, we may be looking at shortages of surgical N95 respirators, which are regulated by FDA. Much of the market is standard N95 respirators, which are for use in non-healthcare settings and which FDA does not regulate. We have developed (b) (5) [redacted] Please see Liz Sandove's email below.

We're a bit confused and are seeking clarity as to what the Agency would like to do. (b) (5) [redacted]

Happy to discuss.

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 20, 2020 at 8:48:52 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: N95 Framework Documents for EUAs

Update from OCET

---

**From:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
**Date:** February 20, 2020 at 8:21:42 PM EST
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Cc:** Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>, O'Callaghan, Kathryn

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<Kathryn.OCallaghan@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
**Subject:** RE: N95 Framework Documents for EUAs

Hi- (b) (5) [redacted]

(b) (5) [redacted]

Thanks, Liz

-----Original Appointment-----
**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 12:05 PM
**To:** Flannery, Ellen; Ross, Jennifer; Busch, Marcy; Dennis, Claire; Sadove, Elizabeth; Agler, Heather L; Ross, Aftin; Marders, Julia A
**Cc:** Kannan, Lakshmi; O'Callaghan, Kathryn; Ricci, Linda J; Tomasello, Jennifer
**Subject:** N95 Framework Documents for EUAs
**When:** Friday, February 21, 2020 3:00 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** 5425

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

Meeting number (access code): (b) (6) [redacted]
Meeting password: (b) (6) [redacted]

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/20/2020 10:59:53 AM
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]
**CC:** Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** RE: COVID-19 Hearings

Jennifer,

Thank you. It would be helpful to know about the outreach to hospitals.

Jeff

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 20, 2020 at 8:30:57 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: COVID-19 Hearings

Jeff,

Staff have also been asking about (b) (5) [redacted]

(b) (5) [redacted]

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(b) (5) [redacted]

Please do let me know if anyone has questions. Will let everyone know if anything new is raised on the HSGAC call today at noon, before the Commissioner's prep this afternoon.

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: (b) (6) [redacted]
jennifer.tomasello@fda.hhs.gov






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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 8:06 AM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** RE: COVID-19 Hearings

Heather,

Great. For Q8, I didn't think (b) (5) [redacted]

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Jeff

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 7:09 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** RE: COVID-19 Hearings

HI Jeff,

Jennifer and I are starting to populate the questions that we received from the HELP Committee. Please see the initial draft of responses. Please note that we are still working on responses to 13, 15, and 16. While that does not provide the type of numbers that we will be preparing for you today, it provides information on how we intend to respond.

Thanks,
Heather

Heather Agler
Devices Lead/Operations
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk: 301-796-6340
Cell: (b) (6)
Email: Heather.Agler@fda.hhs.gov

---

**From:** Shuren, Jeff
**Sent:** Thursday, February 20, 2020 4:36 AM
**To:** O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** COVID-19 Hearings

Dr. Hahn now has three congressional hearings on COVID-19. There is a prep session at 3:30 PM today for the E&C hearing that I am attending. As you've seen from Jennifer's updates on Hill briefings (Heather, I believe you have been participating), much of the focus for devices is on (b) (5) [redacted] There's plenty of interest in what (b) (5) [redacted] etc. All the things the team has been working on.

In light of today's prep, I'll need the latest information on what we know for when we meet later today, including the chart on (b) (5) [redacted], etc.

There also may be other questions E&C staff or members have raised during briefings that Jennifer/Heather can provide more details on.

Jeff

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 19, 2020 at 7:24:53 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A

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<Julia.Marders@fda.hhs.gov>, O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Cc:** CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>
**Subject:** COVID-19 Congressional Update - 2.19.2020

Good evening all,

Below are some updates on FDA's Congressional engagement with respect to COVID-19 response efforts. Please do let me know if anyone has questions.

Best,

Jennifer

**Hearings**

(b) (5)

**Briefings:**

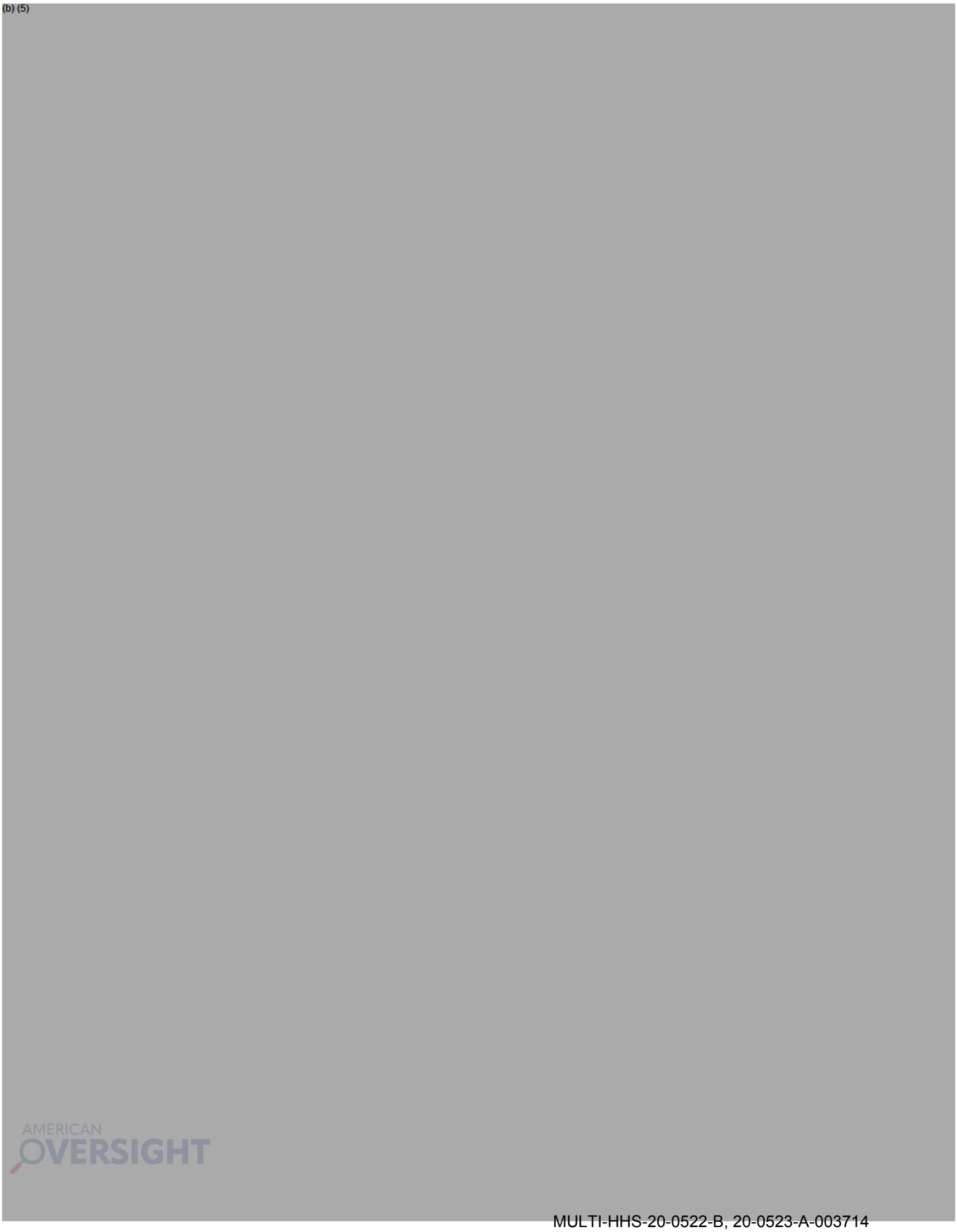
(b) (5)

**Summary of Briefing for bipartisan staff of the Senate HELP Committee – 2.18.2020**

(b) (5)

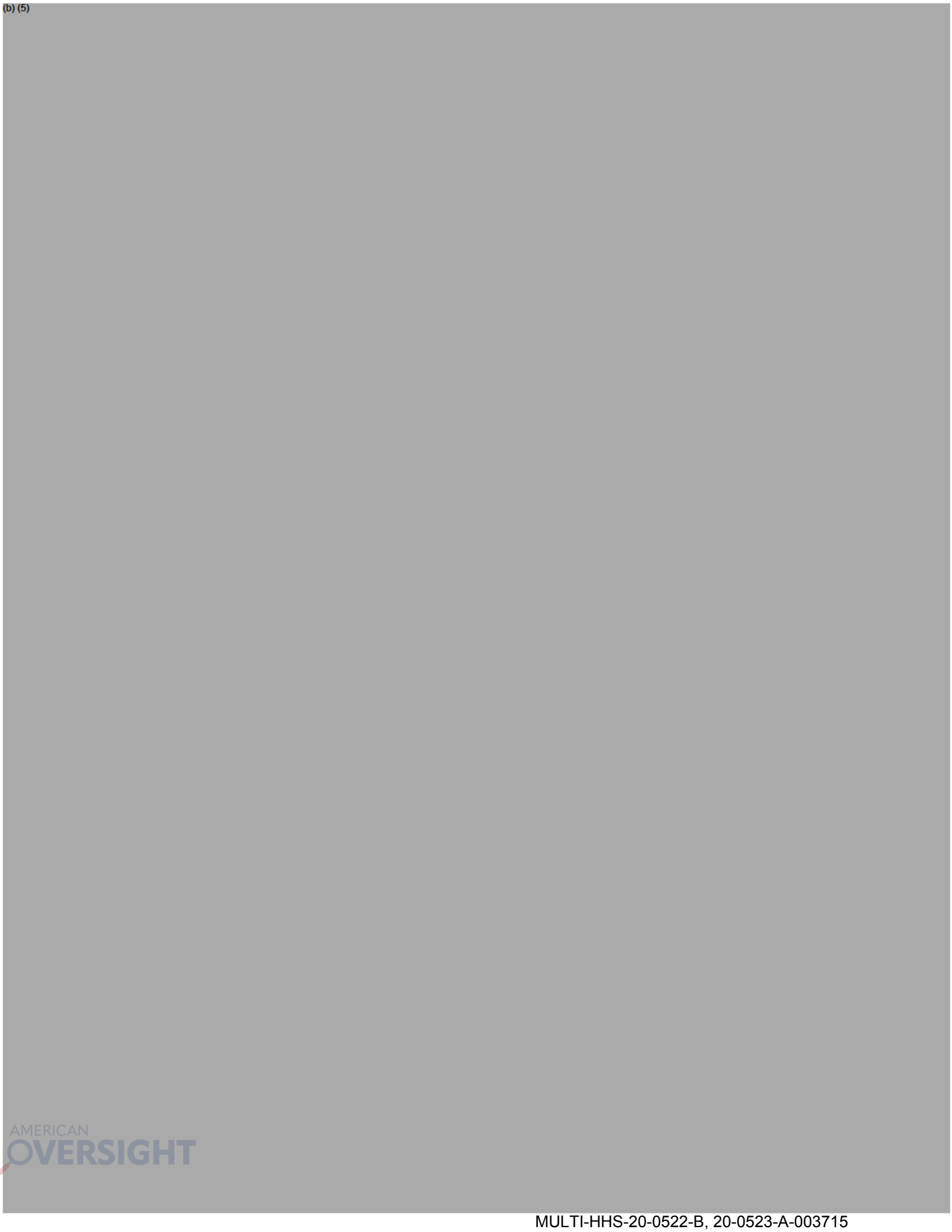
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(b) (5)



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(b) (5)



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(b) (5)

[redacted]

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: (b) (6) [redacted]
jennifer.tomasello@fda.hhs.gov

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/18/2020 7:08:41 PM
**To**: Chang, Cynthia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dcd7bfbdbd3401b8092b3f4cd157208-Cynthia.Cha]
**CC**: Krause, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43e466e978c844dc83be09a25e972eca-dxk]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Claverie, Elizabeth F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=316a6efc030f403398c138d318dc487d-EFC]; Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]
**Subject**: RE: N95 Respirators

Cynthia,

Great. Thank you. Also, I forgot to ask, (b) (5) [redacted]

Jeff

---

**From:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 6:42 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Jeff,

Following our discussion and after conferring with Liz, (b) (5) [redacted]

(b) (5) [redacted]

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OHT4 has not reviewed these yet, but I wanted to provide this based on our discussion.

Best regards,
Cynthia

**Cynthia J. Chang, Ph.D.**
*Director*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4646 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6970 | (301) 796-6891
Cynthia.Chang@fda.hhs.gov

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 5:48 PM
**To:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Cynthia,

Thank you. I'm on a call right now that should end shortly. Can I give you a call in about 5 minutes?

Jeff

---

**From:** Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 5:45 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Dear Dr. Shuren,

(b) (5)

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(b) (5)



The team additionally removed (b) (5) as recommended by Binita.

Please let us know of additional questions or requests.

Best regards,
Cynthia

**Cynthia J. Chang, Ph.D.**
*Director*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4646 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6970 | (301) 796-6891
Cynthia.Chang@fda.hhs.gov

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**From:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 8:34 AM
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 Respirators

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Good morning, All,

I am in receipt of the emails and will work with Cynthia and the team to respond soonest today.

Respectfully,
Liz

**Elizabeth F. Claverie-Williams, MS**
*CAPT, USPHS-CC, Microbiologist*
*Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection*
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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Elizabeth.Claverie@fda.hhs.gov






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**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Sent:** Tuesday, February 18, 2020 7:38 AM
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Krause, David <David.Krause@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: N95 Respirators

Good Morning Liz and Cynthia,

Resensding this email during normal business hours –

(b) (5)

I am on leave today so if you could reply all, that would be helpful.

Thank you.
Binita

**Binita S. Ashar, MD, MBA, FACS**
*Director*
OHT4: Office of Surgical and Infection Control Devices

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Office of Product Evaluation and Quality
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Binita.Ashar@fda.hhs.gov






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---

**From:** Ashar, Binita S
**Sent:** Saturday, February 15, 2020 9:30 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Dear All,

Please see attached:

(b) (5)

I modified these without conferring with the OHT4 team since I am not sure that they are checking email today. Hopefully this serves to keep things moving until they have an opportunity to review.

Binita

**Binita S. Ashar, MD, MBA, FACS**
*Director*

OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G408 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6970
Binita.Ashar@fda.hhs.gov

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 6:45 PM
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Binita,

Sorry for taking so long to get back to you. Ellen has been talking with OCC with the hope of resolving issues today but we are now not expecting a response on whether or not we (b) (5) [redacted]

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 10:13:56 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Okay - so modifying the one sent forward. Is that correct?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 10:06:59 AM EST
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

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Thank you. Adding Ellen.

I think we could also (b) (5) [redacted]

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 9:42:30 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Good Morning,

(b) (5) [redacted]

FYI I was on leave yesterday and will be returning on Wed. All credit for the quick response goes to the team.

Binita

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 8:15:38 AM EST
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** N95 Respirators

Thank you and your team for the quick work on an EUA for N95 respirators and your flexibility. My understanding is (b) (5) [redacted]. Given the current environment, we would expect healthcare workers to use N95 respirators in two types of situations – one in non-surgical/non-emergency settings with known or possible coronavirus patients (or patients with another serious, highly contagious infection) and one in surgical/emergency settings with the same patient population where they may be exposed to high pressure bodily fluids.

Could/should we (b) (5) [redacted]

Jeff

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/21/2020 2:20:42 PM
**To:** Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Re: Coronavirus and MERS culturing

Tim,

Isn't CBER who's handling this?

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 21, 2020 at 2:13:21 PM EST
**To:** Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Coronavirus and MERS culturing

Hi Pillai,

Great to meet you today! I wanted to reach out and have copied Jeff to find out more details about the coronavirus and mers cultures. We have a number of test developers who cannot complete validation of their EUA assays until they have at least mock samples made with virus to test.

How soon will virus be available?
Can we connect developers with someone here at the agency so they can coordinate access?

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov
**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/20/2020 1:58:22 PM
**To**: Sauer, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce3d961aa3ed48fb856a56a618f1f3c1-Jonathan.Sa]
**CC**: Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]; Needham, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f74f493e6c584b159560c932efe2734d-Mark.Needha]; Carr, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c6df5ab0cc6f4f00b90a73a97ae81f0d-CARRP]; Corbin, Rhonda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e0963ce5594ce59eb7ab7da787f639-CorbinR]
**Subject**: RE: Coronavirus Request

Thank you.

Jeff

---

**From:** Sauer, Jonathan <Jonathan.Sauer@fda.hhs.gov>
**Sent:** Thursday, February 20, 2020 1:02 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Needham, Mark <Mark.Needham@fda.hhs.gov>; Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>
**Subject:** Coronavirus Request

Hi Jeff,

In follow-up to the email Denise sent you earlier today regarding our coronavirus budget request, the below narrative provides additional information. Also, the attached Excel file further breaks down the figures by Office and year.

(b) (5)



Jonathan Sauer
*Senior Advisor*
Center for Devices and Radiological Health
Office of Management
U.S. Food & Drug Administration

AMERICAN OVERSIGHT

Tel: 301-796-7564
Jonathan.Sauer@fda.hhs.gov




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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/17/2020 3:29:27 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: N95 Respirators

Deliberative/Predecisional

Ellen,

Thank you. I agree with what you conveyed to OCC with the caveat that (b) (5) [redacted]

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Monday, February 17, 2020 3:16 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: N95 Respirators

Deliberative / Predecisional

Hi Jeff,

Update: (b) (5) [redacted]

We discussed two general approaches that I proposed:

(b) (5) [redacted]

AMERICAN OVERSIGHT

Please let me know if you would like to discuss this update or give me additional direction.

Thanks,
Ellen

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Saturday, February 15, 2020 6:45 PM
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Krause, David <David.Krause@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Binita,

Sorry for taking so long to get back to you. Ellen has been talking with OCC with the hope of resolving issues today but we are now not expecting a response on whether or not we (b) (5) [redacted]
(b) (5) [redacted]

Jeff

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 10:13:56 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Okay - so modifying the one sent forward. Is that correct?

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 10:06:59 AM EST
**To:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Thank you. Adding Ellen.

I think we could also (b) (5) [redacted]

Jeff

AMERICAN OVERSIGHT

---

**From:** Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Date:** February 15, 2020 at 9:42:30 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** Re: N95 Respirators

Good Morning,

(b) (5) [redacted]

FYI I was on leave yesterday and will be returning on Wed. All credit for the quick response goes to the team.

Binita

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 15, 2020 at 8:15:38 AM EST
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
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Thank you and your team for the quick work on an EUA for N95 respirators and your flexibility. My understanding is (b) (5) [redacted]. Given the current environment, we would expect healthcare workers to use N95 respirators in two types of situations – one in non-surgical/non-emergency settings with known or possible coronavirus patients (or patients with another serious, highly contagious infection) and one in surgical/emergency settings with the same patient population where they may be exposed to high pressure bodily fluids.

Could/should we (b) (5) [redacted]

Jeff

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/15/2020 10:06:58 AM
**To:** Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]; Claverie, Elizabeth F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=316a6efc030f403398c138d318dc487d-EFC]; Krause, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43e466e978c844dc83be09a25e972eca-dxk]; Chang, Cynthia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dcd7bfbdbd3401b8092b3f4cd157208-Cynthia.Cha]
**CC:** Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** Re: N95 Respirators

Thank you. Adding Ellen.

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Jeff

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**Date:** February 15, 2020 at 9:42:30 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
**Cc:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
**Subject:** Re: N95 Respirators

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Binita

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AMERICAN OVERSIGHT

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**Date:** February 15, 2020 at 8:15:38 AM EST
**To:** Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
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Could/should we (b) (5) [redacted]

Jeff

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/5/2020 4:48:27 PM
**To:** Stephen Hahn (b) (6) fda.hhs.gov (b) (6) fda.hhs.gov]
**Subject:** FW: Thank you EUA Team

Thank you for sending the email. I know folks greatly appreciate the support and recognition. It means a lot to them to hear it from you.

Jeff

---

**From:** A Message from the Commissioner <message@fda.hhs.gov>
**Sent:** Wednesday, February 5, 2020 4:36 PM
**To:** Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Gagne, Stefan <Stefan.Gagne@fda.hhs.gov>; Giannakopoulos, Eleni <Eleni.Giannakopoulos@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Seligson, Edie D. <Edie.Seligson@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Thank you EUA Team



From the Desk of
**the Commissioner**

U.S. FOOD & DRUG ADMINISTRATION

Dear EUA Team,

I know we are in the middle of responding to the novel 2019-nCoV public health emergency, but I want to pause for just a moment to thank you for your incredible work to bring the Emergency Use Authorization for CDC's test over the finish line. This is a critical milestone in the government's response efforts to mitigate the further spread of the virus. It is also a crystal clear example of how our work makes a difference at home and abroad.

I know there is much more work to be done in the fight against this outbreak. Please know that I am grateful for your commitment and expertise, and for simply--doing what needed to be done--to make the first EUA a reality.

You have my deepest gratitude and many thanks as you continue this important work.

Sincerely,

**Stephen M. Hahn, M.D.**
**Commissioner of Food and Drugs**

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/5/2020 4:28:08 AM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject:** Fwd: News from the MFDS in Korea

Just sharing as an FYI

---

**From:** [redacted]@korea.kr>
**Date:** February 5, 2020 at 4:20:02 AM EST
**To:** [redacted]@health.gov.au [redacted]@health.gov.au>, [redacted]@health.gov.au <[redacted]@health.gov.au>, [redacted]@anvisa.gov.br <[redacted]@anvisa.gov.br>, [redacted]@anvisa.gov.br <[redacted]@anvisa.gov.br>, [redacted]@canada.ca [redacted]@canada.ca>, [redacted]@canada.ca <[redacted]@canada.ca>, [redacted]@nmpa.gov.cn [redacted]@nmpa.gov.cn>, [redacted]@nmpa.gov.cn [redacted]@nmpa.gov.cn>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>, [redacted]@ansm.sante.fr <[redacted]@ansm.sante.fr>, [redacted]@hpra.ie <[redacted]@hpra.ie>, [redacted]@bmg.bund.de [redacted]@bmg.bund.de>, [redacted]@pmda.go.jp <[redacted]-[redacted]@pmda.go.jp>, [redacted]@mhlw.go.jp [redacted]@mhlw.go.jp>, [redacted]@roszdravnadzor.ru [redacted]@roszdravnadzor.ru>, [redacted]@mail.ru <[redacted]@mail.ru>, [redacted]@korea.kr <[redacted]@korea.kr>, [redacted]) <**Cc:** [redacted]@anvisa.gov.br <[redacted]@anvisa.gov.br>, [redacted]@canada.ca <[redacted]@canada.ca>, [redacted]@canada.ca <[redacted]@canada.ca>, [redacted]@nmpa.gov.cn <[redacted]@nmpa.gov.cn>, [redacted]@nmpa.gov.cn <[redacted]@nmpa.gov.cn>, [redacted]@nmpa.gov.cn [redacted]@nmpa.gov.cn>, [redacted]@nmpa.gov.cn <[redacted]@nmpa.gov.cn>, [redacted]@nmpa.gov.cn [redacted]@nmpa.gov.cn>, [redacted]@nmpa.gov.cn [redacted]@nmpa.gov.cn>, [redacted]@pmda.go.jp [redacted]@pmda.go.jp>, [redacted]@pmda.go.jp <[redacted]@pmda.go.jp>, [redacted]@pmda.go.jp <[redacted]@pmda.go.jp>, [redacted]@roszdravnadzor.ru <[redacted]@roszdravnadzor.ru>, [redacted]@roszdravnadzor.ru [redacted]@roszdravnadzor.ru>, [redacted]korea.kr <[redacted]@korea.kr>, [redacted]@korea.kr <[redacted]@korea.kr>, [redacted]<**Subject:** News from the MFDS in Korea

Dear IMDRF MC Members and Official Observer,

You all must have been busy fighting against the novel coronavirus(2019-nCoV).

We inform that the new diagnostic test kit described below was reviewed and approved to be used on 4 February in response to the novel coronavirus crisis.

* Product Name : PowerChek 2019-nCoV Real-time PCR kit
* Manufacturer : Kogen Biotech in the Republic of Korea

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The Republic of Korea has the system for Emergency Use Assessment and Listing(EUAL) that allows a

diagnostic test kit to be produced, distributed and used for a limited time period by the request of the director of the Korea Centers for Disease Control and Prevention(KCDC) on the occasion where there is no approved product in Korea amid the growing need for a diagnostic test kit to detect the epidemic.

Should you have any further questions, please do not hesitate to contact us.

Best Regards,

Hyeonjoo Oh, Ph.D

Director General
Medical Device Evaluation Department
National Institute of Food and Drug Safety Evaluation (NIFDS)
Ministry of Food and Drug Safety (MFDS)
Republic of Korea

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/6/2020 10:40:22 AM
**To:** Zuckerman, Bram [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0ff82d825a6490eb6ffc2dc76bb937e-BDZ]
**Subject:** Re: (b) (4)

(b) (4), (b) (5)

Jeff

---

**From:** Zuckerman, Bram <Bram.Zuckerman@fda.hhs.gov>
**Date:** February 6, 2020 at 8:13:12 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: (b) (4)

Fyi…In case you have not heard from other channels

Bram Zuckerman, MD
Office Director,
OHT2: Office of Cardiovascular Devices

Food and Drug Administration
Center for Devices and Radiological Health
White Oak, Bldg. 66, Rm 2316
10903 New Hampshire Avenue
Silver Spring, MD 20993

Bram.zuckerman@fda.hhs.gov
Tel 301-796-6315

U.S. FOOD & DRUG ADMINISTRATION
AMERICAN OVERSIGHT

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https://www.research.net/s/cdrhcustomerservice?ID=1400&S=E

---

**From:** Desta, Abiy B. <Abiy.Desta@fda.hhs.gov>
**Sent:** Thursday, February 6, 2020 6:55 AM
**To:** Zuckerman, Bram <Bram.Zuckerman@fda.hhs.gov>
**Subject:** RE: (b) (4)

Thank you!

***Abiy Desta***
*CDRH Ombudsman*

**Center for Devices and Radiological Health**

**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-0293
abiy.desta@fda.hhs.gov






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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

---

**From:** Zuckerman, Bram <Bram.Zuckerman@fda.hhs.gov>
**Sent:** Wednesday, February 05, 2020 3:56 PM
**To:** Hillebrenner, Matthew <Matthew.Hillebrenner@fda.hhs.gov>; Desta, Abiy B. <Abiy.Desta@fda.hhs.gov>

AMERICAN OVERSIGHT

**Cc:** Aguel, Fernando <Fernando.Aguel@fda.hhs.gov>; Ibrahim, Nicole <Nicole.Ibrahim@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Zuckerman, Bram (b) (6)
**Subject:** FW: (b) (4)

(b) (4), (b) (5)

Bram Zuckerman, MD
Office Director,
OHT2: Office of Cardiovascular Devices

Food and Drug Administration
Center for Devices and Radiological Health
White Oak, Bldg. 66, Rm 2316
10903 New Hampshire Avenue
Silver Spring, MD 20993

Bram.zuckerman@fda.hhs.gov
Tel 301-796-6315






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https://www.research.net/s/cdrhcustomerservice?ID=1400&S=E

AMERICAN OVERSIGHT

**From:** Desta, Abiy B. <Abiy.Desta@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 10:34 AM
**To:** Zuckerman, Bram <Bram.Zuckerman@fda.hhs.gov>
**Subject:** (b) (4) [redacted]

Good morning Bram,

(b) (4), (b) (5) [redacted]

Thanks

Abiy

***Abiy Desta***
*CDRH Ombudsman*

**Center for Devices and Radiological Health**

**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-0293
abiy.desta@fda.hhs.gov






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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 6:33 PM
**To:** Desta, Abiy B. <Abiy.Desta@fda.hhs.gov>
**Subject:** FW: FDA Commissioner and staff

Hello Abiy,

(b) (5) [redacted] Thank you!

AMERICAN OVERSIGHT

Keagan

---

**From:** Raza, Mark <Mark.Raza@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 11:38 AM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: FDA Commissioner and staff

Hi Keagan – I sent you an email last Thursday with a proposed approach. It is attached. (b) (5) [redacted]

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 10:56 AM
**To:** Raza, Mark <Mark.Raza@fda.hhs.gov>
**Subject:** FW: FDA Commissioner and staff

Here is another one. (b) (5) [redacted]

(b) (4) [redacted]

AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/13/2020 11:38:08 AM
**To:** Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
**Subject:** RE: Greetings

Dear Peter,

That's great to hear. Thank you.

Best regards,

Jeff

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 11:36 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Greetings

Dear Jeff,

Thanks for replying. Our BSL-3 labs should be up and running by Tuesday to be able to work with the samples that we are receiving.

Best Regards,
Peter

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Thursday, February 13, 2020 11:05 AM
**To:** Shearstone, Peter E. <(b) (6) @thermofisher.com>; Marks, Peter <Peter.Marks@fda.hhs.gov>
**Subject:** Re: Greetings

Dear Peter,

I believe Thermo Fisher has has our emergency use authorization (EUA) template and our team is available to engage in pre-EUA meetings/teleconferences to discuss data needs/plan to support an EUA. That is the fastest, most streamlined path forward. Access to testing materials, though, is still limited depending on access to an appropriate BSL lab but the team can work with you.

Best regards,

Jeff

---

**From:** Shearstone, Peter E. <(b) (6) @thermofisher.com>
**Date:** February 13, 2020 at 10:01:11 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
**Subject:** Greetings

AMERICAN OVERSIGHT

Dear Dr. Shuren, Dr. Marks,

Good morning. Hope all is well. Looking forward to our meeting next week.

As things continue to progress with the coronavirus outbreak one of the topics we intended to discuss was the potential to assist FDA/CDC/NIH to help manufacture coronavirus test kits.
Today former FDA Commissioner Gottlieb tweeted that Thermo Fisher, among a few others, could help in this way. (https://twitter.com/ScottGottliebMD/status/1227962496914468865)
How could we collaborate on this? Could there be a pre-meeting with your teams to discuss the potential opportunity and solutions?
We are interested in supporting efforts in this area given the severity of the situation.
Please share your thoughts.

Warm regards,
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) Mobile: +(b) (6)
Internal extension (b) (6)
(b) (6) @thermofisher.com

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/13/2020 7:58:58 AM
**To:** Tomasello, Jennifer (Jennifer.Tomasello@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=Jennifer.Tomasello]
**Subject:** FW: Public health labs report problems with coronavirus test

Jennifer,

For the IVCT hearing prep it would be helpful to have a Q&A on the CDC coronavirus diagnostic test and why FDA oversight is important. Some in the (b) (5) [redacted]

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 4:41 PM
**To:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: Public health labs report problems with coronavirus test

Ellen,
We reported about it before on Monday [on Monday they reported (b) (5) labs] but got update today that (b) (5) labs had problems verifying their test. This verification step is an important assessment of how the test works before it is used on clinical samples. These labs did not run any clinical samples.

(b) (5) [redacted]

[redacted]. We are receiving updates when they are available.

Uwe

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 4:30 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Public health labs report problems with coronavirus test
**Importance:** High

Heads up – news reporting on problems with CDC EUA test --

---

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>
**Sent:** Wednesday, February 12, 2020 4:22 PM
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Public health labs report problems with coronavirus test

AMERICAN OVERSIGHT

**Public health labs report problems with coronavirus test**

By David Lim

02/12/2020 04:21 PM EST

At least 25 public health laboratories around the country say they're unable to test for cases of the coronavirus originating in Wuhan because a test kit distributed by the CDC is delivering inconclusive results.

Some labs that began doing quality checks on the test last weekend found one of three reagents in the kit was ineffective, according to Kelly Wroblewski, director of infectious diseases at the Association of Public Health Laboratories. More labs started reporting similar issues on Monday and Tuesday. None of the diagnostic kits were used to test actual clinical specimens.

The kits allow states and localities to test patients, eliminating the need to confirm cases by sending samples to the CDC's headquarters in Atlanta. CDC is developing replacement tests it can send to the labs.

"Some of the states identified some inconclusive laboratory results, but we're working closely with them to correct the issues," Nancy Messonnier, director of the CDC's Center for the National Center for Immunization and Respiratory Diseases, said Wednesday.

There are 13 confirmed cases of coronavirus in the United States with 60 other people under investigation whose samples are waiting to be tested, according to CDC. More than 44,500 cases and 1,100 deaths are confirmed in China, according to the World Health Organization.

CDC initially made 200 of the diagnostic kits available to U.S. labs last week after receiving emergency use authorization from the FDA on Feb. 4.

"Of course I hoped that this week every state would be up and running," Messonnier said. "How long will that take? I can't tell you that for sure."

A "very small number of labs" in the U.S. have successfully verified the diagnostic test, according to Wroblewski. But states will continue to send all clinical specimens to CDC headquarters in Atlanta as a "backstopping" measure, according to Messonnier.

"Although this is sort of an unfortunate development and nobody wanted to see this happen, this is why there are quality control steps in place," Wroblewski said.

*To view online*:
https://subscriber.politicopro.com/health-care/article/2020/02/public-health-labs-report-problems-with-coronavirus-test-1879161

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AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/6/2020 7:37:49 AM
**To:** Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]
**Subject:** RE: (b) (4)

(b) (4), (b) (5)

Jeff

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Sent:** Thursday, February 6, 2020 7:27 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: (b) (4)

FYI

---

**From:** Zuckerman, Bram <Bram.Zuckerman@fda.hhs.gov>
**Date:** February 5, 2020 at 3:56:15 PM EST
**To:** Hillebrenner, Matthew <Matthew.Hillebrenner@fda.hhs.gov>, Desta, Abiy B. <Abiy.Desta@fda.hhs.gov>
**Cc:** Aguel, Fernando <Fernando.Aguel@fda.hhs.gov>, Ibrahim, Nicole <Nicole.Ibrahim@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Zuckerman, Bram (b) (6)
**Subject:** FW: (b) (4)

(b) (4), (b) (5)

Bram Zuckerman, MD
Office Director,
OHT2: Office of Cardiovascular Devices

Food and Drug Administration
Center for Devices and Radiological Health
White Oak, Bldg. 66, Rm 2316
10903 New Hampshire Avenue
Silver Spring, MD 20993

Bram.zuckerman@fda.hhs.gov
Tel 301-796-6315

AMERICAN OVERSIGHT

FDA U.S. FOOD & DRUG ADMINISTRATION

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https://www.research.net/s/cdrhcustomerservice?ID=1400&S=E

**From:** Desta, Abiy B. <Abiy.Desta@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 10:34 AM
**To:** Zuckerman, Bram <Bram.Zuckerman@fda.hhs.gov>
**Subject:** (b) (4)

Good morning Bram,

(b) (4), (b) (5)

Thanks
Abiy

***Abiy Desta***
*CDRH Ombudsman*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-0293
abiy.desta@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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AMERICAN OVERSIGHT

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
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**To:** Desta, Abiy B. <Abiy.Desta@fda.hhs.gov>
**Subject:** FW: FDA Commissioner and staff

Hello Abiy,

(b) (5) [redacted] Thank you!

Keagan

**From:** Raza, Mark <Mark.Raza@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 11:38 AM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: FDA Commissioner and staff

Hi Keagan – I sent you an email last Thursday with a proposed approach. It is attached. (b) (5) [redacted]

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Monday, January 27, 2020 10:56 AM
**To:** Raza, Mark <Mark.Raza@fda.hhs.gov>
**Subject:** FW: FDA Commissioner and staff

Here is another one. (b) (5) [redacted]

(b) (4) [redacted]

AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

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AMERICAN OVERSIGHT

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AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/4/2020 6:07:01 PM
**To**: Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Faris, Owen P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d919c42856449589d2d24454b2f774e-OPF]
**CC**: Saltman, Adam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=941424473c4e4cfeb01594032f253e91-Adam.Saltma]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; CDRH All Hazards Readiness Response and Cybersecurity [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af150d41dbea48c2b898c3431c24a132-CDRHEMCM]; Deviceshortages [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4f8a29d1ff475585ad83beacabff27-Deviceshort]
**Subject**: RE: Coronavirus Leadership Update February 4 2020

Thank you. In addition to assessing (b) (5) [redacted]

Jeff

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 5:59 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>
**Cc:** Saltman, Adam <Adam.Saltman@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Deviceshortages <Deviceshortages@fda.hhs.gov>
**Subject:** Coronavirus Leadership Update February 4 2020

Good evening,

Below are the daily CDRH Coronavirus (nCoV) updates:

(b) (5) [redacted]

AMERICAN OVERSIGHT

(b) (5)



Please let us know if you have any questions.

Thanks,
Heather

*Heather L. Agler, Ph.D.*
Innovation Program
All-Hazards Readiness, Response, and Cybersecurity (ARC) – *formerly EMCM*
Division of All-Hazards Response, Science and Strategic Partnerships (DARSS)
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
(p) 301-796-6340
Heather.Agler@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/8/2020 3:38:29 PM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]
**CC:** Patel, Bakul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ce7d58d8b9c473c8ba4d6fcb8b02b5a-BYP]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Krueger, Angela C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96c8f1f9d6a8481195be2aa3147e0b4f-ACS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: (b) (4) [redacted]

Thank you, Uwe.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 8, 2020 at 2:59:49 PM EST
**To:** Maisel, William <William.Maisel@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Krueger, Angela C <Angela.Krueger@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: (b) (4) [redacted]

Bill, Jeff,
I confirm this belongs to DMD. We had similar (b) (4) [redacted] for the Zika outbreak and will find out how those request were handled. It is likely not to git the EUA approach since the emergency declaration was specifically for the detection of nCoV. DMD will follow up with a phone call to the sponsor.
Uwe

---

**From:** Maisel, William <William.Maisel@fda.hhs.gov>
**Date:** February 8, 2020 at 2:10:54 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Krueger, Angela C <Angela.Krueger@fda.hhs.gov>
**Subject:** Re: (b) (4) [redacted]

Jeff,
I think this would be in OHT7's DMD. Looping in Tim and Uwe to confirm.
Bill

AMERICAN OVERSIGHT

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** February 8, 2020 at 12:35:19 PM EST
**To:** Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Patel, Bakul <Bakul.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** Fwd: (b) (4) [redacted]

Bill,

A small start up is looking to create (b) (4) [redacted]. The inputs it may use are described in Q3 below but it seems they are still figuring out what they want/will develop. Is there an appropriate person in OPEQ who can speak with them about FDA expectations, depending on what they specifically want to claim, including the merits of a Qsub? They may modify what they do based on the feedback.

I'm including Bakul and Suzanne for awareness.

Jeff

---

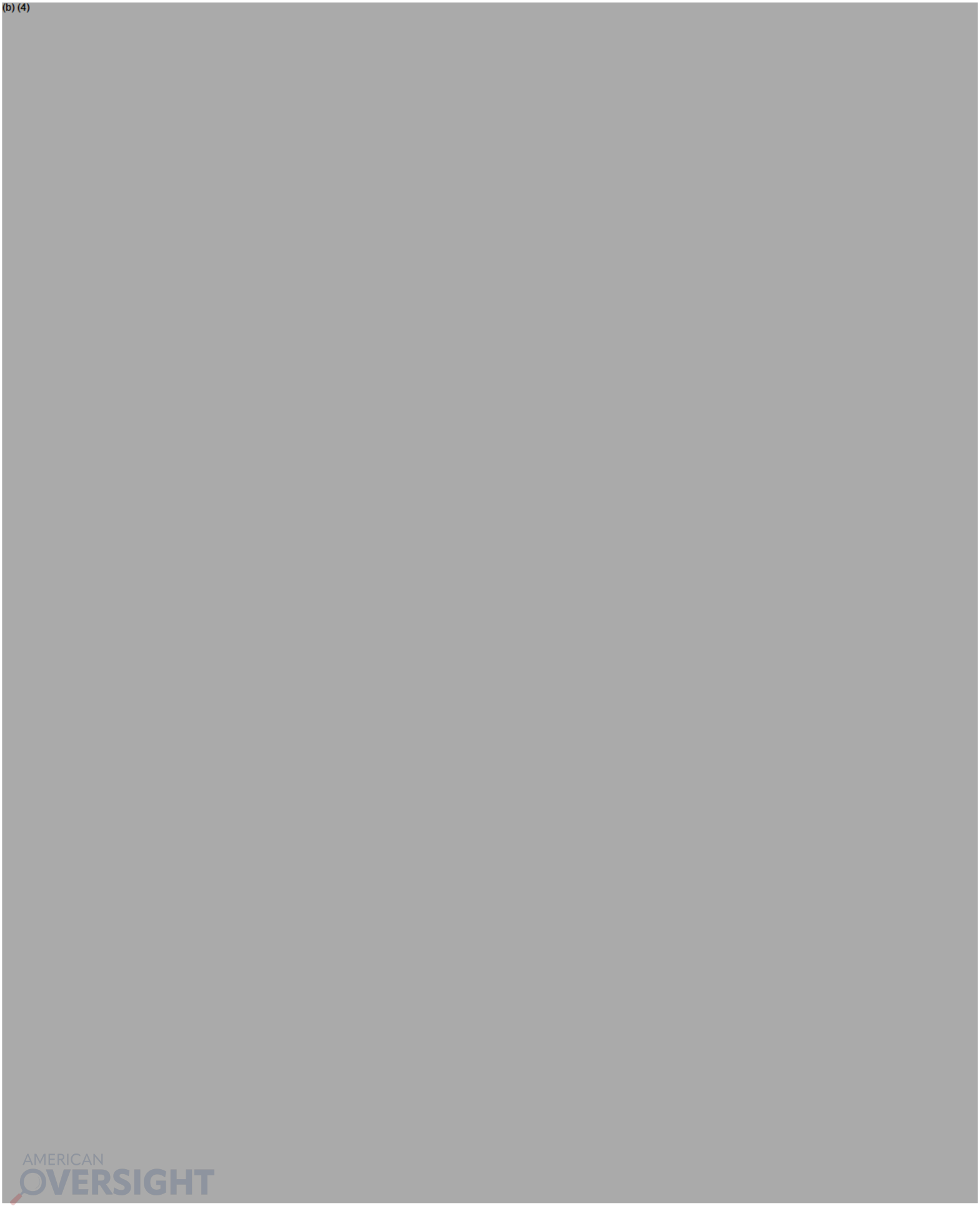
**From:** (b) (6) [redacted]
**Date:** February 8, 2020 at 11:18:36 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** (b) (4) [redacted]

Hi Jeff,

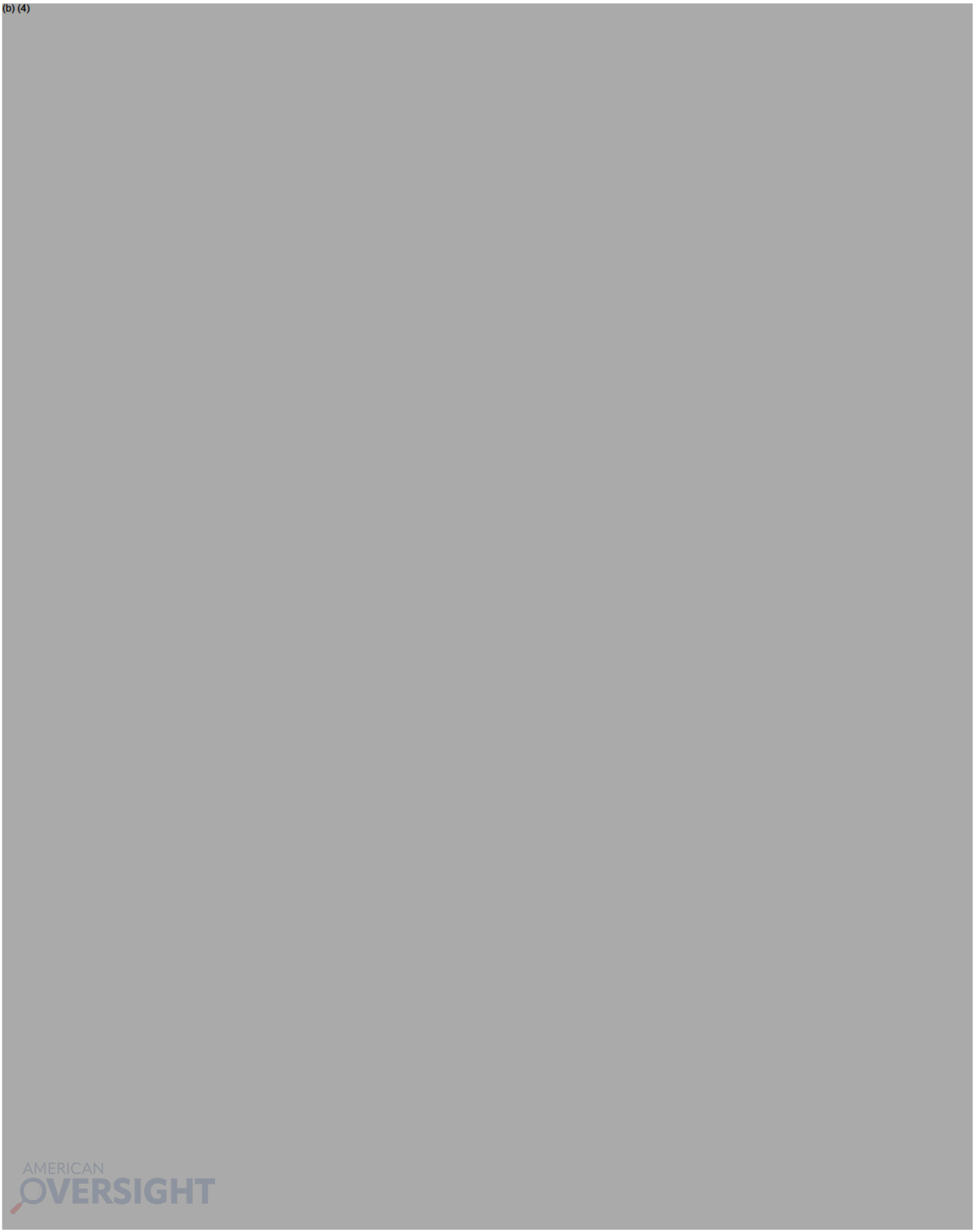
Thank you for the interest. In terms of more information;

(b) (4) [redacted]

AMERICAN OVERSIGHT




AMERICAN OVERSIGHT




AMERICAN OVERSIGHT

(b) (4)

[redacted]

**From:** Shuren, Jeff
**Sent:** Saturday, 8 February 2020 4:13 AM
**To:** (b) (6) [redacted]
**Subject:** Re: (b) (4) [redacted]

Hi Ajintha,

It's good to hear from you. Thank you for reaching out to me.

I reviewed your slide deck and saw the video. It would help me to have a little more information. Can you please describe what the tool is intended to be used for (b) (4) [redacted] who you intend the (b) (4) to be used by (b) (4) [redacted] the specific inputs it would use, and the specific outputs (b) (4) [redacted]

Jeff

---

**From:** (b) (6) [redacted]
**Date:** February 7, 2020 at 10:15:52 PM EST

AMERICAN OVERSIGHT

**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** (b) (4)

(b) (6), (b) (4)



AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/3/2020 10:40:47 AM
**To:** Perea-Henze, Raul [RPereaHenze@cityhall.nyc.gov]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC:** B [BCCD@cityhall.nyc.gov]; Fuleihan, Dean [DFuleihan@cityhall.nyc.gov]; Wolfe, Emma [EWolfe@cityhall.nyc.gov]; Barbot, Oxiris (DOHMH) [obarbot@health.nyc.gov]
**Subject:** RE: Coronavirus testing equipment and materials

Dear Dr. Perea-Henze,

Thank you for reaching out to us. We have been working very closely with the CDC and other parts of government, reviewing data as it comes in in real time, and with a team working around the clock to assure a test is available under an emergency use authorization (EUA) or other appropriate authorities as quickly as possible for use. In addition, the CDC will be able to distribute the test as soon as it is available.

As we all work together to address the coronavirus outbreak please do not hesitate to reach out to us at any time to let us know how we can be helpful.

Best regards,

Jeff

---

**From:** Perea-Henze, Raul <RPereaHenze@cityhall.nyc.gov>
**Sent:** Sunday, February 2, 2020 5:00 PM
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** B <BCCD@cityhall.nyc.gov>; Fuleihan, Dean <DFuleihan@cityhall.nyc.gov>; Wolfe, Emma <EWolfe@cityhall.nyc.gov>; Barbot, Oxiris (DOHMH) <obarbot@health.nyc.gov>
**Subject:** Coronavirus testing equipment and materials

Dear Drs. Hahn and Stenzel,

The commitment of the Food and Drug Administration to the safety and well-being of all Americans is critical to the work that we do every day at the New York City Department of Health and Mental Hygiene, and is especially important in the context of a public health emergency.

The reliability and accuracy of clinical tests is a basic need in health care and public health. In the current 2019-novel coronavirus (nCoV) public health emergency, public health action that will impact the lives of many will be taken based on the result of a single laboratory diagnostic test, and it is therefore critical that the test be as close to 100% accurate, 100% of the time as possible.

We commend the collaboration between the FDA, the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS) to streamline the development, validation, and authorization of clinical tests that meet regulatory requirements in the rapidly evolving setting of an infectious disease public health emergency. The efficiency of this process is being put to the test in this emergency.

AMERICAN OVERSIGHT

We ask that the evaluation and subsequent Emergency Use Authorization of the CDC-developed diagnostic assay for the detection of 2019-nCoV infection be moved forward as quickly as possible. It is critical that local

jurisdictions, including New York City, have access to this test locally to support the rapid and accurate evaluation of patients under investigation (PUI) for 2019-nCoV infection. In New York City, the test result for every PUI will have implications for the health of all New Yorkers. It is imperative that testing be available locally to decrease the time to get a result into the hands of clinicians caring for the patient and the public health officials that need to enact public health interventions to stop the spread of this virus in NYC, and across the country.

As always, thank you for your commitment to the health and safety of New Yorkers and all Americans.

Sincerely,

Raul Perea-Henze, MD, MPH
Deputy Mayor for Health & Human Services
City of New York
(b) (6) @cityhall.nyc.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/3/2020 3:46:54 PM
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

Maybe they are referring to plans for distribution. (b) (5) . I called Uwe to confirm before I sent my reply email to you.

Adding Uwe for any additional clarity.

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 3, 2020 at 3:42:03 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

So this line (b) (5)

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 2:47 PM
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

We haven't received any data today. (b) (5) .

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 3, 2020 at 2:24:25 PM EST
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

(b) (5)

Jeff?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Sent:** Monday, February 3, 2020 2:11 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
**Subject:** FW: CDC wants to distribute coronavirus diagnostic test by end of week

(b) (5)

---

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>
**Sent:** Monday, February 3, 2020 2:09 PM

AMERICAN OVERSIGHT

**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** CDC wants to distribute coronavirus diagnostic test by end of week

**CDC wants to distribute coronavirus diagnostic test by end of week**

By David Lim, Sarah Owermohle

02/03/2020 02:08 PM EST

The CDC wants the FDA to quickly grant an emergency authorization to use its Wuhan coronavirus diagnostic test so it can distribute it to laboratories across the country later this week.

"The process is extremely expedited and our colleagues at FDA have been working with us closely — our plans were submitted to them today, and I expect that means we should be able to start sending them out by the end of the week barring complications," Nancy Messonnier, director of the National Center for Immunization and Respiratory Diseases, said on a press call.

For the FDA to grant emergency authorization for the test, HHS Secretary Alex Azar first must declare that circumstances exist that justify its use — a step that appears imminent after Azar declared the virus a public health emergency late last week. CDC has already sent the test to the International Reagent Resource so states can begin ordering it, according to Messonnier.

*To view online*:
https://subscriber.politicopro.com/health-care/whiteboard/2020/02/cdc-wants-to-distribute-coronavirus-diagnostic-test-by-end-of-week-3976275

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Arlington, VA 22209
USA

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/4/2020 5:01:44 PM
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** EUA Team

**Importance:** High

Below is the list of the key people in the Agency who were involved in the EUA.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 4, 2020 at 4:39:47 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued
**Importance:** High

Thanks to the tireless and extraordinary work of the DMD review team over the last weeks:

- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*
- **Li Li**, Lead Reviewer, Viral Respiratory & HPV Branch,
- **Brittany Goldberg**, MD, Senior Medical Officer, and
- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch
- Uwe Scherf, M.Sc, Ph.D., Director, Division of Microbiological Devices

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, **Megan McSeveney** & **Angela Stark** (press office).

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/4/2020 5:00:17 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

Nothing to apologize about. And definitely get some sleep!

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 4, 2020 at 4:55:45 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

Thank you, again I apologize for this unforgiveable mistake. Uwe

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 4:54 PM
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Re: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

Uwe,

No worries, and thank you.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 4, 2020 at 4:39:47 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued
**Importance:** High

Jeff,

Here is the list of individual being involved in the EUA, and also please see the email I just send out, I am terrible sorry that somehow I missed to send it you to too, getting a little tired.
Uwe

AMERICAN OVERSIGHT

Thanks to the tireless and extraordinary work of the DMD review team over the last weeks:

- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*
- **Li Li**, Lead Reviewer, Viral Respiratory & HPV Branch,
- **Brittany Goldberg**, MD, Senior Medical Officer, and
- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, **Megan McSeveney** & **Angela Stark** (press office).

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 4:27 PM
**To:** CDRH-OIR-IVD-DMD <CDRH-OIR-IVD-DMD@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued
**Importance:** High

**Congratulations!**

FDA just issued the Emergency Use Authorization for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.
Thanks to the tireless and extraordinary work of the DMD review team over the last weeks:

- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*
- **Li Li**, Lead Reviewer, Viral Respiratory & HPV Branch,
- **Brittany Goldberg**, MD, Senior Medical Officer, and
- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, **Megan McSeveney** & **Angela Stark** (press office), and our senior leadership.

These have been incredible 2 weeks and words cannot describe how grateful I am for your phenomenal dedication and extraordinary hard work that made this happen. You are an exceptional team to work with unprecedented commitment to public health!

Thanks you! Thank you! Thank you!

My very kind regards,

Uwe

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**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/4/2020 3:12:14 AM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
**CC**: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Caliguiri, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b585f5da7b2449cb5721a870d4db281-HHS-Laura.C]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Re: Urgent - CDC EUA package received

That's great news. Thank you.

AMERICAN OVERSIGHT

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 3, 2020 at 11:04:26 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>, Stark, Angela <Angela.Stark@fda.hhs.gov>, Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Caliguiri, Laura (OS) <Laura.Caliguiri@hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Urgent - CDC EUA package received
**Importance:** High

Jeff, Denise, Anna, Tim, and Michael,

CDC just submitted their EUA package to request authorization for their 2019-Novel Coronavirus (2019-nCoV) assay. DMD staff has reviewed most of the data package already and will finish the review of the outstanding data as expeditiously as possible. I want to provide a clear update on how long that process could take and next steps once we have completed our review.

We expect that it will take us close 3-4 hours to fully review the outstanding data and prepare all the final documents for clearance in the review division. If the data is acceptable, we plan to send the EUA approval package to OCET & OCC tomorrow morning around 11 AM for final FDA clearance before it goes to Denise for authorization. We have been closely coordinating with OMA and they already have drafted a press release so that we are ready to make an announcement if an EUA can be issued tomorrow.

I will keep this group updated.

Thank you all in advance for your patience and help.

Best,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456

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uwe.scherf@fda.hhs.gov

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/13/2020 11:04:37 AM
**To:** Shearstone, Peter E. (b) (6) @thermofisher.com]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
**Subject:** Re: Greetings

Dear Peter,

I believe Thermo Fisher has has our emergency use authorization (EUA) template and our team is available to engage in pre-EUA meetings/teleconferences to discuss data needs/plan to support an EUA. That is the fastest, most streamlined path forward. Access to testing materials, though, is still limited depending on access to an appropriate BSL lab but the team can work with you.

Best regards,

Jeff

---

**From:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Date:** February 13, 2020 at 10:01:11 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
**Subject:** Greetings

Dear Dr. Shuren, Dr. Marks,

Good morning. Hope all is well. Looking forward to our meeting next week.

As things continue to progress with the coronavirus outbreak one of the topics we intended to discuss was the potential to assist FDA/CDC/NIH to help manufacture coronavirus test kits.
Today former FDA Commissioner Gottlieb tweeted that Thermo Fisher, among a few others, could help in this way. (https://twitter.com/ScottGottliebMD/status/1227962496914468865)
How could we collaborate on this? Could there be a pre-meeting with your teams to discuss the potential opportunity and solutions?
We are interested in supporting efforts in this area given the severity of the situation.
Please share your thoughts.

Warm regards,
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: +(b) (6) Mobile: (b) (6)
Internal extension 110-1333
(b) (6) @thermofisher.com

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/13/2020 4:32:34 AM
**To:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC:** Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject:** Re: 2/13/20 6 AM update - FDA ACTION REQUIRED

Uwe,

Okay from my perspective to use enforcement discretion for the scenarios you identified but Ellen should weigh in as to whether we need to run it by OCC and/or document or communicate our decision to CDC in a particular way. And would we need to (b) (5) [redacted] ?

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 12, 2020 at 10:50:52 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** 2/13/20 6 AM update - FDA ACTION REQUIRED
**Importance:** High

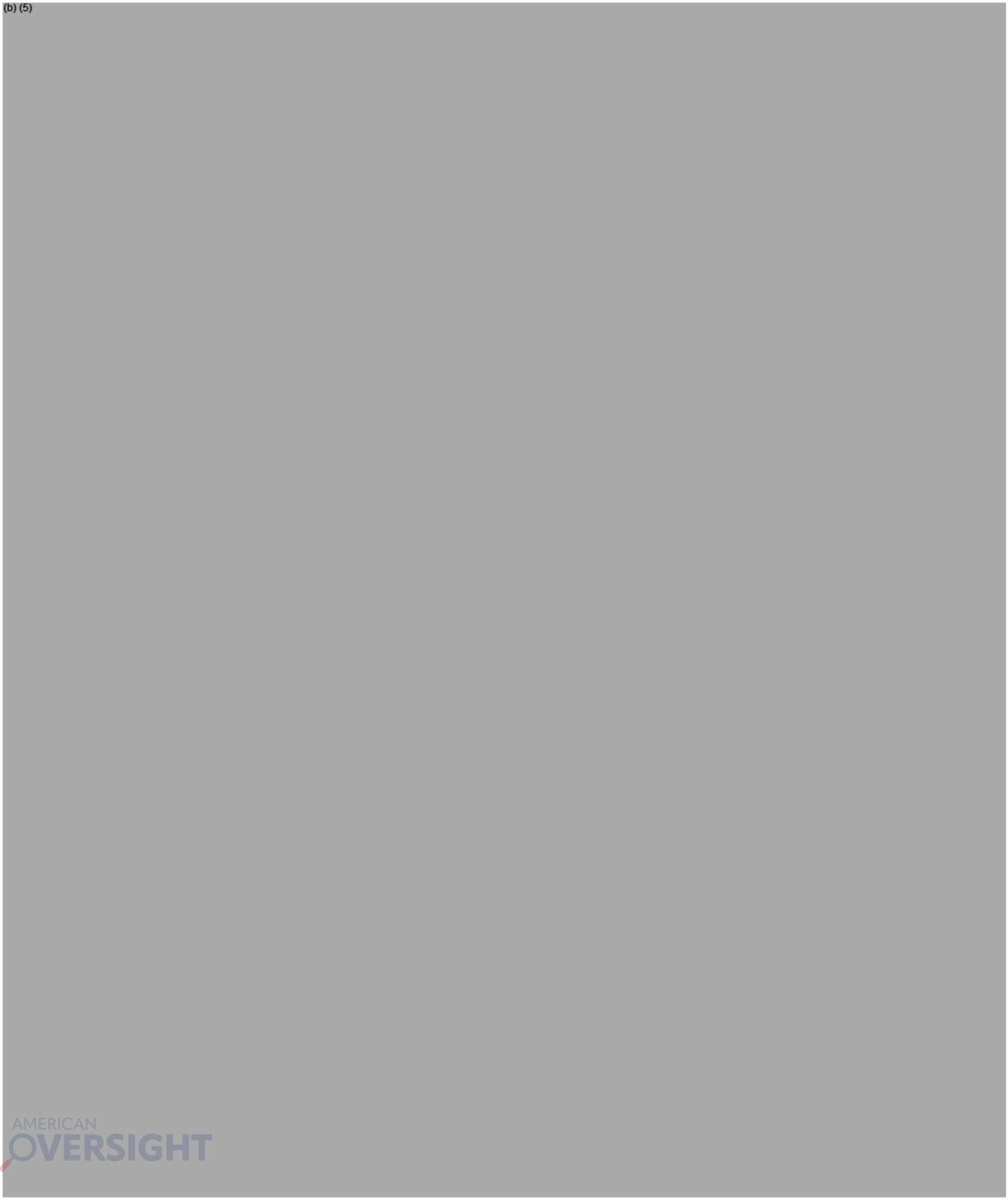
Jeff, Elizabeth, Ellen, Bill and Tim:

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Enclosed the 2/13/20 6 AM update, a number of issues came about this afternoon:

## Status of activities on diagnostics

(b) (5)



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(b) (5)

[redacted]

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/4/2020 4:54:06 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Re: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

Uwe,

No worries, and thank you.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 4, 2020 at 4:39:47 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued
**Importance:** High

Jeff,

Here is the list of individual being involved in the EUA, and also please see the email I just send out, I am terrible sorry that somehow I missed to send it you to too, getting a little tired.
Uwe

Thanks to the tireless and extraordinary work of the DMD review team over the last weeks:

- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*
- **Li Li**, Lead Reviewer, Viral Respiratory & HPV Branch,
- **Brittany Goldberg**, MD, Senior Medical Officer, and
- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, **Megan McSeveney** & **Angela Stark** (press office).

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 4:27 PM
**To:** CDRH-OIR-IVD-DMD <CDRH-OIR-IVD-DMD@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Li, Li (CDRH) <Li.Li2@fda.hhs.gov>; Goldberg, Brittany <Brittany.Goldberg@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen

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<Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued
**Importance:** High

**Congratulations!**

FDA just issued the Emergency Use Authorization for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.
Thanks to the tireless and extraordinary work of the DMD review team over the last weeks:

- **Kim Sapsford-Medintz**, Ph.D. *MCM EUA Team Lead,*
- **Li Li**, Lead Reviewer, Viral Respiratory & HPV Branch,
- **Brittany Goldberg**, MD, Senior Medical Officer, and
- **Tamara Feldblyum**, Ph.D. Branch Chief, Viral Respiratory & HPV Branch

and our colleagues **Jennifer Ross**, **Elizabeth Sadove**, **April Finnen**, **Michael Mair** from OCET, **Marcy Busch** and **Dennis Claire** from OCC, **Megan McSeveney** & **Angela Stark** (press office), and our senior leadership.

These have been incredible 2 weeks and words cannot describe how grateful I am for your phenomenal dedication and extraordinary hard work that made this happen. You are an exceptional team to work with unprecedented commitment to public health!

Thanks you! Thank you! Thank you!

My very kind regards,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/4/2020 9:44:26 AM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Schwartz, Suzanne (Suzanne.Schwartz@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Suzanne.Schwartz]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]
**Subject**: Meeting Today on Coronavirus

Uwe, ARC,

I have a meeting at 3 PM today on coronavirus. Can you each (Uwe and ARC) give me an update early this afternoon before the meeting on the status of the EUA and of possible shortages respectively? (b) (5)

Thank you.

Jeff

**Jeffrey Shuren, MD, JD**
*Director*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 301-796-5900
Email: jeff.shuren@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/4/2020 8:04:20 PM
**To**: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Faris, Owen P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d919c42856449589d2d24454b2f774e-OPF]
**CC**: Saltman, Adam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=941424473c4e4cfeb01594032f253e91-Adam.Saltma]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; CDRH All Hazards Readiness Response and Cybersecurity [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af150d41dbea48c2b898c3431c24a132-CDRHEMCM]; Deviceshortages [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4f8a29d1ff475585ad83beacabff27-Deviceshort]
**Subject**: RE: Coronavirus Leadership Update February 4 2020

Suzanne,

Yes, (b) (5) [redacted]

Jeff

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 4, 2020 at 7:41:25 PM EST
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Faris, Owen P <Owen.Faris@fda.hhs.gov>
**Cc:** Saltman, Adam <Adam.Saltman@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>, Deviceshortages <Deviceshortages@fda.hhs.gov>
**Subject:** RE: Coronavirus Leadership Update February 4 2020

Jeff,

(b) (5) [redacted]

AMERICAN OVERSIGHT

(b) (5)

Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: 202-841-9996

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Date:** February 4, 2020 at 7:31:50 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Faris, Owen P <Owen.Faris@fda.hhs.gov>
**Cc:** Saltman, Adam <Adam.Saltman@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>, Deviceshortages <Deviceshortages@fda.hhs.gov>
**Subject:** RE: Coronavirus Leadership Update February 4 2020

We will discuss it when we meet tomorrow to see how we can get it completed sooner than later.

*Heather L. Agler, Ph.D.*
Innovation Program
All-Hazards Readiness, Response, and Cybersecurity (ARC) – *formerly EMCM*
Division of All-Hazards Response, Science and Strategic Partnerships (DARSS)
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
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(p) 301-796-6340
Heather.Agler@fda.hhs.gov

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---

**From:** Shuren, Jeff
**Sent:** Tuesday, February 4, 2020 7:27 PM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>
**Cc:** Saltman, Adam <Adam.Saltman@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; CDRH All Hazards Readiness

AMERICAN OVERSIGHT

Response and Cybersecurity <cdrharc@fda.hhs.gov>; Deviceshortages <Deviceshortages@fda.hhs.gov>
**Subject:** RE: Coronavirus Leadership Update February 4 2020

Heather,

Thank you. I agree with the priority order. This is a fast moving situation so we may get asked about #6 very soon. Hopefully, we'll have enough people to get going on it in the next day or two.

Jeff

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Date:** February 4, 2020 at 7:16:52 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Faris, Owen P <Owen.Faris@fda.hhs.gov>
**Cc:** Saltman, Adam <Adam.Saltman@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>, Deviceshortages <Deviceshortages@fda.hhs.gov>
**Subject:** RE: Coronavirus Leadership Update February 4 2020

Hi Jeff,

That assessment has not been completed yet. (b) (5) [redacted]

(b) (5) [redacted]

Thanks,
Heather

*Heather L. Agler, Ph.D.*
Innovation ProgramCHina
All-Hazards Readiness, Response, and Cybersecurity (ARC) – *formerly EMCM*
Division of All-Hazards Response, Science and Strategic Partnerships (DARSS)
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
(p) 301-796-6340
Heather.Agler@fda.hhs.gov

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**From:** Shuren, Jeff
**Sent:** Tuesday, February 4, 2020 6:07 PM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>
**Cc:** Saltman, Adam <Adam.Saltman@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Deviceshortages <Deviceshortages@fda.hhs.gov>
**Subject:** RE: Coronavirus Leadership Update February 4 2020

Thank you. In addition to (b) (5) [redacted]

Jeff

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 5:59 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>
**Cc:** Saltman, Adam <Adam.Saltman@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Deviceshortages <Deviceshortages@fda.hhs.gov>
**Subject:** Coronavirus Leadership Update February 4 2020

Good evening,

Below are the daily CDRH Coronavirus (nCoV) updates:

(b) (5) [redacted]

AMERICAN OVERSIGHT

(b) (5)

[redacted]

Please let us know if you have any questions.

Thanks,
Heather

*Heather L. Agler, Ph.D.*
Innovation Program
All-Hazards Readiness, Response, and Cybersecurity (ARC) – *formerly EMCM*
Division of All-Hazards Response, Science and Strategic Partnerships (DARSS)
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
(p) 301-796-6340
Heather.Agler@fda.hhs.gov

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/12/2020 11:12:38 AM
**To:** Lloyd, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338a759166e74b13a5c9b385cde90eb9-Lindsay.Llo]
**Subject:** Re: February 21st Meeting

Lindsay,

CDER is welcome to send someone to our meeting.

Jeff

---

**From:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Date:** February 12, 2020 at 11:04:33 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: February 21st Meeting

Jeff –

Should they be setting a separate meeting with CDER on this additional topic re: their capabilities to manufacture vaccines and drug products or are you OK with them possibly sending someone to attend the meeting we set up? I'm not even sure CDER is interested but before I provide Peter with a CDER POC, I thought I would check.

Original ask: My CEO Marc Casper and I would like to have a meeting with yourself, Dr. Tim Stenzel and Dr. Peter Marks to build a relationship and share what Thermo Fisher is working on in terms of new products.
In addition we'd like to hear from FDA on key 2020 (and beyond ) priorities that we could ensure proper attention to.

Lindsay

---

**From:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Sent:** Wednesday, February 12, 2020 10:53 AM
**To:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
**Subject:** February 21st Meeting

Dear Lindsay,

Good morning. Hope it's a good day for you.
We are setting our discussion topics and determined that the coronavirus and its progress would be top of mind.
We'd like to talk about, among other things, our capabilities to manufacture vaccines and drug products to support its prevention.
Seeing that we did not invite Dr. Janet Woodcock from CDER is it possible she may have availability or perhaps one of her team?
I am sorry to surprise you with this but our company provides many services and we would like a productive discussion to help.

Thanks for helping. If you would rather I reach out to her office any contact information would be great.

Best,
Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

AMERICAN OVERSIGHT

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: +1 (b) (6) Mobile (b) (6)
Internal extension 110-1333
(b) (6)@thermofisher.com

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/11/2020 9:29:05 PM
**To:** Fisher, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb65f25d97a47d8876987ee99c92109-BRF]; Kiang, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c40f9d98f6f8412f9615d3e2f874ea03-TZK]
**Subject:** Fwd: implantable Remodulin Pump
**Attachments:** Implanted pump impact.pages

Just FYI

---

**From:** (b) (6)
**Date:** February 11, 2020 at 9:07:05 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: implantable Remodulin Pump

Jeffrey Shuren, M.D., J.D.
U.S. Food & Drug Administration
Center for Devices and Radiological Health
Office of the Center Director
10903 New Hampshire Avenue
WO66-5431
Silver Spring, MD 20993-0002

February 11. 2020

Dear Dr Shuren,

(b) (6)

AMERICAN OVERSIGHT




AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/11/2020 9:28:43 PM
**To:** (b) (6)
**Subject:** Re: implantable Remodulin Pump

Thank you for sharing your perspective with me. I will share it with the team.

Jeff

---

**From:** (b) (6)
**Date:** February 11, 2020 at 9:07:05 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: implantable Remodulin Pump

Jeffrey Shuren, M.D., J.D.
U.S. Food & Drug Administration
Center for Devices and Radiological Health
Office of the Center Director
10903 New Hampshire Avenue
WO66-5431
Silver Spring, MD 20993-0002

February 11. 2020

Dear Dr Shuren,

(b) (6)

AMERICAN OVERSIGHT




AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/12/2020 6:04:15 PM
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**Subject:** RE: Plz use this: Info on US PPE firms from today's calling

Have we told (b) (4) to get an EUA and tests they'd need to perform? As you know, OHT7 has an EUA template for 2019-nCoV tests. We could have one for N95 masks.

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 12, 2020 at 5:58:17 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Plz use this: Info on US PPE firms from today's calling

Long story short – (b) (5), (b) (4) [redacted]

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov




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---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 5:52 PM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** Re: Plz use this: Info on US PPE firms from today's calling

Can we (b) (5) [redacted]

Jeff

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 12, 2020 at 5:40:40 PM EST

AMERICAN OVERSIGHT

**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Plz use this: Info on US PPE firms from today's calling

**Suzanne B. Schwartz, MD, MBA**
*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation*
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell:202-841-9996
Suzanne.Schwartz@fda.hhs.gov




*Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.*

---

**From:** Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 5:26 PM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Mitchell, Diane <Diane.Mitchell@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Saltman, Adam <Adam.Saltman@fda.hhs.gov>; Kamon-Brancazio, Jamie <Jamie.Kamon-Brancazio@fda.hhs.gov>
**Subject:** Plz use this: Info on US PPE firms from today's calling

Suzanne,

Here is the revised doc with data from US PPE firms. Includes additional info on (b) (5), (b) (4)

Lakshmi

---

**From:** Kamon-Brancazio, Jamie <Jamie.Kamon-Brancazio@fda.hhs.gov>
**Sent:** Wednesday, February 12, 2020 5:22 PM
**To:** Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>
**Subject:** Update on Outreach Responses.docx

AMERICAN OVERSIGHT

OFFICE OF THE MAYOR
THE CITY OF NEW YORK

**RAUL PEREA-HENZE, MD, MPH**
DEPUTY MAYOR FOR HEALTH & HUMAN SERVICES

February 2, 2020

Dear Drs. Hahn and Stenzel,

The commitment of the Food and Drug Administration to the safety and well-being of all Americans is critical to the work that we do every day at the New York City Department of Health and Mental Hygiene, and is especially important in the context of a public health emergency.

The reliability and accuracy of clinical tests is a basic need in health care and public health. In the current 2019-novel coronavirus (nCoV) public health emergency, public health action that will impact the lives of many will be taken based on the result of a single laboratory diagnostic test, and it is therefore critical that the test be as close to 100% accurate, 100% of the time as possible.

We commend the collaboration between the FDA, the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS) to streamline the development, validation, and authorization of clinical tests that meet regulatory requirements in the rapidly evolving setting of an infectious disease public health emergency. The efficiency of this process is being put to the test in this emergency.

We ask that the evaluation and subsequent Emergency Use Authorization of the CDC-developed diagnostic assay for the detection of 2019-nCoV infection be moved forward as quickly as possible. It is critical that local jurisdictions, including New York City, have access to this test locally to support the rapid and accurate evaluation of patients under investigation (PUI) for 2019-nCoV infection. In New York City, the test result for every PUI will have implications for the health of all New Yorkers. It is imperative that testing be available locally to decrease the time to get a result into the hands of clinicians caring for the patient and the public health officials that need to enact public health interventions to stop the spread of this virus in NYC, and across the country.

As always, thank you for your commitment to the health and safety of New Yorkers and all Americans.

Sincerely,

Raul Perea-Henze, MD, MPH

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/3/2020 2:15:22 AM
**To:** 'Hahn, Stephen' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna (Anna.Abram@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Anna.Abram3ba]
**Subject:** FW: Coronavirus testing equipment and materials
**Attachments:** nCOV_FDA Letter_ 02.02.2020.pdf

Given the sensitivities, I wanted to check with you first before responding to the below email from Dr. Perea-Henze, Deputy Mayor of Health & Human Services of NYC. Here's my draft reply:

Dear Dr. Perea-Henze,

(b) (5)

[redacted]

Best regards,

Jeff

---

**From:** Perea-Henze, Raul <RPereaHenze@cityhall.nyc.gov>
**Sent:** Sunday, February 2, 2020 5:00 PM
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** B <BCCD@cityhall.nyc.gov>; Fuleihan, Dean <DFuleihan@cityhall.nyc.gov>; Wolfe, Emma <EWolfe@cityhall.nyc.gov>; Barbot, Oxiris (DOHMH) <obarbot@health.nyc.gov>
**Subject:** Coronavirus testing equipment and materials

Dear Drs. Hahn and Stenzel,

The commitment of the Food and Drug Administration to the safety and well-being of all Americans is critical to the work that we do every day at the New York City Department of Health and Mental Hygiene, and is especially important in the context of a public health emergency.

The reliability and accuracy of clinical tests is a basic need in health care and public health. In the current 2019-novel coronavirus (nCoV) public health emergency, public health action that will impact the lives of many will be taken based on the result of a single laboratory diagnostic test, and it is therefore critical that the test be as close to 100% accurate, 100% of the time as possible.

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As always, thank you for your commitment to the health and safety of New Yorkers and all Americans.

Sincerely,

Raul Perea-Henze, MD, MPH
Deputy Mayor for Health & Human Services
City of New York
(b) (6) @cityhall.nyc.gov

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 2/4/2020 7:27:26 PM
**To:** Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Faris, Owen P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d919c42856449589d2d24454b2f774e-OPF]
**CC:** Saltman, Adam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=941424473c4e4cfeb01594032f253e91-Adam.Saltma]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; CDRH All Hazards Readiness Response and Cybersecurity [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af150d41dbea48c2b898c3431c24a132-CDRHEMCM]; Deviceshortages [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4f8a29d1ff475585ad83beacabff27-Deviceshort]
**Subject:** RE: Coronavirus Leadership Update February 4 2020

Heather,

Thank you. I agree with the priority order. This is a fast moving situation so we may get asked about #6 very soon. Hopefully, we'll have enough people to get going on it in the next day or two.

Jeff

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Date:** February 4, 2020 at 7:16:52 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Faris, Owen P <Owen.Faris@fda.hhs.gov>
**Cc:** Saltman, Adam <Adam.Saltman@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>, Deviceshortages <Deviceshortages@fda.hhs.gov>
**Subject:** RE: Coronavirus Leadership Update February 4 2020

Hi Jeff,

(b) (5)

AMERICAN OVERSIGHT

(b) (5) [redacted]

Thanks,
Heather

*Heather L. Agler, Ph.D.*
Innovation ProgramCHina
All-Hazards Readiness, Response, and Cybersecurity (ARC) – *formerly EMCM*
Division of All-Hazards Response, Science and Strategic Partnerships (DARSS)
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
(p) 301-796-6340
Heather.Agler@fda.hhs.gov

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FDA U.S. FOOD & DRUG ADMINISTRATION

---

**From:** Shuren, Jeff
**Sent:** Tuesday, February 4, 2020 6:07 PM
**To:** Agler, Heather L <Heather.Agler@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>
**Cc:** Saltman, Adam <Adam.Saltman@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Deviceshortages <Deviceshortages@fda.hhs.gov>
**Subject:** RE: Coronavirus Leadership Update February 4 2020

Thank you. In addition to (b) (5) [redacted]

Jeff

---

**From:** Agler, Heather L <Heather.Agler@fda.hhs.gov>
**Sent:** Tuesday, February 4, 2020 5:59 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>

AMERICAN OVERSIGHT

**Cc:** Saltman, Adam <Adam.Saltman@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>; Deviceshortages <Deviceshortages@fda.hhs.gov>
**Subject:** Coronavirus Leadership Update February 4 2020

Good evening,

Below are the daily CDRH Coronavirus (nCoV) updates:

(b) (5)



Please let us know if you have any questions.

Thanks,
Heather

*Heather L. Agler, Ph.D.*
Innovation Program
All-Hazards Readiness, Response, and Cybersecurity (ARC) – *formerly EMCM*
Division of All-Hazards Response, Science and Strategic Partnerships (DARSS)
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
(p) 301-796-6340
Heather.Agler@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/10/2020 12:29:37 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]
**CC**: Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: 2/10/20 6 AM update

Uwe,

Thank you. Please let me know what comes out of the 2 PM call with CDC. I have a call with administration folks today at 4:30 PM on devices/diagnostics.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 11:46 AM
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/10/20 6 AM update

Tim,

(b) (5)

Uwe

AMERICAN OVERSIGHT

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 8:40 AM

**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** RE: 2/10/20 6 AM update

Thank you Uwe for the continued excellent updates. Regarding (b) (5) [redacted], see below:

- Discuss resource needs and timing to generate extracted nucleic acid from viral isolate. Extracted nucleic acid can be used in BSL-2 labs, if material is certified being non-infective. (b) (5) [redacted]]

Of course, you are know all this, just thinking out loud. (b) (5) [redacted]

Finally, do we have an idea of how many non-public health clinical labs are out there in the US that are BSL-3? Am wondering just how widespread testing can be.

Thanks!

Best,
*Tim*

**Timothy T. Stenzel, MD, PhD**
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health*
*Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Timothy.Stenzel@fda.hhs.gov

**Jennifer Campbell**
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Monday, February 10, 2020 6:34 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Cc:** Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; St. Pierre, Don J.

AMERICAN OVERSIGHT

<don.st.pierre@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** RE: 2/10/20 6 AM update

Jeff, Elizabeth, Ellen, Bill and Tim:

Enclosed the 2/10/20 6 AM update

**Status of activities on diagnostics**:

- Issue with rapid verification and implementation of CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel in handful of public health labs:
  - CDC informed FDA yesterday afternoon that APHL has been notified that some laboratories have observed performance issues during verification testing, particularly with the N3 part of the assay showing sporadic aberrant reactivity in the negative controls. CDC is aware of these reports and is investigating.
  - Conference call with CDC has been scheduled for today 2 PM to discuss the issue and any investigation so far.

**New roadblocks/challenges/delays:**

- Delay of verification and implementation of CDC's nCoV assay is some public health labs. DMD will determine specific numbers and any CDC investigations at conference call Monday at 2 PM.

**Enclosed also the compiled activities over the weekend which have been previously communicated:**

**Status of activities on diagnostics previously reported for 2/8/20 @ 2/9/20**:

- A total of 41 IVD Developers have requested and received EUA review template, additional requests (2) are pending clarification about the device technology.
- Conference call with CDC: CDC intends to add 2 additional automated extraction methods to their EUA (Roche MagNA Pure 96 and Roche MagNA Pure 24), to support larger number of State Public Health labs who are only using these instruments. DMD/CDC agreed on bridging study protocol and limited clinical sample testing to demonstrate performance. CDC expects to submit amendment in next 2 weeks.
- On 2/6/20 CDC started shipping CDC's 2019-nCoV PCR assay to 4 public health labs that are strategically located in US and to other public health labs in states with confirmed cases.
- CDC via their IRR (International Reagent Resource) is accepting orders for CDC's 2019-nCoV tests from qualified laboratories.
  - This includes 115 qualified U.S. laboratories [state & local public health labs and DoD labs]
  - 191 qualified international labs, such as the World Health Organization (WHO) Global Influenza Surveillance Response System (GISRS) laboratories.
  - CDC test will not be available in U.S. hospitals or other primary care settings.
- CDC's isolate from infected patient in Washington was shipped to BEI (Biodefense and Emerging Infections Research Resources Repository) on Wednesday (NR-52281). Additional viral Isolates from other patients in US are expected to arrive at BEI in the next 2 weeks. (b) (5)
(b) (5)

- (b) (5)

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(b) (5)

[redacted]

**New roadblocks/challenges/delays:**

(b) (5)

[redacted]

Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:***
https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 2/6/2020 3:09:48 PM
**To**: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]
**CC**: Lloyd, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338a759166e74b13a5c9b385cde90eb9-Lindsay.Llo]; Jenkins, Charlene [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e722b6438b04d2e9029c72543639a67-Charlene.Je]
**Subject**: RE: Inquiry

Chrisy,

No need for Dr. Hahn to attend. He's off the hook.

Jeff

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>
**Sent:** Thursday, February 6, 2020 12:32 PM
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>; Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>
**Subject:** RE: Inquiry

Dear Chrisy,

I defer to Dr. Shuren on this.

Best Regards,
Peter

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>
**Sent:** Thursday, February 6, 2020 12:30 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
**Cc:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>; Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>
**Subject:** FW: Inquiry

Hi Drs Shuren and Marks,

Dr. Hahn will be at HHS on February 21 and unavailable. However, I wanted to check with you to get your thoughts on his attendance and whether it is needed or not? Thank you for your help.

---

**From:** Shearstone, Peter E. (b) (6) @thermofisher.com>
**Sent:** Thursday, February 6, 2020 12:10 PM
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>
**Subject:** Inquiry

Dear Ms. Goldie,

Good afternoon to you. My name is Peter Shearstone and I am the global leader for quality and regulatory affairs for Thermo Fisher Scientific in Waltham Massachusetts.
We are one of the largest life science businesses in the world and are involved in many different parts of the healthcare.

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Earlier this week some of our products were approved for use in the first Coronavirus diagnostic test when the FDA approved the emergency use authorization for the CDC.

My CEO Marc Casper and I will be in Washington D.C. on Friday, February 21st for a meeting with Dr. Shuren, Dr. Stenzel and Dr. Marks to discuss our efforts and where we can help FDA advance science.
I am writing to see if Dr. Hahn would also be available for a quick drive-by hello to meet that day? We are meeting with the Center leaders at 1pm Friday afternoon. I believe a short meeting to discuss our recent and future efforts on Coronavirus would be of interest to the FDA Commissioner.

Your thoughts are appreciated with this request.

Best regards and thank you,

Peter

**Peter E. Shearstone**
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: (b) (6) Mobile: +(b) (6)
Internal extension (b) (6)
(b) (6) @thermofisher.com

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 1/23/2020 5:25:08 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Lias, Courtney H [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98a0fa6159ce418898b4b97381a76112-CDL]
**CC**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: Feedback on prepositioning of tests before authorization - DMD - 2019-nCoV update

Uwe and I had a chance to discuss. I'm fine with exercising enforcement discretion to allow CDC to preposition their test. I'm also supportive of handling the EUA packages with OCET as we've done in the past.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 4:58 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** Feedback on prepositioning of tests before authorization - DMD - 2019-nCoV update

Dear Jeff, Bill, Tim and Courtney,

Feedback requested: CDC has requested the prepositioning of their test (authorization pending) into the Laboratory Respond Network (LRN) labs and some public health labs as soon as the manufacturing or sufficient tests and verification controls is completed. The goal is to train lab personnel on the use of the test as quickly as possible and perform test verification. The prepositioning at this stage of an EUA has not been done before, but OIR believes it is the right thing to do to protect public health. We recommend to use enforcement discretion for this prepositioning request. Please let me know whether you support this recommendation.

Also, in past emergencies, we worked directly with OCET on EUA package requests (draft documents) and cc CDRH as the final package moves up to OCET and the Commissioner. Please let me know, whether under the new OPEQ/CDRH structure this is still the approach we should take or whether OPEQ/CDRH wants to be involved in the review of the EUA request package. We would like to know so we can factor this into the review timelines. If so, please recommend individuals we should bring up to speed – given the time sensitive nature of these EUA requests.

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General update: From the "AMA updates on Coronavirus" call that happened this morning, it appears based on the current case numbers that the mortality rate is about 2.5%. There are current 5 US airports that established screening. The travel alert was updated to a level 3 (highest rating).
CDC is testing 3 alert cases - individuals from the same family – test results are pending, 46 other individuals are also under investigation.

DARPA is involved to support the development of additional diagnostic platforms, but currently all specimens go to CDC for testing. There is consideration of sending sequencing out to LRN, however, CDC expect to have an assay ready to go in 2 weeks. A number of vaccines are in development based on MERS-CoV and SARS but there is a need for wild-type virus for the development of animal models. Funding is under discussion.

In addition, we had a call CDC today to clarify data requirements to support their EUA request. CDC shares data constantly and anticipates a more complete data package for CDRH review very early next week. In other updates WHO have determined at this point that the Wuhan coronavirus is not yet a public health emergency of international concern.

Best, Uwe

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 1/30/2020 7:58:36 PM
**To:** Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject:** Re: Confidential Privileged Draft sent to OCC

Thank you. The email should state that, (b) (5) [redacted]

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** January 30, 2020 at 7:50:52 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Confidential Privileged Draft sent to OCC

**Confidential / Predecisional / Draft 1/29/2020**

(b) (5) [redacted]

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 1/30/2020 5:28:27 PM
**To:** Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]
**Subject:** RE: 9 am Commissioner Call - 1/30/2020

Denise,

Just cc me when you send it forward.

Thank you.

Jeff

---

**From:** Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Date:** January 30, 2020 at 5:07:03 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: 9 am Commissioner Call - 1/30/2020

Jeff
Do you want to review our data before we submit to OB? Our estimate came in at (b) (5)

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** January 30, 2020 at 10:56:56 AM EST
**To:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Foy, Jonette <Jonette.Foy@fda.hhs.gov>
**Subject:** RE: 9 am Commissioner Call - 1/30/2020

I just spoke to Suzanne. She was just asked for OST. So, yes, OIR/OPEQ needs to weigh in with any asks.

Jeff

---

**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Date:** January 30, 2020 at 10:50:39 AM EST
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Foy, Jonette <Jonette.Foy@fda.hhs.gov>
**Subject:** RE: 9 am Commissioner Call - 1/30/2020

Do we need to reach out to OIR regarding their FTE working overtime with developers on assays and review of pre-EUAs (eventually EUAs) or is that already accounted for?

AMERICAN OVERSIGHT

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Thursday, January 30, 2020 10:47 AM
**To:** Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>
**Subject:** Re: 9 am Commissioner Call - 1/30/2020
**Importance:** High

OST responded to Joanna King's RFI yesterday with respect to our projected needs for Corona Virus response.

We indicated that we would anticipate (b) (5)

We calculated this based on the intensity of person hours needed to focus exclusively on Coronavirus response activities.

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b) (6)

---

**From:** Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Date:** January 30, 2020 at 10:42:10 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Foy, Jonette <Jonette.Foy@fda.hhs.gov>
**Subject:** Re: 9 am Commissioner Call - 1/30/2020

Thanks for sharing. We received a data call on the coronavirus last night asking what additional resources would be spent in response to the virus and whether our existing budgets can cover the cost. The one item for CDRH is PPE at a cost of (b) (5) which we could fund. If there are others that need to be included, please send them before 1pm today.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Date:** January 30, 2020 at 10:24:54 AM EST
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Foy, Jonette <Jonette.Foy@fda.hhs.gov>, Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Subject:** Re: 9 am Commissioner Call - 1/30/2020

I agree about authorities. Adding Denise. If there are additional resource needs please flag them for Denise and me to share with Jay Tyler.

Jeff

---

AMERICAN OVERSIGHT

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** January 30, 2020 at 10:20:59 AM EST

**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Foy, Jonette <Jonette.Foy@fda.hhs.gov>
**Subject:** Re: 9 am Commissioner Call - 1/30/2020

Regarding the comment below that the ASPR wants more robust dialogue between his team and FDA on shortages, I'm not sure where that is heading towards.

We have CDRH representation from ARC/OST on the Supply Chain TF that was just set up for this concern...first call was on Tuesday...there's a follow up today at 2:30 and I will make sure our team is on the call and participatory.

I do think that this (b) (5) (b) (5)

Suzanne
Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b) (6)

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** January 30, 2020 at 10:07:03 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Foy, Jonette <Jonette.Foy@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Subject:** 9 am Commissioner Call - 1/30/2020

Commissioner:

- Interesting HHS leadership retreat yesterday. Great presentation by (b) (5)
- Dr. Hahn wants to know the effect of coronavirus on drugs/biologic supplies and inspections, and beyond. What else is out there that we have to worry about. Dr. Hahn has asked Denise Hinton to work with Anna and all of the Centers re worst case scenario. Probably should do a table top exercise.

Keagan:

- Jay is evaluating if there are budgetary needs for FDA for the coronavirus. Make sure you are accounting for your commission corps, as well as shortages – so we have a full picture for HHS. Everyone should re-look at budget implications and if there are changes, let Bill/Jay know.
  - Dr. Hahn said incredibly important to know resource implications. If we are not doing inspections – how will we replace later. How do we catch up?
- Reminder – Commissioner All Hands at 11 am today. Space reserved for senior leadership up front. Webcast available.

OMA/OEA:

- Working to clear travel notice.
- Communication re WL (?) sent.

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- CBD communication?
- FIB on ANDAs, etc.

Amy:

- Yesterday spoke at pharmaceutical manufacturer meeting re tech modernization.
- Speaking to Health Care Executives this evening on FDA tech modernization.
- CBD – Policy workgroup meeting today to discuss actions and review drafts.

Anna:

- This afternoon a team will be sitting down with OIRA on CFSAN rule.
- Mark Abdoo, Anna, and others will be meeting with (b) (5) colleagues re EU shellfish agreement.

Re Coronavirus:

- Request from Sec. Azar re names for HHS team to be deployed to China.
- Significant concern at highest levels re potential shortage impacts for all medical products (drugs, devices, etc.) that would be needed as part of sustained response efforts.
  - Growing concern regarding medical products and drugs needed outside of the coronavirus response but because of uncertainty of travel, etc. and getting API/materials, there could be disruption to the supply chain.
  - ASPR Dr. Kadlec wants a more robust convo between his team and FDA re potential shortages and mitigation steps. Call will be scheduled – Denise Hinton is heading up many of these efforts internally. HHS looking for something more rigorous than current activities to date.

Mark Abdoo

- State Dept issued authorized departure of US employees from embassy in Beijing as of Jan 29th. Voluntary request for non-emergency personnel but staff are being strongly encouraged to leave.
  - Need to come to policy position quickly. Some HHS colleagues want to stay in the country.
  - Travel orders for folks leaving Beijing will be proceed through state emergency management system. We have some at post to help cover expenses but may need an additional funding cable for this purpose.
  - The only approved travel for safe haven is to the U.S. All staff departing Beijing will come to U.S. Unclear whether staff will come to D.C. or go to their District Office or elsewhere.
  - Any travel to China is now being approved at the Undersecretary of Management at State Dept Level – meaning it will not be approved.
  - FDA Country director has revoked any preapproved travel and will not allow more.
  - Need to issue guidance on how staff will apply for expense allowances to cover evacuation costs. Also need to develop policy on how these staff will work when they return.
  - Dr. Hahn asked if there was a plan to communicate policy to the Center Directors; Mark said folks are meeting at 1:30 to discuss and will plan to communicate with everyone if/when decisions are made.

Dr. Shah – Has met with most Center Directors and leadership team. Thank you for the warm welcome.

Frank (Cailtin) – Having some good conversations with (b) (5)

OL:

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- RADM Denise Hinton has joined HHS (BARDA, NIH, CDC) briefing E&C members on efforts to respond to the coronavirus.
- Staff briefing for Sens. Cardin (D-MD), Smith (D-MN), Blumenthal (D-CT) re drug shortage task force report.

OCA: Request from House Approps to meet with FDA re our work on coronavirus, EUAs generally, and budget implications. Will e-mail folks this morning. OCA will try to include Senate approps staff in the request.

CDRH: Nothing to report.

CFSAN: At OIRA meeting with Anna and others today.

CVM – Generic animal drug alliance meeting today.

ORA – Has looked at inspections (b) (5) [redacted]

OCC – (b) (5) [redacted]

OO – OO and Dr. Hahn agree it makes sense for employees to telework for now activities are interrupted by coronavirus. OO said employees without telework agreements can e-mail and follow up with formal documentation later.

OB – OB sent an additional request yesterday for Centers to indicate burden of coronavirus response. (b) (5) [redacted]

CBER, CDER, CDRH, CTP, OCE, OCS, and OO all passed or were not on today.

**Jennifer Brown Tomasello, MPA**
*Senior Policy Advisor*

**Center for Devices and Radiological Health**
**Office of Policy**
**U.S. Food and Drug Administration**
Tel: 301-796-8924 - Cell: 240-328-7224
jennifer.tomasello@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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***https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E***

AMERICAN OVERSIGHT

**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 1/22/2020 9:34:14 PM
**To**: Kannan, Lakshmi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8efc4e7e0adb4246a67ca3e110e46bd6-Lakshmi.Kan]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Faris, Owen P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d919c42856449589d2d24454b2f774e-OPF]
**CC**: Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Saltman, Adam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=941424473c4e4cfeb01594032f253e91-Adam.Saltma]; Yustein, Aron S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49a1dbcd36b64c3abe23da19ee0a73b0-ASY]; Brockman, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0dbb293045cd4e9393e8bc6385d86194-RGB]; Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]; Krause, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43e466e978c844dc83be09a25e972eca-dxk]
**Subject**: Re: Cardinal Heath Surgical Gowns: leadership updates 1-22-2020

Lakshmi,

Thank you. Do we have any sense of the percent of the kits that have the gown or components separated by an impervious barrier?

Jeff

---

**From:** Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>
**Date:** January 22, 2020 at 7:08:16 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Faris, Owen P <Owen.Faris@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Saltman, Adam <Adam.Saltman@fda.hhs.gov>, Yustein, Aron S <Aron.Yustein@fda.hhs.gov>, Brockman, Randall <Randall.Brockman@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Krause, David <David.Krause@fda.hhs.gov>
**Subject:** Cardinal Heath Surgical Gowns: leadership updates 1-22-2020

Good evening.

We are sending you today's updates from OPEQ and ARC on surgical gowns:

**Recalls:**

- Cardinal's 806 package for the gowns is in and being reviewed. The team has decided that there are no future data that would sway their decision to prevent release of Cardinal's on-site, quarantined, single gowns (there are about (b) (4). (b) (5) .

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- Cardinal's 806 package for the kits arrived earlier today and is being reviewed. Most of the discussion is about what to do with the kits, to mitigate a shortage (below).
- We plan to post Early Recall Notification for the single gowns recall by end of this week.

**Shortages:**

(b) (5)



**Communications:**

- OCE is working on draft KMQA to address any questions that might arise from the posting of Early Recall Notifications for both the single gowns.

**Congressional Inquiries:**

- No new inquiries received today. For the inquiry received yesterday, we are putting together a response and CDRH/FDA congressional liaisons plan to speak with the staff for Senators Markey (D-MA) and Warren (D-MA) on Monday (1/27/2020) afternoon.

**External Stakeholder Outreach:**

ASPR/CIP:

- SLT meeting: Today, Linda Ricci represented FDA in ASPR Senior Leadership Team meeting. The meeting went well and there were no questions to FDA. Dr. Kadlec plans to provide situational awareness update on Cardinal gown issue to HHS Secretary during his next meeting on the ongoing Corona Virus incident, due to the potential overlap of these issues (will gown recall impact availability of gowns for Corona Virus response). ASPR/CIP plans to share the draft talking points/updates with FDA for comments/edits prior to presenting to the Secretary.

- Private sector TCON: ASPR/CIP-private sector call is yet to be scheduled. ASPR is waiting for FDA to issue the recall notice to have information publicly available before holding this call with their sector partners. FDA is invited to participate in this call.

American Hospital Association (AHA):

- ARC held a TCON with AHA on 1/22/2020. Key takeaways:
  - Expressed concern about not having more details about the environmental conditions that the gowns were manufactured under. Since the recall goes back to September 2018, their customers have expressed concerns that patients may have already been affected.
  - Indicated that their customers are implementing mitigation strategies such as: putting level 3 gowns on allocation, some hospitals are using gowns from their Ebola cache, and some hospitals are networking a resource sharing with other hospitals in their communities.
  - Asked if the FDA is doing anything to facilitate the rapid importation of Level 3 gowns.

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**Vizient (Group Purchasing Organization):**

- ARC held a TCON with Vizient on 1/22/2020. Key takeaways:
  - Indicated that they speak with the President of Cardinal Health every day and are in daily contact with the largest 24 health systems.
  - Stated that they feel there has been minimal actual impact to elective surgeries at this point.
  - Expressed concern about the event spanning back to September 2018 and stated that their customers want to know what actually went wrong with the gowns, so that they can better manage things from a public relation stand point.
  - Expressed anxiety about the possible convergence of EtO, surgical gown recalls, and the potential spread of coronavirus.
  - Indicated that their customers are implementing mitigation strategies such as: (b) (4) Additionally, Cardinal Health is providing substitutes at no additional cost and Cardinal is assisting hospitals to assemble their own kits.
  - Vizient is helping their customers connect with alternative manufacturers (b) (4)
  - Asked if the FDA has any knowledge of the actual contaminant, and we advised that we did not.

**Health Industry Distributors Association (HIDA):**

- ARC held a TCON with HIDA on 1/22/2020. Key takeaway:
  - Indicated that the CH impact has not actually been felt and that everything is currently "speculative".

**Premier (Group Purchasing Organization):**

- FDA received a list of questions from Premier. We are in the process of drafting responses to their questions and plan to follow up with them by end of this week.

We will continue to keep you posted with new information and updates. Please let us know if you have any questions.

Best,
Lakshmi and Adam

**Lakshmi Kannan, Ph.D.**
*Senior Project Manager*
*Staff Fellow*
**Team: All-Hazards Readiness Response and Cybersecurity (ARC)**
**Division: All hazards Response, Science and Strategic Partnerships (DARSS)**
**Office of Strategic Partnership and Technology Innovation (OST)**
**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
---
WO 66, Room 5561
10903 New Hampshire Ave, Silver Spring, MD 20993
Office: 240-402-7735; Cell: (b) (6)
lakshmi.kannan@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=7011&S=E




AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 1/29/2020 3:09:13 PM
**To:** Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC:** Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject:** Re: Request for Input for 29 Jan Update on FDA activities related to 2019-nCoV response - input needed by 3:00 PM

Kim,

Yes, please cc me going forward just so I know what information they have.

Thank you for asking.

Jeff

---

**From:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Date:** January 29, 2020 at 3:01:30 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Subject:** FW: Request for Input for 29 Jan Update on FDA activities related to 2019-nCoV response - input needed by 3:00 PM

Dear Jeff,

Please find attached the daily SITREP that DMD sends OCET between 2:30-3 pm. Any information that comes in after 3 pm is included in the next day SITREP. Would you like me to cc you also, going forward? I had not included you previously as the updates Uwe sends you at 8 an and 2 pm are much more detailed.

Thanks
Best regards
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Sapsford, Kim E
**Sent:** Wednesday, January 29, 2020 2:44 PM
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Cc:** Uwe Scherf (Uwe.Scherf@fda.hhs.gov) <Uwe.Scherf@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>
**Subject:** RE: Request for Input for 29 Jan Update on FDA activities related to 2019-nCoV response - input needed by 3:00 PM

From DMD
Cheers
Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>
**Sent:** Wednesday, January 29, 2020 1:05 PM
**To:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Kim, Christine <Christine.Kim@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>
**Cc:** FDA Emergency Operations <emergency.operations@fda.hhs.gov>
**Subject:** Request for Input for 29 Jan Update on FDA activities related to 2019-nCoV response - input needed by 3:00 PM

Hi.

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Many thx for your continued assistance with the SITREP.

To enable better information sharing, we have created a sharepoint site (2019-nCoV SitReps) where we can store documents and then link to them from the SITREP. You can find the final versions of the SITREP there as well.

Just a quick note on (b) (5) [redacted]

Attached is a draft 29 Jan SITREP on the FDA response to the 2019-nCoV outbreak.

Please **provide any updates you to me by 3:00 PM.**

Please highlight any info that should not be shared outside of FDA in red.

Many thx for your continued assistance with this. -m

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 1/31/2020 5:32:03 AM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Coronavirus

Uwe,

One other follow up question for the moment: What test performance do we need to see to grant the EUA?

Jeff

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 1/22/2020 11:28:16 AM
**To:** Torres, Melissa A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c012e5b0aa843f78e818a92d82f8d1b-MAT]
**CC:** Hoshi, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e381bd6e59d045da953e80dbe3499a2e-Ryan.Hoshi]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject:** RE: FYI >>> Amb Sondland and Grenell, EU Med Device Updates

Melissa,

Thank you for the heads up.

Jeff

---

**From:** Torres, Melissa A <Melissa.Torres@fda.hhs.gov>
**Date:** January 22, 2020 at 11:11:30 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Hoshi, Ryan <Ryan.Hoshi@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Subject:** RE: FYI >>> Amb Sondland and Grenell, EU Med Device Updates

Jeff,

(b) (5)

[redacted]

Thanks,
Melissa

Melissa Torres
Associate Director for International Affairs, OCD, CDRH
(301) 796-5576

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**From:** Hoshi, Ryan
**Sent:** Tuesday, January 14, 2020 12:35 PM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Torres, Melissa A <Melissa.Torres@fda.hhs.gov>
**Subject:** FYI >>> Amb Sondland and Grenell, EU Med Device Updates

Hi Jeff,

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(b) (5)



Thanks,
Ryan

**Ryan A. Hoshi, Ph.D.**
International Policy Analyst | Center for Devices and Radiological Health | ryan.hoshi@fda.hhs.gov | phone 240.402.5242 | mobile 301.452.1540
FDA U.S. FOOD & DRUG ADMINISTRATION

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**From:** Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>
**Sent:** Tuesday, January 14, 2020 11:26 AM
**To:** Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Rieras, Joseph <Joseph.Rieras@fda.hhs.gov>; Bharwani, Ravi <Ravi.Bharwani@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>; Hoshi, Ryan <Ryan.Hoshi@fda.hhs.gov>
**Cc:** Scherer, Matthew <Matthew.Scherer@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>
**Subject:** MedTech mtg at USEU today

Hi Mark, all – Medical devices updates from events today. Please let me know if we should discuss any of this.
Ritu

---

**At USEU**
-Pre-brief with Amb Sondland and Amb Sondland mtg with Med Tech held today.
-Amb. wants to find a short-term fix to industry concerns about lack of sufficient notified bodies to meet May 2020 compliance date. Dec corrigendum is a positive step but not enough. MDSAP guidance, EU full membership in MDSAP, participation in MDSRP all good for long term. Proposed advocating solutions on both fronts.
-Med Tech supports Amb intervention. Highlighted potential economic impact of May 2020 date without further relief from EP/EC – disruption could cost U.S. industry tens of billions of USD. MedTech expects EC will issue MDSAP guidance in March.
-Amb plans to meet with MEPs and Health Commissioner to push on two points – (1) At a high-level, EC to provide policy direction to EU-MS to prioritize and apply risk-based approach to enforcement. What form such instruction will take is TBD – MedTech suggested a 'Policy Directive' that lists 'significant changes' that do not need re-certification; and (2) EC to issue guidance to accept MDSAP audit reports in lieu of new audits.
-USEU tweet following MedTech mtg:

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*"The U.S. and EU each have high standards that ensure the health and safety of consumers. We are now working with @medtecheurope and the EU to ensure that US-manufactured life-saving devices can continue to be made available to EU citizens."*

**Germany**
-Amb Grenell meeting with DG Anne Bucher (DG for SANTE) is confirmed for Jan 22nd. Pre-brief with FDA and FCS.
-Shared yesterday's TPs with Emb Berlin.

---

**From:** Nalubola, Ritu
**Sent:** Monday, January 13, 2020 5:37 PM
**To:** Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Rieras, Joseph <Joseph.Rieras@fda.hhs.gov>; Bharwani, Ravi <Ravi.Bharwani@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>; Hoshi, Ryan <Ryan.Hoshi@fda.hhs.gov>
**Cc:** Scherer, Matthew <Matthew.Scherer@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>
**Subject:** RE: AMB Grenell Visit to Brussels and Requested FDA Meeting

Thanks, Mark. Call with Berlin was fine – it was a bit of an educational one – there is some confusion about current MRA-pharma scope and so they didn't fully get why we object to MRA concept for medical devices. (b) (5)

Attached is a pared down version for purposes of AMBs briefing books with reworked TPs on how MDSRP can accommodate AMB Grenell's specific ask. New/reworked TPs below – please let me know any concerns as soon as possible.

Many thanks!
Ritu

---

(b) (5)

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 1/31/2020 5:52:51 PM
**To:** Corbin, Rhonda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e0963ce5594ce59eb7ab7da787f639-CorbinR]; Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]
**CC:** Horman, Jaime [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47e207dbba3f4e4aa3f22662b5418af4-Jaime.Horma]; Carr, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c6df5ab0cc6f4f00b90a73a97ae81f0d-CARRP]; Needham, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f74f493e6c584b159560c932efe2734d-Mark.Needha]
**Subject:** Re: URGENT: Coronavirus Data Call

Rhonda,

I'm okay with Bill's statement.

Jeff

---

**From:** Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>
**Date:** January 31, 2020 at 5:44:58 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>
**Cc:** Horman, Jaime <Jaime.Horman@fda.hhs.gov>, Carr, Patricia <Patricia.Carr@fda.hhs.gov>, Needham, Mark <Mark.Needham@fda.hhs.gov>
**Subject:** URGENT: Coronavirus Data Call

Hi Jeff and Denise,

I wanted to make you aware of the Bill Tootle's recent request. (b) (5) [redacted]

Please let us know how you would like to proceed.

Thanks,
Rhonda

**Rhonda Corbin**
*Deputy Division Director*

**Office of Management, Division of Financial Management**
**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 240-402-8043
Rhonda.Corbin@fda.hhs.gov

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---

**From:** Tootle, William <William.Tootle@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:34 PM
**To:** Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>
**Cc:** Willis, Ken <Ken.Willis@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Needham, Mark <Mark.Needham@fda.hhs.gov>; Rodriguez, Christian <Christian.Rodriguez@fda.hhs.gov>
**Subject:** RE: Coronavirus Data Call

Also, I need to provide a general response related to being able to fund with existing resources so I plan to use the following.

(b) (5)

[redacted]

Bill Tootle

*Director, Office of Budget*
*U.S. Food and Drug Administration*
*4041 Powder Mill Road,*
*Beltsville, MD 20705*

*Phone: 301-796-4710/4579*

---

**From:** Tootle, William
**Sent:** Friday, January 31, 2020 5:26 PM
**To:** Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>
**Cc:** Willis, Ken <Ken.Willis@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Needham, Mark <Mark.Needham@fda.hhs.gov>; Rodriguez, Christian <Christian.Rodriguez@fda.hhs.gov>
**Subject:** RE: Coronavirus Data Call

I meant any costs related to shortages for devices as a result of the coronavirus.

Bill Tootle

*Director, Office of Budget*
*U.S. Food and Drug Administration*
*4041 Powder Mill Road,*
*Beltsville, MD 20705*

*Phone: 301-796-4710/4579*

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**From:** Tootle, William
**Sent:** Friday, January 31, 2020 5:22 PM
**To:** Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>
**Cc:** Willis, Ken <Ken.Willis@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Needham, Mark <Mark.Needham@fda.hhs.gov>; Rodriguez, Christian <Christian.Rodriguez@fda.hhs.gov>
**Subject:** RE: Coronavirus Data Call

OK. One other question. Are you aware of any costs associated with or created by the coronavirus?

Bill Tootle

*Director, Office of Budget*
*U.S. Food and Drug Administration*
*4041 Powder Mill Road,*
*Beltsville, MD 20705*

*Phone: 301-796-4710/4579*

**From:** Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 5:09 PM
**To:** Tootle, William <William.Tootle@fda.hhs.gov>
**Cc:** Willis, Ken <Ken.Willis@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Needham, Mark <Mark.Needham@fda.hhs.gov>; Rodriguez, Christian <Christian.Rodriguez@fda.hhs.gov>
**Subject:** RE: Coronavirus Data Call

Hi Bill,

We had a slight addition to the current response:

(b) (5)

[redacted]

Thanks,
Rhonda

**Rhonda Corbin**
***Deputy Division Director***

**Office of Management, Division of Financial Management**
**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
Tel: 240-402-8043
Rhonda.Corbin@fda.hhs.gov

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---

**From:** Tootle, William <William.Tootle@fda.hhs.gov>
**Sent:** Friday, January 31, 2020 4:57 PM
**To:** Corbin, Rhonda <Rhonda.Corbin@fda.hhs.gov>
**Cc:** Willis, Ken <Ken.Willis@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Carr, Patricia <Patricia.Carr@fda.hhs.gov>; Needham, Mark <Mark.Needham@fda.hhs.gov>; Rodriguez, Christian <Christian.Rodriguez@fda.hhs.gov>
**Subject:** RE: Coronavirus Data Call

Thanks, Rhonda. We need to have a single summary for CDRH's response. Below is what we currently have in the table. Would you like to provide a new summary or keep it as is?

(b) (5)



Bill Tootle

*Director, Office of Budget*
*U.S. Food and Drug Administration*
*4041 Powder Mill Road,*
*Beltsville, MD 20705*
*Phone: 301-796-4710/4579*

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 1/28/2020 7:26:35 AM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaef84cef160-DJS]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**Subject**: RE: nCoV 1/28/20 8 AM update:

Uwe,

Thank you. I have a leadership call today at 4 PM which will be a standing call every Tuesday for the present time. Therefore, if anything of relevance comes up before then, please let me know.

Jeff

---

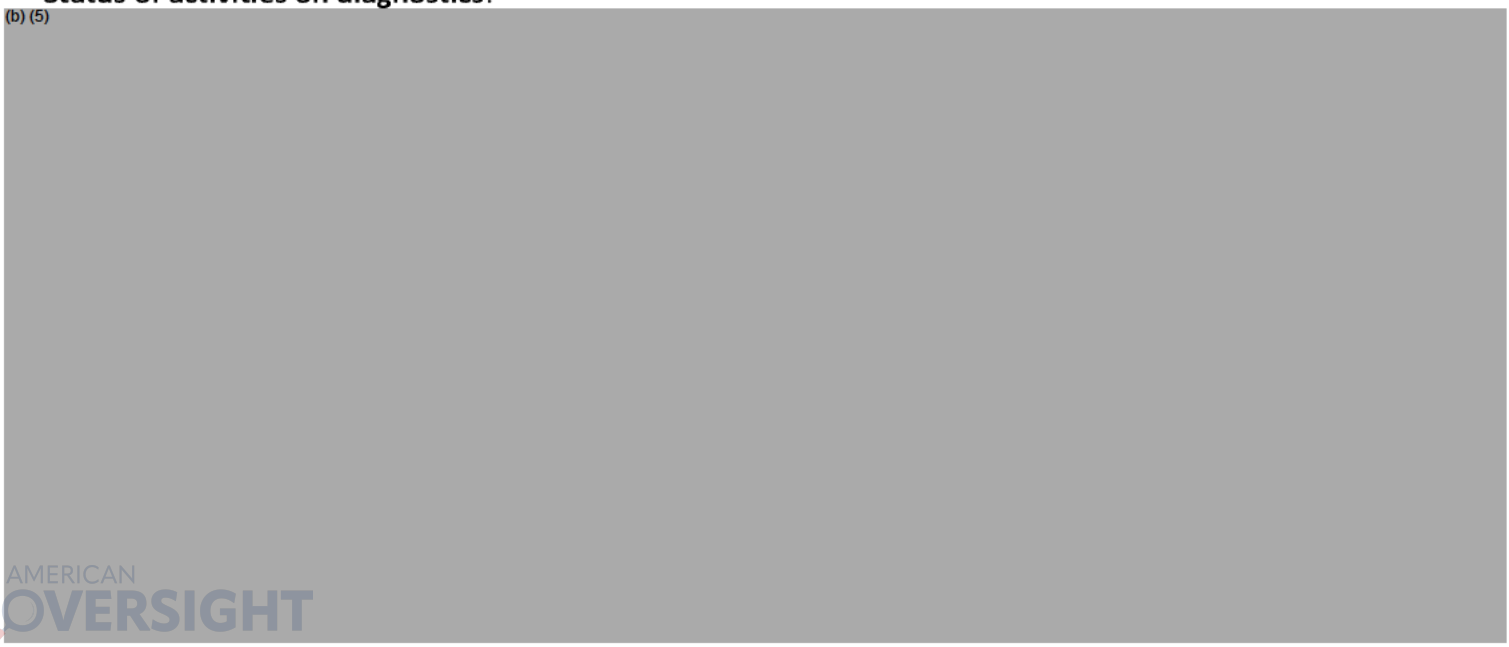
**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Sent:** Tuesday, January 28, 2020 7:07 AM
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** nCoV 1/28/20 8 AM update:

Jeff, Elizabeth, Bill, Don,

Enclosed 1/28/20 8 AM update:

**Status of activities on diagnostics**:

(b) (5)



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(b) (5)



Please let me know if you have any questions

**Uwe Scherf, M.Sc., Ph.D.**
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
uwe.scherf@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E

AMERICAN OVERSIGHT

**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 1/27/2020 12:58:21 PM
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** Re: FDA Commissioner and staff

Abiy Desta. I can fill you in at today's 1:1.

Jeff

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** January 27, 2020 at 12:10:11 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: FDA Commissioner and staff

Hey Jeff – the Commissioner has been receiving a bunch of emails from this person below and (b) (5) [redacted] Thanks!

Keagan

---

**From:** Raza, Mark <Mark.Raza@fda.hhs.gov>
**Sent:** Thursday, January 23, 2020 7:13 PM
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>
**Subject:** FW: FDA Commissioner and staff

Keagan – I have consulted with Claire Davies of my office and Matt Warren, the Director of the Office of Scientific Integrity in OCS. Both Claire and Matt were involved in the attached response, dated October 2016, from the Chief Scientist to similar concerns raised by (b) (5) [redacted].

(b) (5) [redacted]

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(b) (5)

[redacted]

---

**From:** Davies, Claire <Claire.Davies@fda.hhs.gov>
**Sent:** Wednesday, January 22, 2020 10:10 AM
**To:** Raza, Mark <Mark.Raza@fda.hhs.gov>
**Cc:** Mednick, David <David.Mednick@fda.hhs.gov>
**Subject:** RE: FDA Commissioner and staff

Thanks, Mark.

Attached is a copy of Dr. Borio's October 2016 letter to (b) (5) [redacted], in case it is useful background.

(b) (5)

[redacted]

Happy to discuss further, as needed.

Claire

---

**From:** Raza, Mark <Mark.Raza@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 5:11 PM
**To:** Davies, Claire <Claire.Davies@fda.hhs.gov>
**Cc:** Mednick, David <David.Mednick@fda.hhs.gov>
**Subject:** FW: FDA Commissioner and staff

Claire - as mentioned.

(b) (4)

[redacted]

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(b) (4)

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(b) (4)

AMERICAN OVERSIGHT

(b) (4), (b) (6)

AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

AMERICAN OVERSIGHT

(b) (4)

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**From:** Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent:** 1/21/2020 11:49:07 AM
**To:** Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**CC:** Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Kannan, Lakshmi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8efc4e7e0adb4246a67ca3e110e46bd6-Lakshmi.Kan]; Ellis, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dec0284840704f568a8b9f314058ad63-Patricia.El]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; CDRH All Hazards Readiness Response and Cybersecurity [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af150d41dbea48c2b898c3431c24a132-CDRHEMCM]
**Subject:** RE: (b) (5) for Commissioner's Briefing

TY

---

**From:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 11:46 AM
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>; Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>
**Subject:** RE: (b) (5) for Commissioner's Briefing

Good morning. The criteria used to identify essential procodes is found below. For each procode, OHTs were asked to answer the following:

1. Is it used to diagnose, treat or prevent a serious disease or medical condition?
2. Is it used as a necessary tool (e.g. core medical equipment) for life sustaining conditions or patient care?
3. Is this device made by a sole manufacturer?
4. Is it used for a vulnerable population?
5. Does disruption in availability of this device cause concern and significantly impact patient care?

Best,

Aftin

**Aftin Ross, Ph.D.**
*Senior Project Manager*
*Senior Science Health Advisor*
**Team: All-Hazards Readiness Response and Cybersecurity (ARC)**
**Division: All hazards Response, Science and Strategic Partnerships (DARSS)**
**Office of Strategic Partnerships and Technology Innovation (OST)**
**Center for Devices and Radiological Health**
**U.S. Food and Drug Administration**
WO 66, Room 5558
10903 New Hampshire Ave, Silver Spring, MD 20993

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Office: 301-796-5679; Cell: (b) (6)
aftin.ross@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=7011&S=E

U.S. FOOD & DRUG ADMINISTRATION

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Sent:** Tuesday, January 21, 2020 11:38 AM
**To:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>; Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>
**Subject:** Re: (b) (5) for Commissioner's Briefing

Aftin and team,
TY.

(b) (5), (b) (4)

Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b) (6)

---

**From:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>
**Date:** January 21, 2020 at 10:29:39 AM CST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>, Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>
**Subject:** (b) (5) for Commissioner's Briefing

Good morning.

(b) (5), (b) (4)

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(b) (5), (b) (4)



Best,

Aftin
**Aftin Ross, Ph.D.**
*Senior Project Manager*
*Senior Science Health Advisor*
**Team: All-Hazards Readiness Response and Cybersecurity (ARC)**
**Division: All hazards Response, Science and Strategic Partnerships (DARSS)**
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---
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https://www.research.net/s/cdrhcustomerservice?ID=7011&S=E

U.S. FOOD & DRUG ADMINISTRATION

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 1/21/2020 7:18:56 PM
**To**: Kannan, Lakshmi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8efc4e7e0adb4246a67ca3e110e46bd6-Lakshmi.Kan]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Faris, Owen P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d919c42856449589d2d24454b2f774e-OPF]
**CC**: Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Saltman, Adam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=941424473c4e4cfeb01594032f253e91-Adam.Saltma]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; CDRH All Hazards Readiness Response and Cybersecurity [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af150d41dbea48c2b898c3431c24a132-CDRHEMCM]
**Subject**: Re: Cardinal Heath Surgical Gowns: leadership updates 1-21-2020

Thank you.

Jeff

---

**From:** Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>
**Date:** January 21, 2020 at 6:51:47 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Faris, Owen P <Owen.Faris@fda.hhs.gov>
**Cc:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Saltman, Adam <Adam.Saltman@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>
**Subject:** Cardinal Heath Surgical Gowns: leadership updates 1-21-2020

Good evening.

We are sending you today's updates on surgical gowns:

**Recall/Shortages**:

- Gowns: Cardinal's 806 for gowns was received on Tuesday, 1/21/2020. The Cardinal single surgical gown recall does not appear to pose a significant threat to the supply chain as stakeholder outreach suggests that the market has adequate alternatives for AAMI level 3 gowns, including level 4 gowns and gowns produced by competitors.

- Kits: As of Tuesday, 1/21/2020 FDA has received a draft preliminary form of 806 for the Presource kits. The Presource kits are custom and unique to the facility, or even the provider level, making them difficult to otherwise source.

- FDA had a TCON with Cardinal Health (CH) this afternoon. Key takeaways are:
  - FDA requested additional information regarding the kits ASAP.
  - A follow up email was sent to the firm requesting them to submit the following information:
    - 806 recall package for kits by 10am tomorrow, Jan 22nd

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- Descriptions of the configurations of the kits, specifically with attention to how the other kit components are arranged in relation to the potentially contaminated gown(s), and how they are physically separated from those gown(s) and the materials used to physically separate from those gown(s), by 10am tomorrow, Jan 22nd
- Firm's mitigation strategy on potential shortages that may alleviate burden on their customers by 1pm tomorrow, Jan 22nd
  - CH confirmed that all their gowns are sterilized using EtO. They do not use the (b) (4) facility to sterilize their gowns. Their gowns are sterilized at (b) (4) at multiple locations.
  - CH is anticipating to begin the sterility testing on or before Feb 10th.

- The kit shortage is under active and heated discussion internally.
  - The team's decision will hinge on a better understanding of the internal kit configuration, which seems to come in 2 and perhaps more varieties.
  - Some kits have the gowns physically separated from the other components, whereas other kits do not.
  - The risk of harm from use may differ among the different configurations.
  - Right now, with the information we have, (b) (5)

**Communications:**
Today, CH provided a link to their microsite that lists their customer letter. We have updated our Medical Gowns web page to include the link to the Cardinal's microsite.

**Congressional Inquiries:**
We have received questions from Senators Markey's and Warren's office today regarding hospital gown issue. At this time, the questions are very general and high-level such as "whether Cardinal is participating with us", "what are some potential types of adverse events from lack of sterility", etc. ARC is working with Jennifer Tomasello to address these questions.

**External Stakeholder Outreach:**

- ASPR/CIP: ASPR/CIP has relayed that the private sector partners have some questions and concerns for us including but not limited to: more specifics on the contaminant, looking for patient complications, bioburden of the contamination. ARC is coordinating with ASPR to have a call with the private sector partners this week.

- Massachusetts Hospital Association (MHA): ARC spoke with MHA on 01/21/2020 in follow-up to inquiry received from the MA Senators. As of today, MHA has received only 2 comments regarding the CH gown shortage. Both calls were from hospitals with a teaching function. MHA was not comfortable disclosing their names without prior approval. MHA was unable to answer if their concerns centered around the gowns only, Presource kits only, or both items. They did advise that they have a meeting with 35 Massachusetts Hospital CEOs planned for Thursday, 01/23/2020. They are willing to discuss any potential supply chain disruptions, product availability concerns, and mitigation strategies with their members at this meeting. ARC has scheduled a follow-up with MHA following this meeting.

We will continue to keep you posted with new information and updates. Please let us know if you have any questions.

Best,
Lakshmi

**Lakshmi Kannan, Ph.D.**
*Senior Project Manager*
*Staff Fellow*
Team: All-Hazards Readiness Response and Cybersecurity (ARC)
Division: All hazards Response, Science and Strategic Partnerships (DARSS)
Office of Strategic Partnership and Technology Innovation (OST)
Center for Devices and Radiological Health

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lakshmi.kannan@fda.hhs.gov

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**From**: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
**Sent**: 1/21/2020 11:32:57 AM
**To**: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
**Subject**: RE: Coronavirus

CDRH has been proactively coordinating with CDC on diagnostic activities through the Tri-agency Taskforce for Emergency Diagnostics (TTFED): Teleconferences were held Jan 8, 15, and 17, 2020. In anticipation of testing specimens from returning travelers at the selected airports, CDC is developing a molecular test, based on CDC's previously developed MERS-CoV RT-PCR Assay (which FDA authorized for use under EUA in June 2014), that they will CLIA validate for use in CDC laboratories. Primers and probes have been selected and CDC is currently validating the assay. CDC anticipates submitting an EUA package to facilitate distribution of the test within the Laboratory Response Network. We are finalizing an EUA Interactive Review Template specific for Molecular-based technologies detecting the 2019-nCoV to share with all IVD developers that request the template. We are currently working interactively with CDC to complete the data information needed to support an EUA request to FDA. At this time, no other IVD developers have reached out to us to request an EUA Interactive Review Template for the 2019-nCoV. We have also been involved in a recent WHO-USG Telecon on Wuhan Coronavirus Cooperation (Jan 14, 2020) to discuss needs and potential areas of collaboration. OCET is coordinating this interaction for FDA.

Jeff

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, January 21, 2020 11:26 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Coronavirus

On the call with the Secretary - (b) (5) [redacted] (b) (5) [redacted]

Sent from my iPhone

AMERICAN OVERSIGHT

**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/4/2020 5:00:25 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

Nothing to apologize about. And definitely get some sleep!

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 4, 2020 at 4:55:45 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

AMERICAN OVERSIGHT

**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/4/2020 4:54:12 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**CC**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Re: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued

Uwe,

No worries, and thank you.

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 4, 2020 at 4:39:47 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: CONTRATULATIONS! The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Emergency Use Authorization has been issued
**Importance:** High

AMERICAN OVERSIGHT

**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/3/2020 3:47:03 PM
**To**: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: RE: CDC wants to distribute coronavirus diagnostic test by end of week

Maybe (b) (5) [redacted] I called Uwe to confirm before I sent my reply email to you.

Adding Uwe for any additional clarity.

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 3, 2020 at 3:42:03 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/3/2020 2:47:26 PM
**To**: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject**: RE: CDC wants to distribute coronavirus diagnostic test by end of week

We haven't received any data today. We're still waiting for the EUA package.

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>
**Date:** February 3, 2020 at 2:24:25 PM EST
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: CDC wants to distribute coronavirus diagnostic test by end of week

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/12/2020 6:04:24 PM
**To**: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**Subject**: RE: Plz use this: Info on US PPE firms from today's calling

Have we told (b)(4) to get an EUA and tests they'd need to perform? As you know, OHT7 has an EUA template for 2019-nCoV tests. We could have one for N95 masks.

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 12, 2020 at 5:58:17 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: Plz use this: Info on US PPE firms from today's calling

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/26/2020 11:53:51 AM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**Subject**: Re: Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits

I might be able to join a 3 PM call.

Jeff

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 26, 2020 at 11:51:22 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Do not destroy your current CDC 2019 nCoV Coronavirus EUA Kits

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/23/2020 10:44:21 AM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: Re: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

Thank you

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 23, 2020 at 10:38:35 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Re: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/26/2020 9:11:24 PM
**To**: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**CC**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**Subject**: Re: N95 EUA for COVID19

Yep

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 26, 2020 at 9:05:38 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Re: N95 EUA for COVID19

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/26/2020 9:03:54 PM
**To**: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
**CC**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]
**Subject**: Re: N95 EUA for COVID19

If need be it could an EUA with alternatives — NIOSH certified can be used in non-surgical healthcare settings or in a surgical healthcare setting if used with a faceshield or the manufacturer truthfully certifies that it conducted and passed ASTM fluid penetration testing (or our scaled back version). That would not be inconsistent with CDC's current recommendations.

Jeff

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
**Date:** February 26, 2020 at 8:51:44 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Subject:** Fwd: N95 EUA for COVID19

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/22/2020 9:57:25 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: Re: CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

TY!!

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**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 22, 2020 at 9:45:55 PM EST
**To:** Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>
**Cc:** Rose, Laura E (CDC) <zey9@cdc.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel - Regulatory Discretion

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/17/2020 7:26:53 PM
**To**: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**Subject**: RE: 2019-nCoV RT-PCR Test EUA

Thank you.

Jeff

---

**From:** Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
**Date:** February 17, 2020 at 7:23:46 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** RE: 2019-nCoV RT-PCR Test EUA

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 3/1/2020 10:31:56 PM
**To**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
**Subject**: Re: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

Elizabeth,

Yes, please send it to Keagan, Laura Caliguiri, Karas Gross, Lauren Paulos, and Stephanie since the participants may subsequently speak to the media and/or the Hill and/or some of those folks may attend the webinar

Jeff

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**From:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
**Date:** March 1, 2020 at 10:18:06 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: EUA COVID-19 Lab Tests - Webinar deck (003) Tim.Uwe.EH.Uwe.pptx

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/24/2020 7:52:08 PM
**To**: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject**: Re: Public health labs press FDA to allow homegrown coronavirus tests

(b) (5)

[redacted]

And if granting enforcement discretion to the public health labs, there is no basis to exclude other test developers.

The labs should be validating their tests and can submit data/analyses to us on a rolling basis. Once we have the final piece we grant the EUA for valid tests quickly, often within a day. Over 70 developers requested and received our EUA template and are already developing tests. The public health labs could have been doing that but haven't, as far as I've heard.

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**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Date:** February 24, 2020 at 7:37:19 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** Fwd: Public health labs press FDA to allow homegrown coronavirus tests

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/24/2020 7:41:11 PM
**To**: Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Rubinstein, Wendy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3712ebbe444401c81a2a44df908c345-Wendy.Rubin]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
**CC**: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Paulos, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]
**Subject**: Re: Public health labs press FDA to allow homegrown coronavirus tests

David totally missed that EUA authorization is a statutory requirement regardless of who makes it.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
**Date:** February 24, 2020 at 7:31:12 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
**Subject:** FW: Public health labs press FDA to allow homegrown coronavirus tests
**Importance:** High

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/29/2020 3:50:38 PM
**To**: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
**CC**: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Re: NYS Wadsworth Center COVID-19

TY

---

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
**Date:** February 29, 2020 at 3:46:04 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: NYS Wadsworth Center COVID-19

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**[Date]**

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**ATTN:** Division Director: Dr. Uwe Scherf**,** OHT7-OIR/OPEQ/CDRH/FDA

**RE:** Request for Pre-Emergency Use Authorization (Pre-EUA) of the [*Name of the Assay*]

**Dear Dr. Scherf,**

[***Name of the Company***] is submitting a Pre-Emergency Use (Pre-EUA) for the [***Name of the Medical Device Product***] so we can obtain feedback from FDA concerning the studies and/or testing outlined in our Pre-Emergency Use Authorization (Pre-EUA) submission package.

The [***Name of the Medical Device Product***] is [***brief description of the device***] and [***intended use***].

Attached to this letter is the first draft of our device EUA Interactive Review Template for FDA review as a Pre-EUA. One hard copy of the signed EUA Cover Letter and one electronic copy are enclosed. Also, these documents have been sent to you via email.

In case you should have any questions regarding the information provided and/or need additional information/data from us please contact me immediately either via email [_____] or phone [_____].

Sincerely,

[***Name***]

[***Signature block***]

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# EMERGENCY USE AUTHORIZATION (EUA)

## EUA INTERACTIVE REVIEW TEMPLATE FOR MOLECULAR-BASED SINGLE TARGET TESTS FOR 2019 NOVEL CORONAVIRUS (2019-nCoV)

## GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow ***[Text]*** should be completed by the IVD developer (sponsor) as applicable to their specific test. Text in **bold** outlines the Food and Drug Administration (FDA) suggestions and clarifications for the sponsors' consideration when completing the required information in a specific section.

- This is a EUA interactive review template for Pre-EUA/EUA submissions concerning molecular-based single target tests for detection of 2019 Novel Coronavirus (2019-nCoV), Wuhan, China. If you are developing a multiplex molecular-based assay for the detection and differentiation of nucleic acids from a panel of microorganisms, please review Appendix A for FDA recommendations.

- This is a EUA interactive review template for Pre-EUA/EUA submissions and not a guidance document. The template is subject to change as we learn more about the 2019-nCoV disease and its risk-benefit profile. Recipients will receive notice and updated templates as they become available.

- This EUA interactive review template is an FDA internal document and any proprietary information provided within the template and during the interactive review process will remain confidential as it does in a regular FDA premarket submission.

- Feedback provided by FDA during the interactive review of your pre-EUA/EUA is subject to change as we learn more about the 2019-nCoV disease and the risk-benefit profile evolves to address unmet public health needs.

- Prior to a potential authorization FDA will require developers of molecular-based tests to assess traceability of their test to an FDA-recommended reference material panel if available at the time. Specific details about the traceability study and the FDA-recommended reference material panel will be provided by the Lead Reviewer assigned to the Pre-EUA submission once the analytical and clinical evaluation data has been reviewed and found to be acceptable.

- Please be reminded that tests for the detection of 2019-nCoV or 2019-nCoV infection must not be distributed and/or used for clinical diagnoses without premarket clearance, approval, or EUA by the FDA. Clinical samples for 2019-nCoV testing should be sent to the appropriate public health laboratories until the IVD device subject of this Pre-EUA submission has received authorization from the FDA.

- Clinical specimens may be required to support the EUA request. Furthermore, please note that applicable regulations for human subject protection do apply under the

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EUA. Please refer to the Clinical Evaluation section of this document for more details.

- If authorized, the EUA means that this 2019-nCoV IVD is temporarily authorized for use until the public health emergency is terminated or the EUA is revoked by the FDA.

    - FDA recommends that you consider registration and listing your EUA product once you have been issued an EUA. If this is problematic, please notify the Agency during your Pre-EUA.
    - The EUA is not a pathway to permanent marketing of your device. Therefore, we strongly recommend that you consider, in addition to an EUA, a traditional premarket submission for your IVD so that your device can still be legally marketed after termination of the emergency declaration. We recommend that you identify as soon as possible in the Pre-EUA review process any consideration of moving your product forward towards De Novo/510(k) clearance. If so some of our feedback to you may take such a long-term goal into consideration in order to prevent additional testing where it may not be needed. Therefore, please consider submitting a Pre-Submission to inquire what studies would be required for a premarket approval/ clearance of your 2019-nCoV IVD. Details on how to submit a Pre-Submission to the Agency are outlined in the FDA guidance document: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.* [ HYPERLINK "https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program" ]

## A. EXECUTIVE SUMMARY (as of X/XX/20XX)

## B. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the ***[test name]*** to ***[indicate labs, if applicable]*** for the *in vitro* qualitative detection of RNA from the 2019-nCoV in ***[add all claimed specimen types, e.g., nasopharyngeal/oropharyngeal swabs, sputa, BAL, stool, and serum, etc.]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated with 2019-nCoV infection) and CDC novel coronavirus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated) to aid in the diagnosis of 2019-nCoV infection.

## C. MEASURAND

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Specific nucleic acid sequences from the genome of the 2019-nCoV **[*please specify the targeted gene(s) of the pathogen*]**.

## D. APPLICANT

***[Official name, address and contact information of applicant]***

## E. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name - ***[test name]***
Established Name - ***[test name]***

## F. REGULATORY INFORMATION

***Approval/Clearance Status:***
The ***[test name]*** test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

***Product Code:***
[XXX – FDA will complete]

## G. PROPOSED INTENDED USE

***1) Intended Use:***
**The proposed IU will be finalized based on the data and recommendations from Public Health authorities at the time of authorization – example text is provided below for a qualitative molecular test that detects organism RNA but may be adapted according to the specific emergency situation addressed by the device.**

[***Test name***] is a [***specify test technology such as, real-time RT-PCR test***] intended for the qualitative detection of nucleic acid from the 2019-nCoV in [***describe all the specimen types***] from individuals meeting CDC 2019-nCoV clinical criteria (e.g., clinical signs and symptoms associated with 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated). Testing is limited to [***laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories***].

Results are for the identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in **[*name specimen type*]** during the acute phase of infection. Positive results

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are indicative of active infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The ***[test name]*** is intended for use by **[*include intended user, e.g., trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures*]**. The ***[test name]*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

***2) Special Conditions for Use Statements:***

For prescription use only
For in vitro diagnostic use only

***3) Special Instrument Requirements:***

The ***[test name]*** test is to be used with the [***list all RT-PCR Instruments, software requirements, automated extraction instruments***].

## H. DEVICE DESCRIPTION AND TEST PRINCIPLE

**Example text has been added under each of the sub-headings below for a fluorescence based rRT-PCR test for detection of organism RNA. If a different test principle is used by the test for the detection of a specific analyte please modify the description accordingly to capture the salient points in each of the sub-headings below. Please note that for new investigative technologies FDA may request additional detailed information so we can adequately assess the risks and benefits associated with the device.**

***1) Product Overview/Test Principle:***

**Describe the technology of the test and how this technology works to identify the measurand, the instruments employed/required to perform the test from sample collection to result (include all claimed extraction and PCR detection instruments), and the specimen types for which you claim to have specific performance characteristics as described below. If applicable, list all primer and probe sets and briefly describe what they detect. Please include the nucleic acid sequences for all primers and probes used in the test. Please indicate if the test uses biotin-Streptavidin/avidin chemistry in any of the steps for coupling reagents. Please note that an alignment with available reference genomes for different strains of the target pathogen is requested as part of the inclusivity evaluation (Section N).**

The ***[test name]*** is a real-time reverse transcription polymerase chain reaction (rRT - PCR) test. The 2019-nCoV primer and probe set(s) is designed to detect RNA from

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the 2019-nCoV in ***[list all the specimens]*** from patients who meet CDC 2019-nCoV clinical criteria (e.g., signs and symptoms associated 2019-nCoV infection) in conjunction with CDC 2019-nCoV epidemiological criteria (e.g., history of residence in or travel to a geographic region with active 2019-nCoV transmission at the time of travel, or other epidemiologic criteria for which 2019-nCoV testing may be indicated).

2) ***Description of Test Steps:***

**List and describe in detail all the steps of the test sequentially from specimen collection to detection.**

Nucleic acids are isolated and purified from ***[specimens]*** using ***[please describe the method(s) of extraction (please specify the specimen input volume for extraction and/or test, the nucleic acid elution volume and whether isolation/purification is manual and/or automated)].*** The purified nucleic acid is reverse transcribed using ***[enzyme mix/kits – please specify the input volume of purified nucleic acid added to the rRT-PCR reaction mix]*** into cDNA which is then subsequently amplified in ***[please describe the instrument(s) and enzyme mix]***. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by ***[please describe the detection instrument(s)]***.

3) ***Control Material(s) to be Used with [test name]:***

**List all control materials (provided with the test kit and/or required but not provided with the test kit and describe what they are, how they are expected to work, where in the testing process they are used, and the frequency of use. If a control is commercially available, provide supplier's name and catalog number or other identifier; if your device relies on external controls that are manufactured by a third party please note that these controls should also be validated within your analytical and clinical studies described below in Section (N).**

Controls that will be provided with the test kit include:

a) A "no template" (negative) control is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***

b) A positive template control is needed to ***[describe need]*** and is used ***[describe use – please specify the concentration of the positive control relative to the LoD of your test (note that ideally the positive control concentration should be such that it is close to the LoD of your test) and also specify frequency of use]***

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c) An extraction control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use].*** **Please note that if the no template control and positive control, are taken through the entire sample processing procedure, including the extraction, then a separate extraction control is not required**.

d) An internal control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use]***.

Controls that are required but not provided with the test kit include ***[describe control – provide recommended sources of the control materials – either a separate control kit for purchase that you the applicant develops or a control material that can be purchased from a third party].*** This/these control(s) is/are needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***.

**Please note that any control recommended to be used with your device (provided with the kit or not) needs to be validated in the context of your analytical and clinical study (i.e., you will need to run these controls as part of your studies). In instances where control material is not readily available through 3rd party vendors (which is often the case at the beginning of an outbreak) FDA may request that you include suitable control material with your device. Please note that external control materials are considered particularly important in the context of EUA devices because often GMP requirements for the manufacture of the EUA device are waived in emergency situations and reagent stability studies are limited. Hence the external controls offer some assurance of EUA test performance in the hands of the end user.**

## I. INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. **Please describe if a Ct cutoff is used as part of your testing algorithm and/or if the end user is required to review fluorescent curves for weakly positive samples before final interpretation. Although not typical for molecular-based tests, if the test result involves the use of an algorithm/calculation, for example a ratio value, when determining the final patient test result, please include a detailed description and any additional calibration materials that may be required.**

1) ***[Test name] Controls – Positive, Negative and Internal***

**Describe in detail the expected results generated, including acceptance criteria, for all the controls described in detail in Section H above. Describe the measured values (if applicable) for valid and invalid controls and outline the recommended actions the laboratory should take in the event of an invalid control result.**

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2) ***Examination and Interpretation of Patient Specimen Results:***

**Describe when clinical specimen test results should be assessed and outline the criteria for test validity**. **Example text**: Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

**Clearly indicate how to interpret numeric test values (if applicable) as positive or negative for presence of the 2019-nCoV. Indicate if the end user is required to review fluorescent curves for weakly positive samples before final interpretation and how to identify indeterminate/inconclusive results (if they exist) results and how the user should resolve them, e.g. if repeat testing may be required.**

**When applicable, provide a table clearly describing the possible combinations of test result values for each primer/probe set, and how they should be combined into a final interpretation of the result for your test. If the test produces result that will be used as part of a CDC recommended testing algorithm, please indicate what follow-up testing/process should be conducted, if applicable.**

## J. PRODUCT MANUFACTURING

**Please note that if you are developing a test for use at a single site (i.e., a laboratory developed test LDT), some of the information requested in this section may not be applicable. Please contact FDA for additional guidance for an emergency use LDT.**

The ***[test name]*** has been validated using only the components referenced in this submission and shall not be changed without prior concurrence from the FDA.

*1)* ***Overview of Manufacturing and Distribution:***

The product will be manufactured at [***manufacturer's name and FDA registration number (if applicable) or laboratory name if an LDT***] by [***manufacturer name, or laboratory name if an LDT***] personnel consistent with practices for the production of **[*types of devices*]** based on [***type of quality system****]. Material manufactured by [***manufacturer's name, or laboratory name if an LDT***] may be bottled and kitted by [***packager name***] manufacturing facility.

***Under the Emergency Use Authorization (EUA) most of the 21 CFR 820 Quality System Regulation (QSR) requirements can be waived for the duration of the EUA. FDA expects that developers follow comparable practices as much as possible and may consider previous compliance history when determining whether or not to waive certain QSR requirements for a specific product. Please note adverse events, as per 21 CFR Part 803, have to be reported for authorized devices (see Section R).**

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The current manufacturing capabilities include the ability to manufacture approximately **[*please insert the approximate number of units/products that can currently be manufactured per week at the manufacturing facility*]** products per week, however in the event of a surge in demand this could be increased to **[*please insert the approximate maximum number of units/products that could potentially be manufactured per week at the manufacturing facility if there was a surge in demand*]** product per week within a **[*please specify in weeks/months the expected timeframe required to increase product production if required*]** timeframe.

The product will be distributed by **[*please describe the distribution plan for the product and list all current distributors*]**.

2) ***Components Included with the Test***

Components manufactured by [***manufacturer's name and FDA registration number (if applicable)***] and supplied with the test include:

**List all components and reagents provided for your test, including a description of the primers and probes, volumes, concentrations, quantities, buffer components, etc.**

3) ***Components Required But Not Included with the Test***

Components required but not included with the test:

**List all components and reagents not included with the test that must be supplied by the user to perform the test, with specific supplier names and catalog numbers or other identifiers for obtaining these components and reagents. Please include here all specific consumables that were validated for use with your device, that are not interchangeable with other products and that are needed to guarantee device performance as established in the EUA validation studies listed in Section N below.**

4) ***Testing Capabilities***

**Briefly describe current sample throughput capacity, total time required to perform the test (from clinical specimen collection, specimen transport to result), and number of tests that can be performed per instrument run and per day.**

5) ***Reagent Stability:***

**Briefly describe stability test plan for *[test name]* reagents and include any accelerated stability information if available. Please note that reagent stability studies do not need to be completed at the time of EUA issuance, however the study design should be agreed upon during interactive review and the stability studies started immediately following authorization, if not before. When designing your stability study, we have some general recommendations that are outlined in Appendix B, for your consideration.**

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## K. PERFORMANCE EVALUATION

**If you plan to claim multiple target analytes to aid in differential diagnosis or you plan to claim multiple RT-PCR instruments and/or extraction methods, please refer to Appendix A and C, respectively, more information. Please note that any omission of a requested study in this document should be documented and justified.**

### *1) Analytical Sensitivity:*

a) *Limit of Detection (LoD):* **You should determine the LoD of the device utilizing the entire test system from sample preparation to detection for each clinical matrix claimed. Please note that claims for additional anticoagulants, for blood specimens, can be supported by a matrix equivalency study as outlined in Section N, subsection 3 below. The LoD is determined using dilutions of live propagated and titered 2019-nCoV stocks (CFU/mL or PFU/mL) spiked into a relevant clinical matrix. If wild-type virus is not available at the time of your validation studies, please contact FDA to discuss a potential alternative. Please note that if available please also provide Genomic Equivalent Copies (GEC)/mL units for the stock solutions used and include an explanation on how they were determined. Please note that LoD studies should be performed with live organisms, as described above. If you plan to use inactivated organism in your LoD determination you should describe how the material was inactivated and perform a study to determine whether the inactivation process impacted the LoD of the device.**

**First a tentative LoD must be established through limiting dilutions of the prepared material with 3-5 replicate measurements. Please note for all the analytical studies described in Section N that require replicate testing, one replicate equates to one independent extraction and PCR detection. Once a tentative LoD is established, the LoD should be confirmed by preparing at least 20 additional replicates at the LoD concentration and demonstrating that the organism was detected with a minimum 95% positivity (19/20). If this confirmatory study achieves a positivity of 100%, then a lower concentration needs to be tested (with 20 replicates) until <100% positivity is obtained.**

**Please use the following format when submitting LoD information and data:**

LoD studies determine the lowest detectable concentration of 2019-nCoV at which approximately 95% of all (true positive) replicates test positive. The LoD was determined by limiting dilution studies using characterized samples.

**List/describe the following in this section:**

- **Titers and strains of the 2019-nCoV stocks used for the LoD study and describe how the organism stocks were prepared and how the titers were determined.**

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- **The dilution factor and number of serial dilutions of the characterized 2019-nCoV that were tested to determine the LoD for each primer and probe set.**
- **The nucleic acid extraction/purification method.**
- **The real time PCR instrument.**

Serial dilutions of the characterized 2019-nCoV were then tested in **[*number of replicates (i.e., recommend that sample is extracted independently three-five times and each extraction tested once)*]** replicates. The lowest concentration at which all [***number of replicates***] replicates were positive was treated as the tentative LoD for each test. The LoD of each test was then confirmed by testing [***number of replicates (at least 20 recommended)***] with concentrations at the tentative limit of detection. The final LoD of each test was determined to be the lowest concentration resulting in positive detection of [***number of positive replicates (at least 19 out of 20 replicates)***]. [***Include analysis of LoD results, indicating the final LoD for each test***]

**Tentative LoD: [*Please provide a summary of the data for each strain tested]* example table 2019-nCoV stocks is provided below:**

| 2019-nCoV Strain Tested | Stock 2019-nCoV Titer | Serial 10-Fold Dilution Factor | Concentration in Dilution Tested [Include Units] | Replicate 1 $C_t$ | Replicate 2 $C_t$ | Replicate 3 $C_t$ | Replicate 4 $C_t$ | Replicate 5 $C_t$ | Call Rate | Lowest Concentration with Uniform Positivity per Analyte | Limit of Detection (LoD) per Virus Strain |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Example:*** *[analyte]* | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

b) FDA Sensitivity Evaluation: The analytical sensitivity of the test has to be further assessed by evaluating an FDA-recommended reference material using an FDA developed protocol if applicable and/or when available. Details will be provided during the Pre-EUA interactive review.

c) *Reactivity/Inclusivity:* Reactivity of the ***[test name]*** was evaluated for additional isolates of 2019-nCoV.

**Reactivity: *[test name]* example table below**

| 2019-nCoV Strain/Isolate | Source/Sample Type* | Concentration | Ct** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

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| | | | |
|---|---|---|---|
| | | | |

***Please list source of material used for wet testing and sample type tested (i.e., organism – live or inactivated, purified nucleic acid – whole genome etc.).**
**** If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**At a minimum, the strain used in your LoD evaluation should be listed here (multiple isolates of the same 2019-nCoV strain that was used for the LoD studies can also be included if available). If additional isolates are not available at the time of your validation studies, please discuss with FDA. Each isolate should be tested at or near the LoD (no more than 3x LOD) of the test, spiked into clinical matrix utilizing the entire test system, including extraction. If you plan to claim more than one type of clinical matrix, we recommend that you perform this study in the most challenging clinical matrix, testing a minimum of 3 replicates. In addition, the wet testing should be accompanied by extensive inclusivity *in silico* analysis of the test primer and probes with all known strains/isolates (past/present) of 2019-nCoV (including the strain/isolate used for wet testing).**

## 2) *Analytical Specificity:*

a) *Cross-Reactivity:* Cross-reactivity of the ***[test name]*** was evaluated using both *in silico* analysis and by testing whole organisms **[*pathogen*]** (concentration) or purified nucleic acid from other ***[describe organisms]*** (concentration/reaction).

**Cross-Reactivity: *[test name]* example table for wet tested organisms below**

| Virus/Bacteria/Parasite | Strain | Source/ Sample type | Concentration | Ct Values* |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

***If your technology does not produce Ct values, please include instead the signal output for your specific device technology.**

**Cross-reactivity studies are preformed to demonstrate that the test does not react with related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen. The FDA Tables 1 and 2, below are intended to recommend simulate testing of patients having infections with organisms which cause similar symptoms to those observed at the onset of 2019-nCoV infection. The FDA Tables also include other organisms and strains which have significant genetic similarity and therefore a higher likelihood of cross-reacting with 2019-nCoV specific reagents. Also included in the FDA Tables are recommended unclaimed organisms/strains which are likely to be endemic to the currently affected area should be included in cross-reactivity testing since these organisms/strains will be an important aspect of the differential diagnosis of 2019-nCoV infection.**

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**FDA Table 1 Cross-Reactivity: List of Organisms to be wet-tested and analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens**

| Other high priority pathogens from the same genetic family | High priority organisms likely in the circulating area |
|---|---|
| Human coronavirus 229E | Adenovirus (e.g. C1 Ad. 71) |
| Human coronavirus OC43 | Human Metapneumovirus (hMPV) |
| Human coronavirus HKU1 | Parainfluenza virus 1-4 |
| Human coronavirus NL63 | Influenza A |
| SARS-coronavirus | Influenza B |
| MERS-coronavirus | Enterovirus (e.g. EV68) |
| | Respiratory syncytial virus |
| | Rhinovirus |
| | *Chlamydia pneumonia* |
| | *Haemophilus influenzae* |
| | *Legionella pneumophila* |
| | *Mycobacterium tuberculosis* |
| | *Streptococus pneumonia* |
| | *Streptococcus pyogenes* |
| | *Bordetella pertussis* |
| | *Mycoplasma pneumoniae* |
| | *Pneumocystis jirovecii* (PJP) |
| | Pooled human nasal wash - *to represent diverse microbial flora in the human respiratory tract* |
| | |

**FDA Table 2 Cross-Reactivity: List of Organisms to be analyzed *in silico* (for tests detecting 2019-nCoV) in respiratory material or blood specimens:**

| Other high priority pathogens from the same genetic family | High priority organisms, including organisms commonly found in the clinical matrix |
|---|---|
| | Influenza C |
| | Parechovirus |
| | *Candida albicans* |
| | *Corynebacterium diphtheriae* |
| | *Legionella non-pneumophila* |
| | *Bacillus anthracis* (Anthrax) |
| | *Moraxella catarrhalis* |
| | *Neisseria elongate and meningitidis* |
| | *Pseudomonas aeruginosa* |
| | *Staphylococcus epidermis* |
| | *Staphylococcus salivarius* |
| | *Leptospirosis* |

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| | |
|---|---|
| | *Chlamydia psittaci* |
| | *Coxiella burnetii (Q-Fever)* |
| | *Streptococcus aureus* |
| | |

***In silico*** **analysis should be performed on all potentially cross-reactive organisms outlined in the FDA Tables 1 and 2 above. You should provide the result summary of the *in silico* blast analysis (tabular format) evaluating whether there is any significant amplification of non-target sequences that could either result is cross-reactivity or potentially interfere with the detectability of the actual target analyte. As such we are asking that you provide individual blast results (non-truncated alignments) for each of the primers and probes used in your device with potential cross-reacting organisms. Please provide for our review the percent sequence homology for each organism relative to the target analyte primers/probes in your test. Please use the example table below when presenting the results of *in silico* analysis in your submission:**

**Results of *In Silico* Analysis**

| Pathogen | Strain | GenBank Acc# | % Homology Test FP (i.e. 0-100%) | % Homology Test RP | % Homology Test Probe |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**The analysis should include multiple representative strains from GenBank for each organism. If *in silico* analysis reveals other potential cross-reactants (i.e., ≥80% homology between one of your primers or the probe to any of the sequences of listed potential cross reactants), you should carefully review the alignments and determine based on the positions of the homologous stretches and mismatches if additional cross-reactivity and/or interference (please refer to item b below – microbial interference studies) wet testing will be required to rule out cross-reactivity or interference of that organism that may affect the performance of your device. In these circumstances if wet-testing is omitted you should include an explanation as to why *in silico* generated data is not clinically relevant (irrelevant isolate, location/extent of match within primer/probe, etc.), or why the performance of your test would not be impacted.**

**Organisms in FDA Table 1 should be wet tested in addition to the *in silico* analysis. Omissions from wet-testing should be discussed with FDA and supported by a well-documented justification that includes a due diligence attempt to obtain the live or inactivated organisms (and/or purified nucleic acid – which is acceptable for cross reactivity evaluation for an EUA).**

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**The wet testing evaluation should reflect test specimens prepared at the highest clinically relevant level of organism (i.e., a minimum of $10^6$ CFU/ml or higher for bacteria and $10^5$ $TCID_{50}$/mL or PFU/ml or higher for viruses) and should be tested with a minimum of three replicates per organism test specimen. Test specimens can be prepared by spiking cultured isolates/inactivated organisms/ purified nucleic acids (whole genome) into negative clinical matrix and determining cross reactivity based on triplicate replicates. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix.**

**If you plan to claim non-blood or non-respiratory clinical specimen types for diagnostic use with your device, e.g., stool specimens, etc., please consult FDA for more information on additional organisms that may be recommended for cross-reactivity testing, common examples are provided below for stool specimens (FDA Table 3):**

**FDA Table 3: Organisms to be analyzed for non-blood clinical specimens:**

| **Stool** |
|---|
| *Escherichia coli* |
| *Lactobacillus* |
| *Bacillus* spp. |
| *Clostridium* Spp. |
| *Enterobacter* |
| *Enterococcus* |
| Fusobacterium |
| Bacteroidetes |
| Bifidobacterium |
| Ruminococcus |
| |

b) *Microbial Interference Studies:* **If *in silico* analysis reveals ≥ 80% homology between the cross-reactivity microorganisms and your test primers/ probe(s), we recommend that you either perform (1) a microbial interference study with 2019-nCoV and the microorganisms that your test primers/ probe(s) have homology to, (2) as an alternative to the microbial interference study, you may provide justification as to why (e.g., amount of primer(s)/ probe(s) included in your master mix) the performance of your test would not be impacted by the presence of a causative agent of a clinically significant co-infection, or (3) explain why the *in silico* results are clinically irrelevant. In the case of the microbial interference study, interference should be evaluated using samples spiked at a low 2019-nCoV concentration, at 3x LoD, and a high interferent level (either microorganisms or nucleic acids purified from them), to represent the worst-case scenario, with a minimum of 3 replicates. If you plan to claim more than**

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**one type of blood clinical matrix, please note that if significant differences in LoD are observed for the different clinical matrices this may warrant this study being performed in more than one clinical matrix. If the LoDs are similar in the blood clinical matrices the study should be performed in the most challenging matrix, i.e., whole blood. In addition, if you are claiming blood and non-blood clinical specimens you may be required to perform this study in more than one clinical matrix. If interference is observed at the level tested, an additional titration study should be performed to determine the highest microorganism interferent level the 2019-nCoV test can tolerate.**

**c)** *Endogenous Interference Substances Studies*: **The extent of testing for endogenous interference substances depends on the matrix that is claimed for the device as well as on the technology of the device, e.g., if a nucleic extraction procedure is performed prior to testing or not. For EUA we do not typically ask for interference studies for tests that use conventional PCR and/or well-established extraction methods prior to testing (e.g., Boom method and column-based extraction methods).**

**For extraction procedures that are new or for nucleic acid-based technologies that are different from conventional PCR (e.g., various isothermal methods), we expect testing of potential interferents. The impact of interfering substances should be evaluated over the expected clinical range of the potentially interfering substance. Potential sources of endogenous interference include, but are not limited to, the ones listed in the tables below. It is important to note that the evaluation of interference and the generation of false negative results should be done using samples containing the analyte at or near the LoD and should not exceed 3x LoD. You should test a minimum of 3 replicates per substance. If you plan to claim more than one type of clinical matrix, please note that if significant differences in LoD are observed between the different clinical matrices this may warrant this study being performed in more than one clinical matrix. Biotin interference poses a risk to laboratory tests that incorporate the free biotin-streptavidin capture method. Therefore, please review this safety communication [ HYPERLINK "https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication" ] and the following [ HYPERLINK "onenote:http://sharepoint.fda.gov/orgs/CDRH-IVD/Orgs/DMD/DMD%20OneNotes/Language/Analytical%20Studies/Interference.one" \l "DRAFT%20guidance%20-%20Testing%20for%20Biotin%20Interference%20in%20In%20Vitro%20Diagnostic%20Devices&section-id={39D67316-5AE2-4791-958F-9387D384D6FA}&page-id={9298F00C-7C39-43CB-9EBA-29E5BC08BB6E}&end" ] ([ HYPERLINK "http://sharepoint.fda.gov/orgs/CDRH-IVD/Orgs/DMD/_layouts/OneNote.aspx?id=%2Forgs%2FCDRH-IVD%2FOrgs%2FDMD%2FDMD%20OneNotes%2FLanguage&wd=target%28Analytical%20Studies%2FInterference.one%7C39D67316-5AE2-4791-958F-**

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**9387D384D6FA%2FDRAFT%20guidance%20-%20Testing%20for%20Biotin%20Interference%20in%20In%20Vitro%7C9298F00C-7C39-43CB-9EBA-29E5BC08BB6E%2F%29" ]) to determine if biotin interference testing may be warranted for your device. We also recommend you consult with FDA prior to initiating biotin interference testing, if applicable.**

**The tables below indicate the potentially interfering substances that may be found in blood and respiratory specimens. For other non-blood specimen types, such as stool, the list of substances could be expanded – please consult with FDA.**

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *positive* results:**

| Potential Interfering Substance | Concentration | Results (Detected X/3) |
|---|---|---|
| **Respiratory Specimens** | | |
| Mucin: bovine submaxillary gland, type I-S | | |
| Blood (human) | | |
| Nasal sprays or drops | | |
| Nasal corticosteroids | | |
| Nasal gel | | |
| FluMist | | |
| Homeopathic allergy relief medicine | | |
| Throat lozenges, oral anesthetic and analgesic | | |
| Anti-viral drugs | | |
| Antibiotic, nasal ointment | | |
| Antibacterial, systemic | | |
| **Blood Specimens** | | |
| Hemoglobin | 10 mg/mL* | |
| Bilirubin Conjugated | 0.4 mg/mL* | |
| Bilirubin Unconjugated | 0.4 mg/mL* | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | |
| Triglycerides | 15 mg/mL* | |
| Cholesterol | 4 mg/mL* | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | |
| Rheumatoid Factor | 2000 IU/mL* | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

**Interfering Substances: *[test name]* Example table below for evaluation of interfering substances for the ability to generate false *negative* results:**

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| Potential Interfering Substance | Concentration* | Viral Strain Level (In multiples of LoD) | Results (Detected X/3) |
|---|---|---|---|
| **Respiratory Specimens** | | | |
| Mucin: bovine submaxillary gland, type I-S | | | |
| Blood (human) | | | |
| Nasal sprays or drops | | | |
| Nasal corticosteroids | | | |
| Nasal gel | | | |
| FluMist | | | |
| Homeopathic allergy relief medicine | | | |
| Throat lozenges, oral anesthetic and analgesic | | | |
| Anti-viral drugs | | | |
| Antibiotic, nasal ointment | | | |
| Antibacterial, systemic | | | |
| **Blood Specimens** | | | |
| Hemoglobin | 10 mg/mL* | | |
| Bilirubin Conjugated | 0.4 mg/mL* | | |
| Bilirubin Unconjugated | 0.4 mg/mL* | | |
| Serum proteins (e.g., Human Serum Albumin) | 60 mg/mL* | | |
| Triglycerides | 15 mg/mL* | | |
| Cholesterol | 4 mg/mL* | | |
| Human Anti-mouse Antibody (HAMA) | 800 ng/mL* | | |
| Rheumatoid Factor | 2000 IU/mL* | | |

*Taken from the recently-updated 3rd edition of CLSI guideline EP07, Interference Testing in Clinical Chemistry (Section 3.4.2) which now defers to CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry for the recommended concentrations for testing common endogenous substances (Table 2) and have subsequently updated a number of the recommended testing concentrations.

### 3) *Matrix Equivalency (if applicable):*

**A matrix equivalency study may be used to support certain specimen type claims that were not evaluated during the clinical study (e.g., serum versus plasma, use of different anticoagulants, use of difference swab types or viral transport media, etc.). Please note that LoD and clinical specificity studies are required for all claimed matrices. The matrix in which the clinical studies are conducted is the comparator. All other matrices are to be shown to be equivalent to the comparator matrix. We request a minimum of 40 paired samples each obtained from individual persons; negative (10 samples), low positive (1.5-2xLoD, 20 samples), and moderate positive (5-10xLoD, 10 samples) samples should be tested. Positive samples are prepared by spiking paired negative clinical matrix with the same amount of target analyte. Please note that individual (and not pooled) samples should be used in this study.**

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*4) Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method:*

**A comparative LoD study may be required to support use of a comparator method in your clinical evaluation that has not been validated with a specific specimen type. The comparative LoD study should be conducted testing the same dilution series using both, your test and the comparator you chose in parallel (to dilution endpoints for both tests), 3-5 replicates per dilution level are sufficient for this study.**

*5) Specimen Stability and Fresh-frozen Testing:*

**A specimen stability study may be required to support specimen stability claims in the instructions for use outside of those typically outlined in CSLI standards. A fresh/frozen and/or freeze/thaw study may be required to support the use of frozen specimens if they are used as part of the clinical evaluation. Please consult with FDA concerning an appropriate study design prior to initiating any studies.**

*6) Clinical Evaluation:*

**This section should describe the clinical study used to evaluate the performance of your test. Please note that the exact requirements for the clinical evaluation will be very dependent on, access to 2019-nCoV disease clinical specimens at the time of the studies and the nature of the emergency. Our general clinical study evaluation recommendations for respiratory and serum clinical specimens are outlined below. If you are interested in claiming additional specimen types, for example, stool, please contact FDA for current recommendations. Please note these clinical study recommendations may be subject to change as we continue to learn about the 2019-nCoV disease or as the risk benefit analysis changes.**

**The clinical performance in general should be evaluated for each unique claimed clinical specimen type - with the exception of claims that can be supported by a matrix equivalency study (outlined in Section 3 above). The performance characteristics should ideally be established using a clinical study with a limited number of prospective samples. If a prospective study is not feasible, an acceptable alternative would be to test retrospectively collected 2019-nCoV nucleic acid negative and positive specimens from patients, accompanied by some basic information such as, the specimen collection date, date of onset of symptoms (if present/known), tests used to identify 2019-nCoV nucleic acid positive specimens, etc. Depending on the nature of the disease, if no prospective or retrospective specimens are**

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**available at the time of your pre-EUA submission for the 2019-nCoV disease we may accept a fully contrived clinical evaluation. The clinical evaluation should be comprised of a minimum of 100 negative individually collected specimens and 50 individual positive specimens (prospective, retrospective and/or contrived). Use of pooled specimens are not acceptable for the clinical evaluation of your test. Please see FDA Table 5 for more details. Please note that if a fully contrived clinical study is used to support your Pre-EUA submission, additional clinical testing of a limited number of natural clinical positive specimens and potentially negative specimens from the endemic region, if available, may be required at the time when this Pre-EUA transitions to an EUA as a result of an Emergency declaration for 2019-nCoV disease.**

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## FDA Table 5: Clinical study Recommendations:

| Details | Study Including Prospective/ Retrospective Specimens | Fully Contrived Sample Study |
|---|---|---|
| Minimum Number of Positive Specimens | 50<br><br>The number of natural (prospective/retrospective) positive clinical specimens should be at least 25 (collected from symptomatic patients in the 2019-nCoV disease endemic region(s)) and, if necessary, may be supplemented with contrived samples to generate the total of 50 positive specimens. Contrived samples should be prepared as described in the fully contrived sample study column. | 50<br><br>The contrived positive samples should be made in individual negative clinical matrix collected from subjects from a non-endemic population (pooled matrix is not acceptable for the clinical evaluation). Please note that the negative clinical matrix used for spiking should be confirmed negative by your test device prior to spiking. Half of the contrived positive samples can be prepared by spiking the 2019-nCoV at LoD and the remaining contrived positive samples should cover the range of the test up to and not higher than 5 x LoD.<br><br>Negative respiratory specimens: Can be archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection.<br><br>Negative blood specimens: Can be collected from healthy subjects from non-endemic areas. |
| Minimum Number of Negative Specimens | 100<br><br>Note: In general, for EUA the 100 individual negative samples can be collected from; (1) archived/retrospective samples collected from US patients with signs and symptoms of respiratory infection for respiratory specimens, and (2) healthy subjects from non-endemic areas for blood specimens, that are "expected 2019-nCoV disease negative". Note these negative specimens can be used to also prepare any contrived positive specimens used in support of the clinical evaluation of the test.<br><br>Please note this recommendation is dependent on the current outbreak situation and is subject to change as we learn more about the 2019-nCoV disease/outbreak. If the outbreak situation for 2019-nCoV disease is primarily outside of the continental U.S. (OUS) it may be beneficial to consider collecting negative specimens that represent 50% endemic and 50% non-endemic regions. If negative specimens are collected from the endemic region of the 2019-nCoV disease these should be tested with the same comparator chosen for the positive specimens (more details provided below). For non-endemic collected specimens you can compare to the expected "negative" result. | |
| Recommended Comparator Method | Positive: Positive percent agreement should be calculated in comparison to a EUA PCR test (please see the following website for the most recent list of FDA authorized 2019-nCoV | Positive: Compare to expected result.<br><br>Negative: See Minimum Number of Negative Specimens row |

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| | | |
|---|---|---|
| for percent agreement performance calculations | tests: [ HYPERLINK "https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm" ]. If no EUA test available at the time of your EUA submission, please consult with FDA about your choice of comparator method – which ideally should be a well validated PCR test with comparable sensitivity to your subject device. Please note that a well validated PCR test should include evaluation of the tests LoD, inclusivity, exclusivity, interference and any clinical testing.<br><br>Negative: See Minimum Number of Negative Specimens row | |
| Comparator Method Note 1 | Please note when using natural clinical specimens, the comparator method must be validated for the specimen type claimed – if not you should perform a Comparative Limit of Detection (LoD) of the Test vs. the Comparator Method study, as explained above (Section 4), to support its use as a comparator method in your clinical study. | N/A |
| Comparator Method Note 2 | Any occurrences of false results should be investigated with an additional validated PCR test and/or targeted sequencing, and the results of the discordant analysis can be footnoted in your final performance table but cannot be used to change the final performance calculations. | |
| Natural Clinical Specimens IRB/Informed Consent Note | For clinical specimens collected to support the EUA request, please note that sample collection needs to adhere to all applicable rules of human subject protection; as such, sample collection needs IRB approval, which includes review of the informed consent forms. Samples need to be collected with informed consent. If leftover de-identified samples are used, FDA exercises enforcement discretion regarding the informed consent requirement if the specimen collection meets the criteria described in the FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable ([ HYPERLINK "http://www.fda.gov/cdrh/oivd/guidance/1588.pdf" ]).<br>**Note that IRB approval is still required even if leftover de-identified samples are used in your study.** | |
| Additional Studies Warning | N/A | If fully contrived samples were used in your Pre-EUA submission, additional testing of natural clinical specimens may be requested, if available, to support transition of the Pre-EUA to EUA as a result of an Emergency declaration. |
| Testing Approach Note 1 | Please note all clinical specimens (natural and contrived) should be evaluated in accordance with your proposed diagnostic algorithm, including retesting when appropriate. We understand the limited nature of natural specimens may preclude retesting. In instances were retesting is indicated but not performed, for the purposed of performance evaluation, initial results will be analyzed for performance and equivocal/indeterminate results count against your final performance. | |
| Testing Approach Note 2 | Specimens should be tested in a blinded fashion, e.g., positive and negative samples should be mixed and blinded to the end user, end user should also be blinded to the results of any comparator method testing. | |

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**When you describe your clinical study please indicate/include:**

- **How the specimens were generated/collect/sourced**
- **If the study was fully prospective, mix of prospective, retrospective and/or contrived or fully contrived**
- **The rationale for the concentrations/specimens selected (if using contrived or 3-party sourced specimens)**
- **The total number of specimens tested**
- **The specimen types (clinical matrix)**
- **A summary of the study results**

**In the case of real-time PCR tests, please provide the line data in an Excel file as part of the Pre-EUA submission for each specimen (please indicate for each specimen if it was prospective, retrospective or contrived and the clinical matrix it represents); the data should include the $C_T$ values (for the specimen and the controls) and call/result for your device and, in the case of the natural clinical specimens, the comparator method results should be included as well.**

## L. UNMET NEED ADDRESSED BY THE PRODUCT

**This section will be finalized by FDA based on the state of the emergency at the time of authorization and based on recommendations from Public Health authorities at that time. Example text is provided below but may be adapted according to the specific emergency situation that is addressed by the device and the need at the specific time of the outbreak.**

[Outline background of pathogen, disease and current outbreak]

[Outline details of the disease such as the following:

- likely sources of transmission
- likely symptoms – if any
- Prevalence of symptomatic disease (what fraction of infection results in symptomatic disease)]

Laboratories in the United States are in need of diagnostic tools for use in the 2019-nCoV emergency for rapid diagnosis of acute 2019-nCoV infection.

A public health emergency has been declared by the Secretary of Health and Human Services (HHS) on [Month Day, YEAR] justifying the authorization of emergency use of *in vitro* diagnostic tests for detection of 2019-nCoV and/or diagnosis of 2019-nCoV infection.

The ***[test name]*** can augment clinically important laboratory evidence for individuals with active infection. The 2019-nCoV nucleic acid is generally detectable in [name

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specimen type] during the acute phase of infection (approximately [7] days following onset of symptoms, if present) [and possibly for longer in other specimen types].

Under emergency use authorization (EUA), ***[applicant name]*** plans to distribute the test or accept sample for testing with the ***[test name]*** for the detection of nucleic acid from 2019-nCoV in clinical specimens collected from individuals meeting CDC's 2019-nCoV clinical and/or epidemiological criteria. This EUA request for the ***[test name]*** is intended to expand domestic readiness within the United States and its territories by expanding diagnostic testing capabilities for 2019-nCoV during public health emergency.

FDA consulted with subject matter experts within HHS on the public health needs for diagnostic devices to detect 2019-nCoV nucleic acid. It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for 2019-nCoV detection during the public health emergency.

## M. APPROVED/CLEARED ALTERNATIVE PRODUCTS

Currently no methods for the detection of the 2019-nCoV have been approved/ cleared by FDA.

## N. RISKS AND BENEFITS:

**The Risks and Benefits section should be updated according to your specific device, some example language is given below but should be tailored to the device and the disease.**

Risks

The ***[test name]*** has been designed to minimize the likelihood of false test results. However, should false results occur, they may present risks to patients:

- False positive result:
  - A false positive 2019-nCoV result could [***update based on the pathogen***].
  - A false positive result in the context of the current public health emergency could lead to misallocation of resources used for surveillance and prevention.
  - A false positive result could delay correct diagnosis and initiation of appropriate treatment for the actual cause of patient illness.
- False negative result:
  - Although a negative result does not rule out 2019-nCoV infection, a false negative has the potential to result in initiation of inappropriate treatment and a delay in correct diagnosis.
  - A false negative result can trigger a waste of health care resources, as additional evaluations are pursued in the effort to establish the true diagnosis.
  - A false negative results can contribute to further spread of the disease.

Benefits

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The primary benefit of distributing the ***[test name]*** for clinical use is that it provides a relatively fast diagnostic method for symptomatic patients, which enables faster intervention.

- True positive test results provide support for the diagnosis of a 2019-nCoV infection. The results can be used in conjunction with clinical and epidemiological information to guide patient management.
- Distribution of the factsheets can help healthcare professionals and the public learn more about 2019-nCoV disease and how to avoid acquiring it.

Risk Assessment

- Negative results may not preclude a 2019-nCoV infection. It is emphasized that the ***[test name]*** should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure must be considered pivotal to making patient management decisions. A negative test should not be interpreted as definitive, if other aspects of the patient's clinical presentation or recent epidemiologic exposures indicate such is likely, and diagnostic tests for other diseases are negative.
- False negative results due to failure of PCR are minimized by the presence of controls that monitor nucleic acid extraction and PCR efficiency.
- Risk of patient discomfort or harm during sample collection is minimal.

Risk-Benefit Assessment

The risks posed by use of the ***[test name]*** are mitigated by:

- Use of the ***[test name]*** in conjunction with other laboratory, epidemiological, and clinical evaluation tools
- Distribution of Healthcare Provider and Patient fact sheets.
- Post-market studies/reporting or conditions of Authorization.

Based on these factors, the potential benefits from the use of the ***[test name]*** are expected to outweigh the risks.

## O. FACT SHEET FOR HEALTHCARE PROVIDERS AND PATIENTS:

**Include proposed Fact Sheets for Patients and Healthcare Providers**

## P. INSTRUCTIONS FOR USE/ PROPOSED LABELING/PACKAGE INSERT:

**Include Instructions for Use, Box Labels, Vial Labels and any other proposed labeling.**

## Q. RECORD KEEPING AND REPORTING INFORMATION TO FDA:

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[***Manufacturer name***] will track adverse events and report to FDA under 21 CFR Part 803. A website is available to report on adverse events, and this website is referenced in the Fact Sheet for Health Care providers as well as through the [***Manufacturer name***] Product Support website: [***Include link to Website***]. Each report of an adverse event will be processed according to [***Manufacturer name]***'s Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the FDA as required. Through a process of inventory control, [***Manufacturer name]*** will also maintain records of device usage/purchase. [***Manufacturer name]*** will collect information on the performance of the test, and report to FDA any suspected occurrence of false positive or false negative results of which [***Manufacturer name]*** becomes aware. [***Manufacturer name]*** will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

## R. ADMINISTRATIVE INFORMATION:

**Interactive Review Log:** Please use the table below to document interactive review with FDA and include interactions initiated by either FDA or yourself

| **Date** | **Type of Interaction** (phone/ email/ formal submission-DCC) | **Brief Description** (e.g., questions asked/ feedback from FDA received / any word documents included) |
|---|---|---|
| [X] | [X] | [X] |
| | | |
| | | |

## S. FDA ADMINISTRATIVE INFORMATION:

**This section will be finalized by the FDA Lead Reviewer upon completion of the review process and documents the interactive review of this submission and any conclusions resulting from the interactive review.**

1) **Summary of Interactive Review – Lead Reviewer to use this section to highlight any major issues solved during interactive review.**
2) **Final Conclusions for Interactive Review -** It is FDA's conclusion that there currently exists a public health need for such devices, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[test name]*** for [pathogen] detection during the public health emergency. **Conclusion should include an outline the unique features of the device compared to currently issued EUA's under the declaration, if applicable.**
3) **Upon competition of this section the Lead Reviewer should also sign this document and save the file as the final Decision Memorandum.**

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## APPENDIX A – Multiplex Panels Under EUA:

An emergency declaration by the HHS Secretary is typically specific for a pathogen/disease (i.e., there is a publicly declared health emergency involving a particular etiologic agent). Therefore, the EUA pathway is only applicable for testing patients with signs/symptoms/risk of exposure for that single agent in a given emergency. FDA has occasionally allowed limited additional target pathogens to be claimed for EUA devices, but panel members must be relevant to the event/disease outbreak subject of the specific emergency declaration. When determining whether to issue an EUA for a multiplex panel FDA takes into consideration the utility of the test (multiplex pathogen detection as an aid in differential diagnosis), clearance/approval status of IVDs for the other panel members, whether the proposed Intended Use fits within the HHS emergency declaration and the how the multiplex panel would fit into current public health authority patient testing algorithm recommendations. We recommend you contact FDA for specific feedback if you plan to claim multiple target analytes as part of your EUA test. If it is determined that a multiplex test is beneficial to the emergency response, please note that analytical and clinical evaluations for each of the target analytes will be required.

## APPENDIX B – General Study Design Recommendations for Reagent Stability:

- For EUAs you may follow the current FDA recognized CLSI Standard EP25 – Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline when evaluating the suitability of stability study designs. If you are planning to pursue a De Novo/510(k) for your device we recommend discussing in more detail your stability design to facilitate potential use of the EUA data in your regular premarket submission.
- Please note that use of only the positive controls is not acceptable for reagent stability evaluation because controls are usually formulated at a moderate positive level. For all the stability evaluations in addition to your external positive and negative controls and the no-template control you should include for the EUA evaluation at least one sample, that should be prepared by spiking negative clinical matrix at an analyte concentration of 3-5xLoD.
- If you are claiming multiple blood clinical specimen types in which similar LoDs are determined, you should use the most challenging clinical matrix for this study.
- Please note we typically recommend your stability study design includes the evaluation of at least 5 replicates. You should also evaluate, if available, 3 different lots of reagents.
- You should design your study to provide data for a timeframe that is about 10% longer than the one to be claimed – for example; a claim of 18 months should be supported by stability data out to 20 months and a claim of 7 days should include stability data out to 8 days.
- FDA considers 15-30°C to represent room temperature conditions. Ideally you should evaluate stability at both 15°C and 30°C, however, for the purposes of the EUA evaluation at 30°C is acceptable as the worse-case scenario.
- Shelf-Life Stability- Unopened kit:
    - You should evaluate real-time kit stability studies with unopened kits stored at the claimed storage temperature for your test.

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  - Accelerated stability evaluations for unopened kits is acceptable for EUA submissions while the real-time studies are on-going. However, please note real-time stability data is required to support regular pre-market submissions and for the final claim of an EUA.
- Shipping Stability - Unopened kit: Study should evaluate the anticipated handling and shipping times and temperatures expected for unopened kits.
- In-use/Opened Kit Stability: Depending on your device your stability study design should also support in-use stability of the kit reagents once the kit has been opened, e.g., storage at 2-8 $^{o}$C for 7 days. This includes on board stability once reagents have been placed on the instrument (if applicable).
- Inverted stability (if applicable): Study should support inverted stability for of kits.
- Freeze-thaw Stability: If you recommend aliquoting the reagents to meet the end-users needs following the initial thaw this recommendation should be supported by a freeze-thaw stability study, including the specific number of allowed freeze-thaw cycles.
- FDA analysis recommendations for real time stability studies are as follows:
  - Baseline of the study (t=0 of stability study) should not exceed a month from bottling
  - Clear baselines should be described (e.g., a month from bottling) for each stability claim under each study
  - Claims should be determined based on regression analysis. Any %change (%shift) from time zero (baseline) should be calculated between the target claim and the zero-time as (Ttest-Tbaseline)/ Tbaseline*100 with 95%CI using the regression equation obtained from plotting the mean values. When formulating your acceptance criteria for evaluating the shift from baseline you should consider the reproducibility of your device. However, generally, that the shift at the target claim due to storage cannot exceed 10-15%. The target stability is the next to last tested point that was within +/- 10% of time zero.
  - Acceptance criterion may be different, depending on the test samples analyte concentration distribution in the intended use population and the risk, in other words, the impact of false results to public health.

**APPENDIX C – Claiming Multiple Instruments and/or Extraction Methods:**

If you wish to claim multiple instruments and/or extraction methods for use with your test, please review the study recommendations provided below and contact FDA for any additional feedback. Please note that these analytical and clinical evaluation recommendations are based on the assumption that the elution volumes from the extraction methods and PCR volumes on the different RT-PCR instruments are identical.

- Limit of Detection (LoD): Please note that these studies should be repeated for each clinical matrix claimed in the Intended Use. Pick one RT-PCR instrument and determine the tentative LoD (using 5 replicates in 10-fold dilution) followed by the confirmatory LoD (20 replicates spiked at tentative LoD) for each extraction method on the chosen instrument. Note: If you detect 20/20 replicates in your confirmatory LOD study you should test the next lower concentration, using a 3-fold dilution, until

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you achieve a hit rate of <20/20.

- If the different extraction methods yield the same LoD (≤3xLOD) on the RT-PCR instrument chosen for initial testing, pick one extraction method for further LoD determination on the remaining RT-PCR instruments and follow the recommendations below.
- If the extraction methods do not yield the same LoD on the chosen RT-PCR instrument, please choose the extraction method with the worst LoD for further comparison of the LoD on all RT-PCR instruments.

For all other RT-PCR instruments you should use the following adaptive LoD study design:

- Please perform a refined tentative LoD study with 5 replicates at 0.5x, 1x, and 1.5 to 2x LoD. If you detect 4/5 replicates as positive at all the tested levels, you need to include the next higher concentration (i.e., 3x LoD). If you obtain 5/5 replicates at 0.5x LoD, you need to test the next lower concentration (i.e., 0.25x LoD). You will test in this manner until you find the lowest concentration that gives you 5/5 positive results for the tested RT-PCR instrument. This concentration should be used for a confirmatory LoD study for the given RT-PCR instrument using 20 replicates.

Final reported LoD: Please list all RT-PCR instruments with their respective LoDs if different LoDs are obtained. LoDs are considered comparable if they are between 1-3xLoD. These studies should be repeated for each clinical matrix claimed in the Intended Use.

- Interference Substances Studies (if applicable): Pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Inclusivity Testing: For the inclusivity testing, pick one extraction method and RT-PCR instrument combination, preferably the one with the worst overall LoD (if one or more of the RT-PCR instruments has a different LoD).

- Exclusivity Testing: For exclusivity, you can perform this study using any extraction/instrument combination.

- Clinical study: If equivalency of the RT-PCR instruments is shown in an LoD study that tests and confirms that the LoD is the same or very similar for all of the RT-PCR instruments (between 2-3xLoD), then you can pick one RT-PCR instrument for your clinical study provided that the RT-PCR instruments in question are known to FDA for other *in vitro* diagnostic devices. If you find that one or more RT-PCR instruments machines has/have a different LoD, you should pick the extraction method / RT-PCR instrument combination with the worst LoD.

Note, if there are differences in the extraction input volume, extraction elution volume

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and PCR input volume (extracted nucleic acid) then the LoD should be confirmed, for each.

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**From:** Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent:** 2/28/2020 4:07:11 AM
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**Subject:** NYS
**Attachments:** Draft cover letter for Sponsor 01212020.docx; EUA Review Template_NAT_Novel Coronavirus 1.19.2020.doc

Additional communication — as of February 25th Wadsworth hadn't finished validating their test.

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 27, 2020 at 10:01:33 PM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Subject:** FW: Pre-EUA IVD template request

FYI

---

**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 4:03 PM
**To:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** FW: Pre-EUA IVD template request

FYI – see information in red in the email below and:

Wadsworth:

(b) (4), (b) (5)



Best regards

Kim

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**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov






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**From:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Sent:** Tuesday, February 25, 2020 3:50 PM
**To:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>; CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** RE: Pre-EUA IVD template request

Dear Jill,

Thank you very much for reaching out to us about the test you have validated at Wadsworth Center, NYS Department of Health it was very nice to chat with you. As discussed please find attached the current EUA Interactive Review Template draft for molecular-based assays for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [formally - 2019-novel coronavirus (2019-nCoV)]. I suggest the first step is to populate this draft template with the validation information and data that you currently have about your device and sent it back to us for review as a Pre-EUA submission (to be sent to the Document Control Center). The Pre-EUA review is an interactive process, so we will provide feedback after receiving and reviewing the information provided. The draft review template is a shared "work-in-progress" document which you will populate with information and data as obtained and which we will review and provide feedback to you. **Please make sure to capture in the EUA review template that you performed the validation using the SIGMA primer/probes sets, sensitivity was evaluated with the positive control material provided in the CDC EUA test kit and that validation studies were performed used the commercial primer/probe materials using the CDC EUA Protocol (please be sure to include information the extraction method and instrument used).**

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I have also attached a draft cover letter you can use to submit your Pre-EUA for detection of SARS-CoV-2 to FDA (it includes the address for the Document Control Center). Please include in your Pre-EUA submission package:

- The populated EUA Review Template draft
- FDA Form 3514 (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf) - under Section A (type of submission) please check "other" and specify Pre-EUA; please also complete Sections B, C, F and G. For G please use the information provided in this link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=3669.

One hard copy of the signed EUA Cover Letter and one electronic copy (CD or thumb drive) of you Pre-EUA submission package should be enclosed in your Pre-EUA submission package mailed to FDA (recommend FedEx). In addition to mailing your Pre-EUA package to FDA we also request that you submit the package to the review division via electronic mail (including the EUA Review Template in MS word) to myself Kim.Sapsford@fda.hhs.gov, as well as carbon copying (cc:) the following email addresses:

- Division Director: Dr Uwe Scherf, email address: Uwe.Scherf@fda.hhs.gov;
- Branch Chief: Dr Tamara Feldblyum, email address: Tamara.Feldblyum@fda.hhs.gov

Please let me know if you have ANY questions I am happy to assist if you are not sure about certain sections in the template.

Best regards

Kim

**Kim Sapsford-Medintz, Ph.D.**
*MCM EUA Team Lead*

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
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Kim.Sapsford@fda.hhs.gov






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**From:** Taylor, Jill (HEALTH) <jill.taylor@health.ny.gov>
**Sent:** Tuesday, February 25, 2020 1:08 PM
**To:** CDRH-EUA-Templates <CDRH-EUA-Templates@fda.hhs.gov>
**Cc:** St. George, Kirsten (HEALTH) <kirsten.st.george@health.ny.gov>; Derbyshire, Victoria (HEALTH) <victoria.derbyshire@health.ny.gov>; Hutton, Brad J (HEALTH) <brad.hutton@health.ny.gov>
**Subject:** Pre-EUA IVD template request

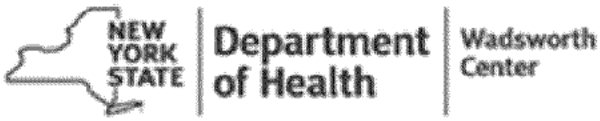
At your earliest convenience, I wish to request a copy of the most recent EUA review template relevant to an assay for the SARS-CoV-2 pathogen.

(b) (4)

Thank you,

**Jill Taylor, Ph.D.**
Director

Wadsworth Center, NYS Department of Health
Room E-260, Biggs Laboratory
(518) 474-3157 | jill.taylor@health.ny.gov
www.wadsworth.org




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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/25/2020 12:11:12 PM
**To**: Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
**CC**: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]
**Subject**: Re: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

If CDC has verified these probes can the public health labs proceed with the CDC test using these probes and then avoid the need for a new EUA for using just N1 and N2?

Also, if live or inactivated viral samples are not available to validate tests, can test developers use contrived samples in the interim?

Jeff

---

**From:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Date:** February 25, 2020 at 11:24:51 AM EST
**To:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
**Cc:** Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
**Subject:** IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/16/2020 9:33:57 AM
**To**: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
**CC**: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
**Subject**: Re: CDC 2019-nCoV Test

Thank you. Latest update is (b) (5)

(b) (5), (b) (4)

Jeff

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>
**Date:** February 16, 2020 at 9:16:31 AM EST
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
**Cc:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Hahn, Stephen (b) (6) @fda.hhs.gov>
**Subject:** Re: CDC 2019-nCoV Test

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**From**: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
**Sent**: 2/15/2020 5:45:36 PM
**To**: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
**Subject**: Fwd: FYI - Signed copy: CDC 2019-nCoV EUA

---

**From:** Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
**Date:** February 4, 2020 at 3:28:14 PM EST
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Lowe, Toby A <Toby.Lowe@fda.hhs.gov>, McFarland, Scott <Scott.McFarland@fda.hhs.gov>, St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>, Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Maisel, William <William.Maisel@fda.hhs.gov>, Russ, Wanda <Wanda.Russ@fda.hhs.gov>, Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
**Subject:** FYI - Signed copy: CDC 2019-nCoV EUA

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***Vaughn Index (V2) for FOIA Request No. 2020-2531***
***American Oversight v. HHS et. al., Case No. 1:20-cv-0947 (D.D.C.)***

| Doc Start* | Doc. End* | Date of Redacted Doc | Author(s) of Redacted Doc | Document Title | Exemption(s)** | Explanation |
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| 002588 | 002598 | 3/1/2020 | Jeff Shuren, M.D., J.D. | FW: Cut-off change - lot release testing criteria | (b)(5) | FDA-CVD-SHURENJ-00017261<br><br>Bates: 002589, 002591 – 002598<br><br>Deliberative Process Privilege: The redacted information in this email exchange with CDC contains a discussion of the conditions under which CDC manufactured and evaluated its test for SARS-CoV-2, the results of these evaluations, and recommendations from CDC and FDA to ensure the efficacy of this test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002602 | 002606 | 2/24/2020 | Jeff Shuren, M.D., J.D. | Senate HELP Bipartisan Staff Briefing on Supply Chain: Follow-up Questions | (b)(5) | FDA-CVD-SHURENJ-00019598.0001<br>Attachment to FDA-CVD-SHURENJ-00019598.<br><br>Bates: 002602 – 002606<br>Deliberative Process Privilege: The redacted information in this email attachment contains a list of questions and draft answers for the Senate HELP Bipartisan Staff Briefing on the impact of the COVID-19 pandemic on pharmaceutical and medical device manufacturing and supply chains, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002607 | 002614 | 2/25/2020 | Jeff Shuren, M.D., J.D. | FW: COVID Congressional Engagement | (b)(5) | FDA-CVD-SHURENJ-00019598<br><br>Bates: 002607 – 002609<br>The redacted information in this email exchange contains internal deliberations about the questions FDA anticipates congressional staffers will ask during a briefing on how the outbreak of COVID-19 in China |

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| | | | | | | affects pharmaceutical and medical device manufacturing and supply chains, and draft talking points for FDA officials to rely on during this briefing, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002672 | 002677 | 2/23/2020 | Jeff Shuren, M.D., J.D. | Fwd: Request for Input for 20 Feb Update on FDA 2019-nCoV SITREP | (b)(4), (b)(5), (b)(6) | FDA-CVD-SHURENJ-00020134<br><br>Bates: 002674-002675<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about FDA's outreach to manufacturers of personal protective equipment (PPE) and updates from FDA's Center for Devices and Radiological Health (CDRH) about PPE and other devices being manufactured to prevent the spread of COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002672–002675<br>Confidential Commercial Information: The redacted information relates to updates on the development of immunotherapeutics for COVID-19 that were shared with FDA's Center for Biologics Evaluation and Research (CBER) during meetings with biologics/pharmaceutical manufacturers. The release of this information would inform competitors about these manufacturers' operations and would lead to predictable harm.<br><br>Bates: 002675<br>Personal Privacy Information: The redacted information contains the private cell phone number of an FDA employee. |
| 002678 | 002680 | 2/29/2020 | Jeff Shuren, M.D., J.D. | RE: If possible, to review by 9pm | (b)(5) | FDA-CVD-SHURENJ-00034441<br><br>Bates: 002678, 002679, 002680<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about draft talking points for the |

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| | | | | | | Vice President and Secretary of the Department of Health and Human Services (HHS) to use during television interviews, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002681 | 002687 | 3/1/2020 | Jeff Shuren, M.D., J.D. | Re: URGENT REVIEW NEEDED TODAY: (b)(5) | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034449<br><br>Bates: 002681 – 002687<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about draft language for legislation and a mandate for FDA to issue guidance within a specified time period after the legislation takes effect, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002687<br>Personal Privacy Information: The redacted information contains the private cellphone number of an FDA employee. |
| 002688 | 002689 | 3/1/2020 | Jeff Shuren, M.D., J.D. | RE: Need help asap--test kits | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034479<br><br>Bates: 002688<br>Deliberative Process Privilege: The redacted information in this exchange contains internal deliberations about the number of individuals that can be tested for SARS-CoV-2 based on the number of kits said to be available, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002689<br>Personal Privacy Information: The redacted information contains the private phone numbers of a CNN White House Reporter. |

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| 002690 | 002692 | 3/1/2020 | Jeff Shuren, M.D., J.D. | RE: Update re Hill Calls Tomorrow | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034555<br><br>Bates: 002690, 002691<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about COVID-19 testing matters to be discussed in two phone conferences with congressional staff and CDC, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002691<br>Personal Privacy Information: The redacted information contains the private cell phone number of an FDA employee. |
| 002693 | 002702 | 2/29/2020 | Jeff Shuren, M.D., J.D. | RE: NYS EUA | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034576<br><br>Bates: 002696, 002699, 002701<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the communication plan related to FDA guidance on the use of diagnostic tests for SARS-CoV-2 in qualifying laboratories prior to the submission of applications for Emergency Use Authorization (EUA), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002702<br>Personal Privacy Information: The withheld information relates to the work email address of an Office of Management and Budget (OMB) employee. This information was also withheld pursuant to a privilege asserted by the Executive Office of the President (EOP). |
| 002703 | 002706 | 3/1/2020 | Jeff Shuren, M.D., J.D. | RE: idea for ACLA speech | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034611<br><br>Bates: 002703, 002704, 002705, 002706 |

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| | | | | | | Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the Commissioner of Food and Drugs' speech at a conference hosted by the American Clinical Laboratories Association (ACLA), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002706<br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee. |
| 002707 | 002709 | 3/1/2020 | Jeff Shuren, M.D., J.D. | RE: Need help asap--test kits | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034636<br><br>Bates: 002707, 002708, 002709<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations between employees of multiple agencies about the contemporaneous testing capacity for SARS-CoV-2 based on the number of test kits available at that time, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002709<br>Personal Privacy Information: The redacted information contains the private phone numbers of a CNN White House Reporter. |
| 002710 | 002716 | 3/1/2020 | Jeff Shuren, M.D., J.D. | RE: HHS Secretary's News Briefing for Sunday, March 01, 2020 | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034649<br><br>Bates: 002710<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the World Health Organization's (WHO) publication of guidance for developing a test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the |

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| | | | | | | agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002710<br>Personal Privacy Information: The redacted information contains the private email address of the former Commissioner of Food and Drugs. |
| 002717 | 002720 | 3/1/2020 | Jeff Shuren, M.D., J.D. | Re: EUA COVID-19 Lab Tests – Webinar deck (003) Tim.Uwe.EH.Uwe.pptx | (b)(5) | FDA-CVD-SHURENJ-00034681<br><br>Bates: 002717, 002719<br>Deliberative Process Privilege: The redacted information in this email exchange contains pre-decisional discussions about draft language for a PowerPoint presentation on Emergency Use Authorization (EUA) for SARS-CoV-2 tests, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002717, 002719<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel (OCC) regarding the elements of a particular entity's COVID-19 test kit. |
| 002721 | 002726 | 2/29/2020 | Jeff Shuren | Re: PREP Act - N95 Masks | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034690<br><br>Bates: 002721, 002722, 002723, 002724, 002725<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the Public Readiness and Emergency Preparedness (PREP) Act as it relates to liability protections and/or enforcement discretion for personal protective equipment (PPE) like N95 masks, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. Some of this information was also withheld pursuant to a privilege asserted by the Executive Office of the President (EOP). |

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| | | | | | | Bates: 002721 – 002724<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel (OCC) regarding the Public Readiness and Emergency Preparedness (PREP) Act as it pertains to liability protections and/or enforcement discretion for personal protective equipment (PPE) like N95 masks.<br><br>Bates: 002724 – 002726<br>Personal Privacy Information: The redacted information contains the email addresses of White House employees. The redacted information also contains the phone numbers of a White House employee. This information was also withheld pursuant to a privilege asserted by the Executive Office of the President (EOP). |
| 002727 | 002737 | 2/29/2020 | Jeff Shuren, M.D., J.D. | RE: NYS EUA | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034744<br><br>Bates: 002731, 002734, 002737<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the communication plan related to FDA guidance on the use of diagnostic tests for SARS-CoV-2 in qualifying laboratories prior to the submission of applications for Emergency Use Authorization (EUA), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002737<br>Personal Privacy Information: The redacted information contains the email address of an Office of Management and Budget (OMB) employee. This information was also withheld pursuant to a privilege asserted by the Executive Office of the President (EOP). |
| 002738 | 002740 | 2/29/2020 | Jeff Shuren, M.D., J.D. | Re: NVS Wadsworth Center COVID-19 | (b)(4), (b)(5) | FDA-CVD-SHURENJ-00034784<br><br>Bates: 002740 |

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| | | | | | | Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the New York State Department of Health (NYSDOH) Wadsworth Center's application for Emergency Use Authorization (EUA) for its test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002738 – 002739<br>Confidential Commercial Information: The redacted information relates to third party companies' reliance on CDC's guidance for developing tests for SARS-CoV-2. The release of this information would inform competitors about these companies' operations and would lead to predictable harm. |
| 002741 | 002741 | 2/25/2020 | Jeff Shuren, M.D., J.D. | FDA comments on H.R. 4982 | (b)(5) | FDA-CVD-SHURENJ-00034792.0001 attachment of FDA-CVD-SHURENJ-00034792<br><br>Bates: 002741<br>Deliberative Process Privilege: The redacted information contains internal deliberations about draft language for a bill, the Health Care Workforce Protection Act of 2019, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002742 | 002745 | 2/29/2020 | Jeff Shuren, M.D., J.D. | Fwd: PREP Act - N95 Masks | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034792<br><br>Bates: 002742 - 002745<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the Public Readiness and Emergency Preparedness (PREP) Act as it relates to liability protections and/or enforcement discretion for personal protective equipment (PPE) like N95 masks, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the |

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| 002746 | 002747 | 2/25/2020 | Jeff Shuren, M.D., J.D. | RE: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests | (b)(5) | FDA-CVD-SHURENJ-00034871<br><br>Bates: 002746<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about a response to an article citing laboratories' concerns about the availability of test kits for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002748 | 002750 | 2/27/2020 | Jeff Shuren, M.D., J.D. | Re: (b)(5) | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034894<br><br>Bates: 002748, 002749<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the requirement that laboratories use CDC's diagnostic assay for SARS-CoV-2 testing until other tests are approved or authorized, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 002751 | 002755 | 2/29/2020 | Jeff Shuren, M.D., J.D. | Re: Diagnostics | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034904<br><br>Bates: 002752, 002753, 002754<br>Deliberative Process Privilege: The redacted information in this email exchange between multiple agencies and offices contains internal deliberations about guidance on the development of tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002754<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel (OCC) regarding FDA guidance on the development of tests for SARS-CoV-2.<br><br>Bates: 002754<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee. |
| 002756 | 002757 | 2/25/2020 | Jeff Shuren, M.D., J.D. | Re: enforcement discretion request for COVID-19 for PHLs final.pdf | (b)(6) | FDA-CVD-SHURENJ-00034933<br><br>Bates: 002756<br>Personal Privacy Information: The redacted information contains the private email addresses of a former Commissioner of Food and Drugs. |
| 002758 | 002759 | 2/29/2020 | Jeff Shuren, M.D., J.D. | FW: NYS Wadsworth | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00034936<br><br>Bates: 002758<br>Personal Privacy Information: The redacted information contains the private email address of a former Commissioner of Food and Drugs. |

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| 002760 | 002760 | 2/26/2020 | Jeff Shuren, M.D., J.D. | RE: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing | (b)(6) | FDA-CVD-SHURENJ-00034938<br><br>Bates: 002760<br>Personal Privacy Information: The redacted information contains the private location of an FDA employee and the private cell phone number of the President of the American Clinical Laboratory Association (ACLA). |
| 002761 | 002763 | 2/28/2020 | Jeff Shuren, M.D., J.D. | RE: Final "Plan for Improving Testing in the US" | (b)(5) | FDA-CVD-SHURENJ-00034939<br><br>Bates: 002761, 002763<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the Emergency Use Authorization (EUA) application requirements for developers of tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002764 | 002765 | 2/28/2020 | Jeff Shuren, M.D., J.D. | RE: Guidance on Minimum Criteria for LDTs | (b)(5) | FDA-CVD-SHURENJ-00034956<br><br>Bates: 002764 – 002765<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the minimum acceptance criteria for validation of SARS-CoV-2 tests developed by laboratories, |

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| 002767 | 002768 | 2/24/2020 | Jeff Shuren, M.D., J.D. | Fwd: enforcement discretion request for COVID-19 for PHls final.pdf | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035034<br><br>Bates: 002767<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about a request for enforcement discretion for public health laboratories that develop tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002769 | 002771 | 2/27/2020 | Jeff Shuren, M.D., J.D. | Food and Drug Administration COVID-19 Response Activities | (b)(5) | FDA-CVD-SHURENJ-00035062.0001 attachment to FDA-CVD-SHURENJ-00035062<br><br>Bates: 002769 – 002771<br><br>Deliberative Process Privilege: The redacted information in this email attachment is a draft document that discusses the FDA's response to the COVID-19 outbreak and its requests for additional funding to continue addressing issues related to the outbreak, as well as comments about the draft document, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002772 | 002775 | 2/27/2020 | Jeff Shuren, M.D., J.D. | Fwd: Hill call tomorrow after 1:00 | (b)(5) | FDA-CVD-SHURENJ-00035062<br><br>Bates: 002772, 002773, 002775<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the substance of responses to questions from congressional staff for members on the Appropriations |

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| | | | | | | Committee, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002776 | 002777 | 2/26/2020 | Jeff Shuren, M.D., J.D. | RE: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035064<br><br>Bates: 002776<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about a presentation at a meeting hosted by the American Clinical Laboratories Association (ACLA), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002777<br>Personal Privacy Information: The redacted information contains the private cell phone number of the President of the American Clinical Laboratories Association (ACLA). |
| 002778 | 002779 | 2/27/2020 | Jeff Shuren, M.D., J.D. | Re: (b)(5) | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035080<br><br>Bates: 002778 – 002779<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about public health laboratories' use of CDC's diagnostic assay for SARS-CoV-2 testing until other tests are approved or authorized, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002779<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Biomedical Advanced Research and Development Authority (BARDA) employee. |

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| 002780 | 002782 | 2/26/2020 | Jeff Shuren, M.D., J.D. | RE: TIME SENSITIVE Response to APHL Regarding Enforcement Discretion for LDTs | (b)(5) | FDA-CVD-SHURENJ-00035085<br><br>Bates: 002780<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the exercise of enforcement discretion with respect to lab developed tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002783 | 002787 | 2/28/2020 | Jeff Shuren, M.D., J.D. | RE: FDA contact and potentials for KCDC assay (UNCLASSIFIED) | (b)(4), (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035092<br><br>Bates: 002783<br>Confidential Commercial Information: The redacted information relates to considerations about an assay for SARS-CoV-2 developed by the Korean Centers for Disease Control and Prevention (KCDC). The release of this information would inform competitors about KCDC's operations and would lead to predictable harm.<br><br>Bates: 002783-002784, 002786–002787<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about an assay for SARS-CoV-2 developed by KCDC, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002786<br>Personal Privacy Information: The redacted information contains the private cell phone number of a U.S. Army Corp of Engineers employee. |
| 002788 | 002789 | 2/27/2020 | Jeff Shuren, M.D., J.D. | Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035111<br><br>Bates: 002788, 002789<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about FDA and CDC |

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| | | | | | | representatives speaking at the annual meeting of the American Clinical Laboratories Association (ACLA), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002789<br>Personal Privacy Information: The redacted information contains the private cell phone number of the American Clinical Laboratories Association (ACLA) president. |
| 002790 | 002793 | 2/28/2020 | Jeff Shuren, M.D., J.D. | RE: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035112<br><br>Bates: 002790, 002791, 002792, 002793<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about comments from the Office of Management and Budget (OMB), Office of Intergovernmental Regulatory Affairs (OIRA), and the Department of Health and Human Services (HHS), and additional edits from FDA, to FDA's guidance for clinical laboratories developing tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002793<br>Personal Privacy Information: The redacted information contains the private cell phone number of an FDA employee. |
| 002794 | 002794 | 2/28/2020 | Jeff Shuren, M.D., J.D. | RE: Posting | (b)(5) | FDA-CVD-SHURENJ-00035131<br><br>Bates: 002794<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about posting information relating to Laboratory Developed Tests (LDTs) for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to |

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| 002795 | 002800 | 2/29/2020 | Jeff Shuren, M.D., J.D. | RE: IIE nCoV guidance CDRH OCC cleared.docx | (b)(5) | FDA-CVD-SHURENJ-00035144<br><br>Bates: 002795 – 002800<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about guidance relating to which laboratories can develop and use Laboratory Developed Tests (LDTs) for SARS-CoV-2 under the Clinical Laboratory Improvement Amendments (CLIA), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002807 | 002810 | 2/25/2020 | Jeff Shuren, M.D., J.D. | RE: As CDC warns of US COVID-19 spread, labs frustrated over lack of tests | (b)(5) | FDA-CVD-SHURENJ-00035161<br><br>Bates: 002808<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about a draft response to a letter from the Association of Public Health Laboratories (APHL), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002811 | 002813 | 2/27/2020 | Jeff Shuren, M.D., J.D. | FW: Call with Approps Subcommittee Staff on COVID-19 Funding Needs | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035162<br><br>Bates: 002812 – 002813<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about agenda items for a meeting with the Subcommittee on Appropriations regarding COVID-19 funding needs, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002811 |

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| 002814 | 002817 | 2/28/2020 | Jeff Shuren, M.D., J.D. | FW: OMB COMMENTS on the PLAN, ATTACHED: Heads up: FDA guidance on clinical laboratories | (b)(4), (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035176<br><br>Bates: 002816<br>Confidential Commercial Information: The redacted information relates to third party companies that satisfy the regulatory requirements under the Clinical Laboratory Improvement Amendments (CLIA) with respect to the development of tests for SARS-CoV-2. The release of this information would inform competitors about these companies' operations and would lead to predictable harm.<br><br>Bates: 002815 – 002816<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about guidance relating to which laboratories can develop and use Laboratory Developed Tests (LDTs) for SARS-CoV-2 under the Clinical Laboratory Improvement Amendments (CLIA), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002817<br>Personal Privacy Information: The redacted information contains the private cell phone number of an FDA employee. |
| 002818 | 002822 | 2/28/2020 | Jeff Shuren, M.D., J.D. | Plan to increase Coronavirus Disease-2019 (COVID-19) Testing in the U.S. – Accelerated EUA Authorization Pathway for High-Complexity Molecular Diagnostics CLIA-Certified Laboratories | (b)(5) | Attachment to FDA-CVD-SHURENJ-00035178.0001 attachment to FDA-CVD-SHURENJ-00035178<br><br>Bates: 002818, 002819, 002820, 002821, 002822<br>Deliberative Process Privilege: The redacted information in this email attachment contains edits from FDA personnel to a draft plan to increase testing for SARS-CoV-2 in the United States by utilizing an accelerated Emergency Use Authorization (EUA) pathway, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid |

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| 002823 | 002824 | 2/28/2020 | Jeff Shuren, M.D., J.D. | FW: DIAGNOSTIC TESTING DOCUMENT | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035178<br><br>Bates: 002823<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about a plan to increase testing for SARS-CoV-2 in the United States, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002824<br>Personal Privacy Information: The redacted information contains the private cell phone number of a University of Nebraska Medical Center employee. |
| 002825 | 002831 | 2/25/2020 | Jeff Shuren, M.D., J.D. | Re: COVID Congressional Engagement | (b)(5) | FDA-CVD-SHURENJ-00035183<br><br>Bates: 002825 – 002827<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the items FDA would and/or should discuss at a briefing between the agency and healthcare legislative aids for members serving on the Senate Committee on Health, Education, Labor, and Pensions (HELP), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002832 | 002833 | 2/27/2020 | Jeff Shuren, M.D., J.D. | FW: Pre-Briefing Meeting for Call with Approps Subcommittee Staff on COVID-19 Funding Needs | (b)(5) | FDA-CVD-SHURENJ-00035184<br><br>Bates: 002832 – 002833<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about agenda items for a meeting with the Subcommittee on Appropriations regarding COVID-19 funding needs, the release of which would cause foreseeable harm as it would |

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| 002834 | 002838 | 2/27/2020 | Jeff Shuren, M.D., J.D. | RE: (b)(5) | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035187<br><br>Bates: 002834 – 002837<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about public health laboratories' use of CDC's diagnostic assay for SARS-CoV-2 testing until other tests are approved or authorized, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002838<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Biomedical Advanced Research and Development Authority (BARDA) employee. |
| 002839 | 002841 | 2/27/2020 | Jeff Shuren, M.D., J.D. | FW: Pre-EUA IVD template request | (b)(4), (b)(5) | FDA-CVD-SHURENJ-00035203<br><br>Bates: 002839 – 002841<br>Confidential Commercial Information: The redacted information relates to the New York State Department of Health (NYSDOH) Wadsworth Center's efforts to validate its test for SARS-CoV-2. The release of this information would inform competitors about the NYSDOH Wadsworth Center's operations and would lead to predictable harm.<br><br>Bates: 002839<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the New York State Department of Health (NYSDOH) Wadsworth Center's efforts to validate its test for SARS-CoV-2 in advance of its submission of an application for Emergency Use Authorization (EUA) of this test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid |

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| 002842 | 002844 | 2/24/2020 | Jeff Shuren, M.D., J.D. | Re: (b)(5) | (b)(5) | FDA-CVD-SHURENJ-00035203<br><br>Bates: 002842<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about an article from POLITICO that discusses public health laboratories push for FDA to allow them to create their own tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002845 | 002850 | 2/25/2020 | Jeff Shuren, M.D., J.D. | FW: COVID Congressional Engagement | (b)(5) | FDA-CVD-SHURENJ-00035222<br><br>Bates: 002845 – 002846<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the items FDA would and/or should discuss at a briefing between the agency and healthcare legislative aids for members serving on the Senate Committee on Health, Education, Labor, and Pensions (HELP), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002851 | 002852 | 2/27/2020 | Jeff Shuren, M.D., J.D. | RE: UC Testkit information. | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035243<br><br>Bates: 002851<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about SARS-CoV-2 diagnostic tests being developed by third party entities, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 002853 | 002855 | 2/24/2020 | Jeff Shuren, M.D., J.D. | Fwd: PREP Act liability coverage | (b)(5) | FDA-CVD-SHURENJ-00035281<br><br>Bates 002853 – 002854<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the Public Readiness and Emergency Preparedness (PREP) Act liability coverage for personal protective equipment (PPE), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002856 | 002857 | 2/24/2020 | Jeff Shuren, M.D., J.D. | Re: COVID-19 Diagnostics Validation materials (update Feb 24, 2020) | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035296<br><br>Bates: 002856, 002857<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the materials needed to validate diagnostic tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002857<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee. |
| 002858 | 002859 | 2/27/2020 | Jeff Shuren, M.D., J.D. | FW: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035297<br><br>Bates: 002858<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about a presentation at a meeting hosted by the American Clinical Laboratories Association (ACLA), the release of which would cause foreseeable harm as it would reveal internal |

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| 002860 | 002864 | 2/26/2020 | Jeff Shuren, M.D., J.D. | Re: N95 EUA for COVID19 | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035303<br><br>Bates: 002860 – 002861, 002864<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the potential and scope of a grant of Emergency Use Authorization (EUA) for N95 masks to protect against the contraction and transmission of SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002862<br>Personal Privacy Information: The redacted information contains a meeting number (access code) and password. |
| 002865 | 002867 | 2/29/2020 | Jeff Shuren, M.D., J.D. | RE: NYS Wadsworth Center COVID-19 | (b)(4), (b)(5) | FDA-CVD-SHURENJ-00035304<br><br>Bates: 002865<br>Confidential Commercial Information: The redacted information relates to third party entities that developed tests for SARS-CoV-2 based on the design and specifications of CDC's test. The release of this information would inform competitors about these entities' operations and would lead to predictable harm.<br><br>Bates: 002865<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal discussions about which SARS-CoV-2 test |

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| | | | | | | developers CDC is willing to permit under its grant of Emergency Use Authorization (EUA) in light of their development of tests that relied on CDC's design specifications, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002868 | 002872 | 2/27/2020 | Jeff Shuren, M.D., J.D. | Re: Hill call tomorrow after 1:00 | (b)(5) | FDA-CVD-SHURENJ-00035305<br><br>Bates: 002868 – 002871<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about agenda items for a meeting with the Subcommittee on Appropriations regarding COVID-19 funding needs, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

* Page prefix is FDACDRH-p3-AO
** Exemption codes refer to sections of the Freedom of Information Act, *see* 5 U.S.C. § 552(b).

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***Vaughn Index for FOIA Request No. 2020-2531 (V2)***
***American Oversight v. HHS et. al., Case No. 1:20-cv-0947 (D.D.C.)***

| Doc Start | Doc. End | Date of Redacted Doc | Author(s) of Redacted Doc | Document Title | Exemption(s)** | Explanation |
|---|---|---|---|---|---|---|
| 002006 | 002012 | 2/24/2020 | Jeff Shuren, M.D., J.D. | Re: Monday, February 24 Update on Response to Cybersecurity Signal (Sweyn Tooth) | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035340<br><br>Bates: 002007–002012<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations regarding the possible impacts of a cybersecurity threat on the functioning of particular medical devices and proposed plans to respond to the manifestation of this threat, including possible communications and ongoing coordination with other entities, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002008, 002010, 002012<br><br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee. |
| 002013 | 002014 | 2/25/2020 | Jeff Shuren, M.D., J.D. | RE: IDT provides 2019-nCoV Kits that include the CDC 2019-nCoV/SARS-CoV-2 published assays in individual tubes | (b)(5) | FDA-CVD-SHURENJ-00035351<br>Bates: 002013-002014<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the supply of test kits for SARS-CoV-2 being provided by Integrated DNA Technologies and the regulatory requirements for public health laboratories that receive and use these test kits, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002015 | 002017 | 2/19/2020 | Jeff Shuren, M.D., J.D. | Re: N95 EUA Approach | (b)(5) | FDA-CVD-SHURENJ-00035375 |

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| | | | | | | Bates: 002015–002017<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the potential to grant Emergency Use Authorization (EUA) to N95 masks and other personal protective equipment (PPE) under the Public Readiness and Emergency Preparedness (PREP) Act, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002015-002017<br><br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinions/advice from FDA's Office of the Chief Counsel (OCC) regarding the potential for N95 masks and other personal protective equipment (PPE) to receive Emergency Use Authorization (EUA) under the Public Readiness and Emergency Preparedness (PREP) Act. |
| 002018 | 002030 | 2/18/2020 | Jeff Shuren, M.D., J.D. | FDA's Recommendations on EUA Non-Surgical N95 Respirators for Use In Health Care | (b)(5) | FDA-CVD-SHURENJ-00035381.0001 attachment to FDA-CVD-SHURENJ-00035381<br><br>Bates: 002018-002030<br>Deliberative Process Privilege: The email attachment contains a draft of FDA's recommendations for Emergency Use Authorization (EUA) of non-surgical N95 respirators for use in healthcare settings and edits and comments about these recommendations from FDA personnel, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002031 | 002038 | 2/19/2020 | Jeff Shuren, M.D., J.D. | Fwd: N95 Respirators | (b)(5) | FDA-CVD-SHURENJ-00035381<br><br>Bates: 002031–002034, 002034, 002037–002038<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about what kinds of testing, results, and documentation may be needed to support the grant of Emergency Use |

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| | | | | | | Authorization (EUA) for N95 respirators for use in healthcare settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002039 | 002044 | 2/20/2020 | Jeff Shuren, M.D., J.D. | RE: COVID-19 Hearings | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035386<br><br>Bates: 002039–002044<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about communication between FDA and manufacturers of medical devices needed to care for patients with serious medical conditions in light of the COVID-19 pandemic, as well as draft notes prepared by FDA personnel for the Commissioner of Food and Drugs and other agency personnel so they can brief various committees of Congress on the effect of the COVID-19 pandemic on the medical device supply chain, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002039, 002044<br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee. |
| 002045 | 002048 | 2/16/2020 | Jeff Shuren, M.D., J.D. | Re: CDC 2019-nCoV Test | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035389<br><br>Bates: 002045, 002046–002048<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the efficacy of the Centers for Disease Control and Prevention's (CDC) test for SAR-CoV-2 and potential modifications to the grant of Emergency Use Authorization (EUA) for this test to ensure its continued efficacy, and a request from the CDC for guidance on the testing of passengers aboard a cruise ship that was docked in Japan and will be returning to the United States, the release of which would cause |

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| | | | | | | foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002045–002047<br><br>Personal Privacy Information: The redacted information contains the private email address of the former Commissioner of Food and Drugs. |
| 002049 | 002050 | 2/21/2020 | Jeff Shuren, M.D., J.D. | Re: 2/21/20 6 AM update | (b)(4), (b)(5) | FDA-CVD-SHURENJ-00035389<br><br>Bates: 002049<br><br>Confidential Commercial Information: The redacted information relates to a company that submitted an application for Emergency Use Authorization (EUA) for its test for SARS-CoV-2 and four other entities that made pre-EUA submissions to FDA for their tests for SARS-CoV-2. The release of this information would inform competitors about these entities' operations and would lead to predictable harm.<br><br>Bates: 002049<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the actions FDA anticipates the Centers for Disease Control and Prevention (CDC) and others will take to advance the status of diagnostic tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002052 | 002060 | 2/19/2020 | Jeff Shuren, M.D., J.D. | RE: N95 Respirators | (b)(5) | FDA-CVD-SHUREN-00035457<br><br>Bates: 002052–002053, 002055, 002058<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the kinds of testing, results, and documentation needed to support the grant of Emergency Use Authorization |

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| | | | | | | (EUA) for N95 respirators for use in healthcare settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002061 | 002064 | 2/21/2020 | Jeff Shuren, M.D., J.D. | RE: N95 Framework Documents for EUAs | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035482<br><br>Bates: 002061–002063<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the agency's regulation of N95 respirators, including deliberations about the issuance of Emergency Use Authorization (EUA) for general N95 respirators in healthcare settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002061–002063<br><br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinions/advice from FDA's Office of the Chief Counsel (OCC) regarding the regulation of N95 respirators in healthcare settings.<br><br>Bates: 002063–002064<br><br>Personal Privacy Information: The redacted information contains a Webex meeting number (access code) and meeting password. |
| 002065 | 002068 | 2/20/2020 | Jeff Shuren, M.D., J.D. | Re: COVID-19 updates: For today's 3:30 briefing | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035485<br><br>Bates: 002065–002067<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains draft notes for a briefing about the availability, distribution, and regulation of personal protective equipment (PPE), including N95 respirators, in the wake of the COVID-19 pandemic, the release of which |

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| | | | | | | would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002068<br><br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee. |
| 002069 | 002071 | 2/20/2020 | Jeff Shuren, M.D., J.D. | Re: 2/20/20 6 AM update | (b)(5) | FDA-CVD-SHURENJ-00035492<br><br>Bates: 002069–002070<br>Deliberative Process Privilege: The redacted information in this email exchange contains updates on the Centers for Disease Control and Prevention's (CDC) draft plans for surveillance of community transmission of SARS-CoV-2 and notes from FDA personnel about these draft plans, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002074 | 002077 | 2/18/2020 | Jeff Shuren, M.D., J.D. | RE: Seeking help from FDA | (b)(6) | FDA-CVD-SHURENJ-00035503<br><br>Bates: 002076-002077<br>Personal Privacy Information: The redacted information contains the private email address and phone number of a Hospital Authority employee. |
| 002078 | 002079 | 2/17/2020 | Jeff Shuren, M.D., J.D. | RE: 2019-nCoV RT-PCR Test EUA | (b)(5) | FDA-CVD-SHURENJ-00035505<br>Bates: 002078-002079<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the scope of the grant of Emergency Use Authorization (EUA) to the Centers for Disease Control and Prevention (CDC) for its test for SARS-CoV-2 and whether the EUA in existence at the time of this email exchange covered the production of CDC's tests by contract manufacturers, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 002080 | 002083 | 2/22/2020 | Jeff Shuren, M.D., J.D. | RE: [Time Sensitive Leadership Policy Question] Insertion of Section on FDA Regulated Products into SNS: Dear HCP letter for expired SNS PPE Letter | (b)(5) | FDA-CVD-SHURENJ-00035532<br><br>Bates: 002080–002083<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about a draft letter for healthcare providers that receive expired N95 respirators and other personal protective equipment (PPE) from the Strategic National Stockpile (SNS), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002084 | 002089 | 2/18/2020 | Jeff Shuren, M.D., J.D. | RE: N95 Respirators | (b)(5) | FDA-CVD-SHURENJ-00035549<br><br>Bates: 002084–002085, 002088<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about what kinds of testing, results, and documentation may be needed to support the grant of Emergency Use Authorization (EUA) for N95 respirators, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002090 | 002090 | 2/15/2020 | Jeff Shuren, M.D., J.D. | CDC 2019-nCoV Test | (b)(5) | FDA-CVD-SHURENJ-00035562<br>Bates: 002090<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about quality control issues related to the diagnostic test for SARS-CoV-2 developed by the Centers for Disease Control and Prevention (CDC) and testing of passengers aboard a cruise ship that was docked in Japan for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002091 | 002094 | 2/21/2020 | Jeff Shuren, M.D., J.D. | Fwd: N95 Framework Documents for EUAs | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035567<br><br>Bates: 002091–002093<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about documents relating to the |

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| | | | | | | issuance of Emergency Use Authorization (EUA) for N95 respirators being used in healthcare settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002091-002093<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinions/advice from FDA's Office of the Chief Counsel (OCC) regarding the issuance of Emergency Use Authorization (EUA) for N95 respirators being used in healthcare settings.<br><br>Bates: 002093<br>Personal Privacy Information: The redacted information contains a Webex meeting number (access code) and meeting password. |
| 002099 | 002099 | 2/17/2020 | Jeff Shuren, M.D., J.D. | 2019-nCoV RT-PCR Test EUA | (b)(5) | FDA-CVD-SHURENJ-00035608<br>Bates: 2099<br>Deliberative Process Privilege: The redacted information in this email exchange contains information about and a question relating to the scope of the Centers for Disease Control and Prevention's (CDC) grant of Emergency Use Authorization (EUA) for its test for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002100 | 002103 | 2/18/2020 | Jeff Shuren, M.D., J.D. | RE: N95 Respirators | (b)(5) | FDA-CVD-SHURENJ-00035630<br><br>Bates: 002100–002103<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the extent of testing and evidence of safety and effectiveness necessary to grant Emergency Use Authorization (EUA) to N95 respirators for use in healthcare settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive |

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| 002104 | 002107 | 2/15/2020 | Jeff Shuren, M.D., J.D. | RE: N95 Respirators | (b)(5) | FDA-CVD-SHURENJ-00035631<br><br>Bates: 002104–002107<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the extent of testing and evidence of safety and effectiveness necessary to grant Emergency Use Authorization (EUA) to N95 respirators for use in healthcare settings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002108 | 002109 | 2/15/2020 | Jeff Shuren, M.D., J.D. | RE: Urgent – Action needed | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035637<br>Bates: 002108<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the testing of passengers aboard a cruise ship for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002109<br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee. |
| 002112 | 002113 | 2/18/2020 | Jeff Shuren | Re: BARDA Coronavirus support | (b)(5) | FDA-CVD-SHURENJ-00035646<br><br>Bates: 002112<br><br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding BARDA Coronavirus support, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the |

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| 002114 | 002115 | 2/24/2020 | Jeff Shuren | RE: enforcement discretion request for COVID-19 for PHLs final.pdf | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035661<br><br>Bates: 002114<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding enforcement discretion request for COVID-19 for PHLs, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br>Bates: 002114<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel (OCC) regarding enforcement discretion request for COVID-19 for PHLs. |
| 002116 | 002116 | 2/14/2020 | Jeff Shuren | Re: [(b)(4)] | (b)(4) | FDA-CVD-SHURENJ-00035702<br>Bates: 002116<br>Confidential Commercial Information: The withheld information contains information regarding the inventory of a specific, named company's approved device. |
| 002117 | 002118 | 2/19/2020 | Jeff Shuren | RE: what do I need to know for AMA check in at 3:30 today? thanks. | (b)(5) | FDA-CVD-SHURENJ-00035703<br>Bates: 002117<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding pre-AMA check in briefing, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002119 | 002122 | 2/15/2020 | Jeff Shuren | RE: N95 Respirators | (b)(4), (b)(5) | FDA-CVD-SHURENJ-00035704<br><br>Bates: 002119–002122 |

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| | | | | | | Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding N95 Respirator EUAs, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002119<br>Confidential Commercial Information: The withheld information contains confidential commercial information regarding a specific company's device. |
| 002123 | 002125 | 2/20/2020 | Jeff Shuren | FW: Problems with CDC coronavirus test delay expanded US screening | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035705<br><br>Bates: 002123<br>Deliberative Process Privilege: The redacted information in this internal agency email exchange contains pre-decisional, internal deliberations regarding the Politico article "Problems with CDC coronavirus test delay expanded US screening," the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002123<br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee. |
| 002126 | 002128 | 2/20/2020 | Jeff Shuren | Fwd: N95 Framework Documents for EUAs | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035709<br><br>Bates: 002126-002127<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel (OCC) regarding N95 Framework Documents for EUAs.<br><br>Bates: 002126–002127<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding N95 Framework Documents for Emergency Use Authorizations (EUA), the release |

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| | | | | | | of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002128<br><br>Personal Privacy Information: The redacted information contains an FDA Webex access code and password. |
| 002129 | 002132 | 2/18/20 | | Senate HELP Bipar follow-up Questions | (b)(5) | FDA-CVD-SHURENJ-00035722.001<br>Attachment to FDA-CVD-SHURENJ-00035722<br><br>Bates: 002129–002132<br>Deliberative Process Privilege: The redacted information in this email attachment contains pre-decisional, internal deliberations regarding a draft slide deck for Senate HELP Bipartisan Staff Briefing on Supply Chain, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002133 | 002138 | 2/20/2020 | Jeff Shuren | COVID-19 Hearings | (b)(5) | FDA-CVD-SHURENJ-00035722<br><br>Bates: 002133–002138<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding COVID-19 Hearings and subsequent follow up questions, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002141 | 002143 | 2/19/2020 | Jeff Shuren | RE: [idsd] – CDC LOCS communication: Reminder: COVID-19 Diagnostic Testing | (b)(6) | FDA-CVD-SHURENJ-00035748<br><br>Bates: 002141<br>Personal Privacy Information: The redacted information contains a personal email address of FDA employee.<br><br>Bates: 002143 |

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| 002146 | 002146 | 2/13/2020 | Jeff Shuren | Re: N95 Respirators | (b)(4), (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035774<br>Bates: 002146<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding N95 Respirator Emergency Use Authorizations (EUA), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002146<br>Confidential Commercial Information: The withheld information contains confidential commercial information regarding a specific company's medical device.<br><br>Bates: 002146<br>Personal Privacy Information: The redacted information contains the private email address of the then FDA Commissioner. |
| 002147 | 002148 | 2/19/2020 | Jeff Shuren | Re: Today's CDC Call | (b)(5) | FDA-CVD-SHURENJ-00035782<br><br>Bates: 002147<br><br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding medical device distribution plans discussed on a Centers for Disease Control and Prevention (CDC) conference call, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002149 | 002151 | 2/20/2020 | Jeff Shuren | Fwd: N95 Framework Documents for EUAs | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035791<br><br>Bates: 002149–002150<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding N95 |

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| | | | | | | Framework Documents for Emergency Use Authorizations (EUA), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations.<br><br>Bates: 002150<br>Personal Privacy Information: The redacted information contains an FDA Webex access code and FDA Webex password. |
| 002152 | 002159 | 2/20/2020 | Jeff Shuren | RE: COVID-19 Hearings | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035793<br><br>Bates: 002152–002158<br><br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding prep questions for COVID-19 Congressional Hearings, draft responses to briefing follow up questions, as well as deliberations on how to prepare and proceed after hearings and briefings, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002153, 002154, 002158<br><br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee. |
| 002160 | 002166 | 2/18/2020 | Jeff Shuren | RE: N95 Respirators | (b)(5) | FDA-CVD-SHURENJ-00035799<br><br>Bates: 002160–002166<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about what kinds of testing, results, and documentation may be needed to support the grant of Emergency Use Authorization (EUA) for N95 respirators, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and |

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| 002168 | 002169 | 2/20/2020 | Jeff Shuren | RE: Coronavirus Request | (b)(5) | FDA-CVD-SHURENJ-00035816<br><br>Bates: 002168<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding a draft coronavirus public health emergency budget request, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002170 | 002172 | 2/17/2020 | Jeff Shuren | RE: N95 Respirators | (b)(5) | FDA-CVD-SHURENJ-00035828<br><br>Bates: 002170–002172<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding N95 Respirator Emergency Use Authorizations (EUAs), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002170<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion and advice from FDA's Office of the Chief Counsel (OCC) regarding N95 Respirator Emergency Use Authorizations (EUA). |
| 002173 | 002174 | 2/15/2020 | Jeff Shuren | Re: N95 Respirators | (b)(5) | FDA-CVD-SHURENJ-00035831<br>Bates: 002173-002174<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding N95 Respirator Emergency Use Authorizations (EUA), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 002175 | 002176 | 2/5/2020 | Jeff Shuren | FW: Thank you EUA Team | (b)(6) | FDA-CVD-SHURENJ-00035871<br><br>Bates: 002175<br>Personal Privacy Information: The redacted information contains the private email address of the then FDA Commissioner. |
| 002177 | 002178 | 2/5/2020 | Jeff Shuren | Fwd: News from the MFDS in Korea | (b)(6) | FDA-CVD-SHURENJ-00035880<br><br>Bates: 002177<br><br>Personal Privacy Information: The redacted information contains the private email addresses of various medical field contractors and employees. |
| 002179 | 002194 | 2/6/2020 | Jeff Shuren | Re: (b)(4) | (b)(4), (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035899<br><br>Bates: 002179–-002194<br><br>Confidential Commercial Information: The redacted information contains information regarding an investigation into a specific, named company's device.<br><br>Bates: 002179, 002181–002183<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding an investigation concerning a specific company's device, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002181<br>Personal Privacy Information: The redacted information contains a private email address of an FDA employee.<br><br>Bates: 002183<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel |

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| | | | | | | (OCC) regarding coronavirus testing equipment and materials and an investigation concerning a specific company's device. |
| 002195 | 002196 | 2/13/2020 | Jeff Shuren | RE: Greetings | (b)(6) | FDA-CVD-SHURENJ-00035908<br>Bates: 002195-002196<br>Personal Privacy Information: The redacted information contains the email address and phone numbers of a Thermo Fisher Scientific Inc. employee. |
| 002197 | 002199 | 2/13/2020 | Jeff Shuren | FW: Public health labs report problems with coronavirus test | (b)(5) | FDA-CVD-SHURENJ-00035919<br><br>Bates: 002197<br><br>Deliberative Process Privilege: The redacted information in this internal agency email exchange contains pre-decisional, internal deliberations regarding the Politico article "Problems with CDC coronavirus test delay expanded US screening," the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002200 | 002212 | 2/6/2020 | Jeff Shuren | RE: (b)(4) | (b)(4), (b)(5), (b)(6) | FDA-CVD-SHURENJ-00035935<br><br>Bates: 02200<br>Personal Privacy Information: The redacted information contains a private email address of an FDA employee.<br><br>Bates: 02202<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel (OCC) regarding an investigation concerning a specific company's device.<br><br>Bates: 002200–002212<br>Confidential Commercial Information: The withheld information contains confidential commercial information regarding an investigation concerning a specific company's device.<br><br>Bates: 002200–002202 |

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| | | | | | | Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding an investigation concerning a specific company's device, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002213 | 002214 | 2/4/2020 | Jeff Shuren | RE: Coronavirus Leadership Update February 4 2020 | (b)(5) | FDA-CVD-SHURENJ-00035943<br>Bates: 002213-002214<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding coronavirus-related device concerns relevant to FDA's Center for Devices and Radiologic Health (CDRH)'s leadership, including statements about how CDRH might address some concerns and seeking further input from other agency employees, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002215 | 002220 | 2/8/2020 | Jeff Shuren | Re: (b)(4) | (b)(4), (b)(6) | FDA-CVD-SHURENJ-00035990<br>Bates: 002215-002220<br>Confidential Commercial Information: The withheld information contains specific information about a device designed by a specific firm that was interested in screening for Coronavirus.<br><br>Bates: 002216, 002219<br>Personal Privacy Information: The redacted information contains the private email address of an employee for a private firm.<br><br>Bates: 002220<br>Personal Privacy Information: The redacted information contains personal information regarding an individual's employment status. |
| 002221 | 002222 | 2/3/2020 | Jeff Shuren | RE: Coronavirus testing equipment and materials | (b)(6) | FDA-CVD-SHURENJ-00035998<br>Bates: 002222<br>Personal Privacy Information: The redacted information contains a private email address for the New York City Deputy Mayor for Health & Human Services. |

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| 002223 | 002224 | 2/3/2020 | Jeff Shuren | RE: CDC wants to distribute coronavirus diagnostic test by end of week | (b)(5) | FDA-CVD-SHURENJ-00036005<br>Bates: 002223<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding the potential Centers for Disease Control and Prevention's (CDC) distribution of Coronavirus diagnostic test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002232 | 002232 | 2/13/2020 | Jeff Shuren | Re: Greetings | (b)(6) | FDA-CVD-SHURENJ-00036075<br>Bates: 002232<br>Personal Privacy Information: The redacted information contains the private email address and phone numbers of a Thermo Fisher Scientific Inc. employee. |
| 002233 | 002235 | 2/13/2020 | Jeff Shuren | Re: 2/13/20 6 AM update- FDA ACTION REQUIRED | (b)(5) | FDA-CVD-SHURENJ-00036083<br><br>Bates: 002233–002235<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding FDA's discussion of the status of activities on diagnostics, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002238 | 002238 | 2/4/2020 | Jeff Shuren | Meeting Today on Coronavirus | (b)(5) | FDA-CVD-SHURENJ-00036104<br>Bates: 002238<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding potential information needed for a Coronavirus pre-meeting briefing, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002239 | 002243 | 2/4/2023 | Jeff Shuren | RE: Coronavirus Leadership Update February 4 2020 | (b)(5) | FDA-CVD-SHURENJ-00036114<br><br>Bates: 002239–002243<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding coronavirus- |

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| | | | | | | related device concerns relevant to FDA's Center for Devices and Radiologic Health (CDRH)'s leadership, including statements about how CDRH might address some concerns and seeking further input from other agency employees, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the Agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002244 | 002245 | 2/12/2020 | Jeff Shuren | Re: February 21st Meeting | (b)(6) | FDA-CVD-SHURENJ-00036131<br>Bates: 002244-002245<br>Personal Privacy Information: The redacted information contains the private email address and phone numbers of a Thermo Fisher Scientific Inc. employee. |
| 002246 | 002247 | 2/11/2020 | Jeff Shuren | Fwd: implantable Remodulin Pump | (b)(6) | FDA-CVD-SHURENJ-00036146<br><br>Bates: 002246–002247<br>Personal Privacy Information: The redacted information contains private, personal medical information about the writer's family member and their private, personal experience with medical devices.<br><br>Bates: 002246, 002247<br>Personal Privacy Information: The redacted information contains a private, personal email address. |
| 002248 | 002249 | 2/11/2020 | Jeff Shuren | Re: implantable Remodulin Pump | (b)(6) | FDA-CVD-SHURENJ-00036154<br><br>Bates: 002248–002249<br>Personal Privacy Information: The redacted information contains a private, personal email address.<br><br>Bates: 002248–002249<br>Personal Privacy Information: The redacted information contains private medical information about the writer's family member and their private, personal experience with medical devices. |
| 002250 | 002251 | 2/12/2020 | Jeff Shuren | RE: Plz this: Info on US PPE Firms from today's calling | (b)(4), (b)(5) | FDA-CVD-SHURENJ-00036155<br>Bates: 002250-002251<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations related to whether or |

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| 002253 | 002254 | 2/3/2020 | Jeff Shuren | FW: Coronavirus testing equipment and materials | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036186<br><br>Bates: 002253<br><br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding a draft response letter to Dr. Perea-Henze, the Deputy Major of Health & Human Services of NYC related to coronavirus testing equipment and materials, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002254<br>Personal Privacy Information: The redacted information contains the private email address of Dr. Raul Perea-Henze. |
| 002255 | 002258 | 2/4/2020 | Jeff Shuren | RE: Coronavirus Leadership Update February 4 2020 | (b)(5) | FDA-CVD-SHURENJ-00036194<br><br>Bates: 002255–002257<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding coronavirus-related device concerns relevant to FDA's Center for Devices and Radiologic |

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| | | | | | | Health (CDRH)'s leadership, including statements about how CDRH might address some concerns and seeking further input from other agency employees, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002259 | 002262 | 2/10/2020 | Jeff Shuren | RE: 2/10/20 6 AM update | (b)(5) | FDA-CVD-SHURENJ-00036212<br><br>Bates: 002259–002262<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding updates on various internal matters of interest related to the then status of activities on diagnostics, and deliberations related to devices, diagnostics, and coronavirus, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002263 | 002264 | 2/6/2020 | Jeff Shuren | RE: Inquiry | (b)(6) | FDA-CVD-SHURENJ-00036243<br>Bates: 002263-002264<br>Personal Privacy Information: The redacted information contains the private email address and phone numbers of Thermo Fisher Scientific Inc. employee. |
| 002267 | 02267 | 1/30/2020 | Jeff Shuren | Re: Confidential Privileged Draft sent to OCC | (b)(5) | FDA-CVD-SHURENJ-00036404<br>Bates: 002267<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding draft language that FDA's Center for Devices and Radiological Health (CDRH) sent to FDA's Office of the Chief Counsel (OCC) for review, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002268 | 002272 | 1/30/2020 | Jeff Shuren | RE: 9 am Commissioner Call – 1/30/2020 | (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036469<br><br>Bates: 002268–002272<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding discussion |

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| | | | | | | points for a conference call with the commissioner on January 30, 2020, including deliberations such as then estimates regarding the amount of employee overtime hours and money needed as part of a proposal for FDA employees to work with developers on assays and pre-Emergency Use Authorizations (EUA), as well as other proposed considerations for handling device shortages, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002269-002270<br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee. |
| 002273 | 002275 | 1/22/2020 | Jeff Shuren | Re: Cardinal Heath Surgical Gowns: leadership updates 1-22-2020 | (b)(4), (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036490<br><br>Bates: 002273,002275<br><br>Confidential Commercial Information: The withheld information contains confidential commercial information regarding an investigation concerning a specific company's surgical gown device, including the quantity of the device under discussion and other organizations that might be impacted by a shortage of the device.<br><br>Bates: 002273–002274<br><br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding surgical gown shortages, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002275<br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee. |

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| 002276 | 002278 | 1/29/2020 | Jeff Shuren | Re: Request for Input for 29 Jan Update on FDA activities related to 2019-nCoV response – input needed by 3:00 PM | (b)(5) | FDA-CVD-SHURENJ-00036507<br><br>Bates: 002278<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding internal strategies for updates on FDA activities related to 2019-nCoV response, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002280 | 002282 | 1/22/2020 | Jeff Shuren | RE: FYI.>>> Amb Sondland and Grenell, EU Med Device Updates | (b)(5) | FDA-CVD-SHURENJ-00036592<br><br>Bates: 002280–002282<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations for how to address medical device information from the European Union, including draft talking points to provide information sought by then Ambassador Grenell, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002283 | 002287 | 1/31/2020 | Jeff Shuren | Re: URGENT: Coronavirus Data Call | (b)(5) | FDA-CVD-SHURENJ-00036611<br><br>Bates: 002283–002286<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding a coronavirus data call, how to fund costs related to device shortages caused by the coronavirus, and other potential cost concerns related to coronavirus, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002288 | 002289 | 1/28/2020 | Jeff Shuren | RE: nCoV 1/28/20 8 AM update: | (b)(5) | FDA-CVD-SHURENJ-00036623<br>Bates: 002288-002289<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding coronavirus |

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| | | | | | | updates on January 28, 2020 concerning the status of activities on diagnostics, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002290 | 002297 | 1/27/2020 | Jeff Shuren | Re: FDA Commissioner and staff | (b)(4), (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036645<br><br>Bates: 002290–002291<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel (OCC) to the FDA Commissioner and staff regarding FDA's potential response to communications received by FDA.<br><br>Bates: 002291–002297<br>Confidential Commercial Information: The withheld information contains confidential commercial information regarding an investigation concerning a specific company's device.<br><br>Bates: 002294<br>Personal Privacy Information: The redacted information contains the private phone number of a third party. |
| 002298 | 002300 | 1/21/2020 | Jeff Shuren | RE: (b)(5) for Commissioner's Briefing | (b)(5), (b)(6) | Bates: 002299–002300<br><br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee.<br><br>Bates: 002299–002300<br><br>Confidential Commercial Information: The redacted information contains confidential commercial information related to a sterilization company's operations.<br><br>Bates: 002298-002300<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding material for |

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| | | | | | | a commissioner's briefing in January 2020, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002301 | 002303 | 1/21/2020 | Jeff Shuren | Re: Cardinal Heath Surgical Gowns: leadership updates 1-21-2020 | (b)(4), (b)(5), (b)(6) | FDA-CVD-SHURENJ-00036694<br><br>Bates: 002302<br><br>Confidential Commercial Information: The redacted information relates to companies who provide sterilization services and testing.<br><br>Bates: 002302<br><br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding surgical gowns sterilization and leadership updates, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002303<br><br>Personal Privacy Information: The redacted information contains the private phone number of an FDA employee. |
| 002304 | 002304 | 1/21/2020 | Jeff Shuren | RE: Coronavirus | (b)(5) | FDA-CVD-SHURENJ-00036719<br>Bates: 002304<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding diagnostic testing activities with CDC, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002307 | 002307 | 2/3/2020 | Jeff Shuren | RE: CDC wants to distribute coronavirus | (b)(5) | FDA-CVD-SHURENJ-00039394<br>Bates: 002307 |

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| | | | | diagnostic test by end of week | | Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding the Centers for Disease Control and Prevention's (CDC) potential coronavirus diagnostic test distribution, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002309 | 002309 | 2/12/2020 | Jeff Shuren | RE: Plz use this: Info on US PPE firms from today's calling | (b)(4) | FDA-CVD-SHURENJ-00039599<br>Bates: 002309<br>Confidential Commercial Information: The redacted information relates to the name of a company that might have been considering an Emergency Use Authorization (EUA) submission. |
| 002317 | 002317 | 2/24/2020 | Jeff Shuren | Re: Public health labs press FDA to allow homegrown coronavirus tests | (b)(5) | FDA-CVD-SHURENJ-00043594<br>Bates: 002317<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding homegrown coronavirus tests, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002351 | 002354 | 2/28/2020 | Jeff Shuren | NYS | (b)(4), (b)(5) | FDA-CVD-SHURENJ-00043781<br><br>Bates: 002351, 002354<br>Confidential Commercial Information: The redacted information relates to specific information in and concerning Wadsworth's Emergency Use Authorization (EUA) submission.<br><br>Bates: 002351<br><br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding thoughts and considerations about Wadsworth's EUA submission, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 002356 | 002356 | 2/16/2020 | Jeff Shuren | Re: CDC 2019-nCoV Test | (b)(4), (b)(5), (b)(6) | FDA-CVD-SHURENJ-00043896<br>Bates: 002356<br>Confidential Commercial Information: The redacted information relates to specific information in and concerning the Centers for Disease Control and Prevention's (CDC) Emergency Use Authorization (EUA) submission.<br><br>Bates: 002356<br>Deliberative Process Privilege: The redacted information in this internal email exchange contains pre-decisional, internal deliberations regarding CDC 2019-nCoV testing, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002356<br>Personal Privacy Information: The redacted information contains the private email address of the FDA Commissioner. |

* Page prefix is FDACDRH-p4-AO
** Exemption codes refer to sections of the Freedom of Information Act, *see* 5 U.S.C. § 552(b).

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CONFIDENTIAL SETTLEMENT COMMUNICATION PROTECTED BY FED. RULE OF EVIDENCE 408

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***Vaughn Index for FOIA Request No. 2020-2531***
***American Oversight v. HHS et. al., Case No. 1:20-cv-0947 (D.D.C.)***

| Doc Start* | Doc. End* | Date of Redacted Doc | Author(s) of Redacted Doc | Document Title | Exemption(s)** | Explanation |
|---|---|---|---|---|---|---|
| 002358 | 002362 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: for OMB Review: Diagnostics (FDA Guidance) | (b)(5), (b)(6) | FDA-CVD-STENZELT-00013090<br><br>Bates: 002359<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the substance of documents generated by FDA and other agencies that provide guidance on diagnostic testing for SARS-Cov-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002362<br><br>Personal Privacy Information: The redacted information contains the email address of an Office of Management and Budget (OMB) employee. This email address was also withheld pursuant to a privilege asserted by the Executive Office of the President (EOP). |
| 002363 | 002364 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: If possible to review by 9pm | (b)(5) | FDA-CVD-STENZELT-00013183<br>Bates: 002363-002364<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations among FDA employees regarding draft talking points for the Vice President and Secretary of the Department of Health and Human Services (HHS) about testing for SARS-CoV-2, the release of which |

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| | | | | | | would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002365 | 002368 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Questions | (b)(5), (b)(6) | FDA-CVD-STENZELT-00024860<br><br>Bates: 002366 – 002368<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the ability of clinical entities engaged in the development of tests for SARS-CoV-2 to use certain test kits to develop their assays, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002368<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee. |
| 002369 | 002371 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: IDT lot numbers | (b)(4) | Bates: 002370 – 002371<br><br>Confidential Commercial Information: The redacted information contains confidential commercial information related to lot numbers for test kits for SARS-CoV-2 developed by Integrated DNA Technologies (IDT). The release of this information would inform competitors about IDT's operations and lead to predictable harm. |
| 002373 | 002376 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)- | (b)(6) | FDA-CVD-STENZELT-00024952<br><br>Bates: 002376 |

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| | | | | PCR Diagnostic Panel | | Personal Privacy Information: The redacted information contains the private phone number of a New York State Department of Health Wadsworth Center employee. |
| 002377 | 002378 | 2/27/2020 | Timothy Stenzel, M.D., Ph.D. | RE: IDT Kit CoA, Lot number, inventory, etc | (b)(4), (b)(6) | FDA-CVD-STENZELT-00024997<br><br>Bates: 002377 – 002378<br>Confidential Commercial Information: The redacted information relates to the inventory and lot numbers of SARS-CoV-2 test kits developed by Integrated DNA Technologies (IDT). The release of this information would inform competitors about IDT's operations and lead to predictable harm.<br><br>Bates: 002377 – 002378<br>Personal Privacy Information: The redacted information contains the private email address and phone numbers of an IDT Technologies employee. |
| 002380 | 002385 | 2/27/2020 | Timothy Stenzel, M.D., Ph.D. | RE: For OMB Review: Diagnostics (FDA Guidance) | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025033<br><br>Bates: 002382<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the substance of documents generated by FDA and other agencies that provide guidance on diagnostic testing for SARS-Cov-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002385<br>Personal Privacy Information: The redacted information contains the email address of an Office of Management and Budget (OMB) employee. This information was also withheld |

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| | | | | | | pursuant to a privilege asserted by the Executive Office of the President (EOP). |
| 002386 | 002388 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Question | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025097<br><br>Bates: 002388<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee.<br><br>Bates: 002386 – 002388<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the ability of clinical entities engaged in the development of tests for SARS-CoV-2 to use certain test kits to develop their assays, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002389 | 002395 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: For OMB Review: Diagnostics (FDA Guidance) | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025122<br><br>Bates: 002392<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the substance of documents generated by FDA and other agencies that provide guidance on diagnostic testing for SARS-Cov-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002395<br>Personal Privacy Information: The redacted information contains the email address of an Office of Management and |

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| | | | | | | Budget (OMB) employee. This information was also withheld pursuant to a privilege asserted by the Executive Office of the President (EOP). |
| 002396 | 002398 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | Fwd: SEATTLE Flu Study Lab Result | (b)(6) | FDA-CVD-STENZELT-00025134<br><br>Bates: 002396 – 002398<br>Personal Privacy Information: The redacted information contains the private email addresses of a Seattle Children's Hospital employee and a Bedford employee, and the private phone numbers of Seattle/King County, Washington State employees. The redacted information also contains a Zoom meeting ID number and call-in information. |
| 002399 | 002401 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Questions | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025166<br><br>Bates: 002400<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee.<br><br>Bates: 002399 – 002400<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the ability of clinical entities engaged in the development of tests for SARS-CoV-2 to use certain test kits to develop their assays, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002405 | 002410 | 2/26/2020 | Timothy Stenzel, M.D., Ph.D. | RE: LGC | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025198<br><br>Bates: 002405 – 002407 |

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| | | | | | | Confidential Commercial Information: The redacted information contains confidential commercial information related to the SARS-CoV-2 test kit production capabilities of LGC Group and standing orders it has with the federal government. The release of this information would inform competitors about LGC Group's operations and lead to predictable harm.<br><br>Bates: 002405 – 002410<br>Personal Privacy Information: The redacted information contains the private email addresses and work and cell phone numbers of LGC Group employees. The redacted information also contains the private phone number of an FDA employee. |
| 002411 | 002413 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025205<br><br>Bates: 002412<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the American Clinical Laboratories Association (ACLA) Annual Meeting, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002413<br>Personal Privacy Information: The redacted information contains the private cell phone number of an ACLA member. |
| 002414 | 002415 | 2/28/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Questions | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025248<br><br>Bates: 002415<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the ability of clinical entities engaged in the development of tests for SARS-CoV-2 to use certain test kits to develop their assays, the |

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| | | | | | | release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002415<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee. |
| 002416 | 002419 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: SEATTLE Flu Study Lab Result | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025269<br>Bates: 002416<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains deliberations about the dissemination of results obtained from the Seattle Flu Study's (SFS) test for SARS-CoV-2, and how these results relate to SFS's application for Emergency Use Authorization (EUA) for their test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002416 – 002419<br>Personal Privacy Information: The redacted information contains the private email addresses of Seattle Children's Hospital employees and a Bedford employee, the private phone numbers of Seattle/King County, Washington State employees, and Zoom meeting ID numbers and call-in information. |
| 002420 | 002425 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: RE: RE: LabCorp update | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025329<br><br>Bates: 002420 – 002424<br>Personal Privacy Information: The redacted information contains the private email addresses and cell phone numbers of |

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| | | | | | | LabCorp employees, and the private home address of a LabCorp employee.<br><br>Bates: 002420, 002421, 002423, 002424<br>Confidential Commercial Information: The redacted information contains confidential commercial information related to LabCorp's SARS-CoV-2 testing capacity. The redacted information also mentions a third party entity. The release of this information would inform competitors about LabCorp's operations and the operations of this third party entity and this would lead to predictable harm. |
| 002426 | 002428 | 2/27/2020 | Timothy Stenzel, M.D., Ph.D. | Re: (b)(4) | (b)(4) | FDA-CVD-STENZELT-00025372<br><br>Bates: 002426<br>Confidential Commercial Information: The redacted information relates to the name of a company from which FDA discussed buying SARS-CoV-2 test kits. The release of this information would inform this company's competitors about its operations and lead to predictable harm. |
| 002429 | 002432 | 2/29/2020 | Timothy Stenzel, M.D., Ph.D. | RE: RE: RE: LabCorp update | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025400<br><br>Bates: 002429 – 002432<br>Personal Privacy Information: The redacted information contains the private email addresses of LabCorp employees, the private cell phone number of a LabCorp employee, and the private home address of a LabCorp employee.<br><br>Bates: 002429, 002431 – 002432<br>Confidential Commercial Information: The redacted information contains confidential commercial information related to the the name of a third party company. The release of this information would inform this company's competitors about its operations, and this would lead to predictable harm. |

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| 002433 | 002438 | 2/27/2020 | Timothy Stenzel, M.D., Ph.D. | Must haves this morning | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025404<br><br>Bates: 002435, 002436, 002437 – 002438<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations between FDA employees, and FDA and CDC employees, regarding the status of quality control studies conducted on tests for SARS-CoV-2 developed by the Center for Disease Control and Prevention (CDC) and Integrated DNA Technologies (IDT), the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002435 – 002436<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to the lot numbers of IDT's SARS-CoV-2 test kits. The release of this information would inform competitors about IDT's operations and lead to predictable harm. |
| 002439 | 002446 | 2/26/2020 | Timothy Stenzel, M.D., Ph.D. | Quality Control Testing | (b)(5) | FDA-CVD-STENZELT-00025404.0001 Attachment of FDA-CVD-STENZELT-00025404<br><br>Bates: 002439 – 002446<br>Deliberative Process Privilege: The redacted information in this draft document contains internal deliberations regarding the Standard Operating Procedures (SOP) for Quality Control Testing of the CDC's 2019-nCoV rRt-PCR Primer and Probes, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 002447 | 002453 | 2/26/2020 | Timothy Stenzel, M.D., Ph.D. | RE: LGC | (b)(4), (b)(6) | FDA-CVD-STENZELT-00025442<br><br>Bates: 002447 – 002453<br>Personal Privacy Information: The redacted information contains the private email addresses of LGC Group employees, the private telephone and cell phone number of a LGC Group employee, and the private cell phone number of an FDA employee.<br><br>Bates: 002447 – 002450<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to potential orders of test kits for SARS-CoV-2 from, and the production capacity of LGC Group. The release of this information would inform LGC Group's competitors about its operations and would lead to predictable harm. |
| 002457 | 002459 | 2/18/2020 | Timothy Stenzel, M.D., Ph.D. | FW: CDC Coronavirus assay question | (b)(5) | FDA-CVD-STENZELT-00025459<br><br>Bates: 002457 – 002459<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about authorizing the distribution of the CDC's SARS-CoV-2 test to non-public health labs, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002460 | 002461 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | Re: COVID-19 Diagnostic Validation materials (update Feb 24, 2020) | (b)(4), (b)(5), (b)(6) | FDA-CVD-STENZELT-00025466<br><br>Bates: 002460<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to the name of a third party company. The release of this information |

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| | | | | | | would this third party company's competitors about its operations and would lead to predictable harm.<br><br>Bates: 002460<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the availability and access to SARS-CoV-2 viral RNA and inactivated virus, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002461<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee. |
| 002462 | 002463 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | Re: COVID-19 Diagnostic Validation materials (update Feb 24, 2020) | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025468<br>Bates: 002462--002463<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the availability and access to SARS-CoV-2 viral RNA and inactivated virus, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002463<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee. |

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| 002464 | 002467 | 2/18/2020 | Timothy Stenzel, M.D., Ph.D. | FW: BY Noon tomorrow | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025469<br><br>Bates: 002464 – 002466<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the distribution of CDC's SARS-CoV-2 assay to clinical labs in light of governing regulatory requirements, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002467<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee. |
| 002468 | 002470 | 2/18/2020 | Timothy Stenzel, M.D., Ph.D. | RE: CDC Coronavirus assay question | (b)(5) | FDA-CVD-STENZELT-00025477<br><br>Bates: 002468 – 002469<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the distribution of CDC's SARS-CoV-2 assay to non-public health labs in light of governing regulatory requirements, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002473 | 002478 | 2/22/2020 | Timothy Stenzel, M.D., Ph.D. | Fwd: Cut-off change- Number of public health labs that verified CDC panel for use | (b)(5) | FDA-CVD-STENZELT-00025498<br><br>Bates: 002473, 002475, 002477, 002478<br><br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about a |

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| 002479 | 002480 | 2/24/2020 | Timothy Stenzel, M.D., Ph.D. | Re: COVID-19 Diagnostic Validation materials (update Feb 24, 2020) | (b)(4), (b)(5), (b)(6) | FDA-CVD-STENZELT-00025516<br>Bates: 002479<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the availability and access to SARS-CoV-2 viral RNA and inactivated virus, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002479<br>Confidential Commercial Information: The redacted information contains confidential commercial information regarding the name of a third-party company. The release of this information would inform competitors about this company's operations and would lead to predictable harm.<br><br>Bates: 002479<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee. |
| 002481 | 002486 | 2/22/2020 | Timothy Stenzel, M.D., Ph.D. | Re: Cut-off change – Number of public health labs that verified CDC panel for use | (b)(5) | FDA-CVD-STENZELT-00025517<br><br>Bates: 002483, 002485<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about a |

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| | | | | | | discussion between FDA and CDC regarding the number of labs/facilities that verified CDC's SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002487 | 002490 | 2/17/2020 | Timothy Stenzel, M.D., Ph.D. | RE: BY noon tomorrow | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025520<br><br>Bates: 002487 – 002489<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the distribution of CDC's SARS-CoV-2 assay to non-public health labs in light of governing regulatory requirements, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002490<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee. |
| 002491 | 002494 | 2/25/2020 | Timothy Stenzel, M.D., Ph.D. | RE: CDC | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025522<br><br>Bates: 002491 – 002492<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about changes to the Emergency Use Authorization (EUA) of CDC's SARS-CoV-2 test regarding the use of primers and probe reagents, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| | | | | | | Bates: 002493<br>Personal Privacy Information: The redacted information contains a Webex meeting number access code and password. |
| 002495 | 002498 | 2/18/2020 | Timothy Stenzel, M.D., Ph.D. | FW: BY noon tomorrow | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025534<br><br>Bates: 002495 – 002498<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the distribution of CDC's SARS-CoV-2 assay to clinical labs in light of governing regulatory requirements, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002498<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee. |
| 002499 | 002503 | 2/19/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission | (b)(5) | FDA-CVD-STENZELT-00025548<br><br>Bates: 002500 – 002503<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the issuance of Emergency Use Authorization (EUA) for CDC's SARS-CoV-2 test so that it can be used for the surveillance of community transmission of COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 002504 | 002508 | 2/19/2020 | Timothy Stenzel, M.D., Ph.D. | RE: COVID_sentinel surveillance Feb 18,2020 to FDA.docx | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025560<br><br>Bates: 002505, 002506, 002508<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about CDC's plan to submit a second application for Emergency Use Authorization (EUA) of its SARS-CoV-2 test for the surveillance of community transmission of COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002505<br>Attorney-Client Privilege: The redacted information contains embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel (OCC) regarding who to include on a call related to CDC's new application for Emergency Use Authorization (EUA) for its SARS-CoV-2 test.<br><br>Bates: 002506 – 002508<br>Commercial Confidential Information: The redacted information contains confidential commercial information regarding a copyrighted article pertaining to CDC's plans for surveillance of community transmission of SARS-CoV-2. The release of this information would inform competitors about CDC's operations and would lead to predictable harm. |
| 002509 | 002517 | 2/21/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Cut-off change – lot release testing criteria | (b)(5) | FDA-CVD-STENZELT-00025563<br><br>Bates: 002509 – 002517<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the primers and reagent probes used in CDC's test for SARS-CoV-2 and the |

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| 002518 | 002522 | 2/20/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Cut-off change – Number of public health labs that verified CDC panel for use | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025564<br><br>Bates: 002519, 002521, 002522<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about a discussion between FDA and CDC regarding the number of labs/facilities that verified CDC's SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002518<br>Personal Privacy Information: The redacted information contains the private cell phone number of an FDA employee. |
| 002523 | 002524 | 2/22/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Follow Up | (b)(5) | FDA-CVD-STENZELT-00025570<br>Bates: 002523<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about data relating to one of the primers used in CDC's test for SARS-CoV-2, the development of a rapid test for SARS-CoV-2, and the scheduling of a conference call, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 002525 | 002526 | 2/18/2020 | Timothy Stenzel, M.D., Ph.D. | FW: CDC Coronavirus assay question | (b)(5) | FDA-CVD-STENZELT-00025600<br>Bates: 002525-002526<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the distribution of CDC's test for SARS-CoV-2 to non-public health laboratories in light of governing regulatory requirements, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002527 | 002531 | 2/20/2020 | Timothy Stenzel, M.D., Ph.D. | FW: Cut-off change – Number of public health labs that verified CDC panel for use | (b)(5) | FDA-CVD-STENZELT-00025605<br><br>Bates: 002528, 002530, 002531<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the number of public health laboratories that had been able to validate CDC's test for SARS-CoV-2, and a discussion between FDA and CDC regarding the number of labs/facilities that verified CDC's SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002532 | 002534 | 2/18/2020 | Timothy Stenzel, M.D., Ph.D. | 2019-nCoV Diagnostics Landscape-POC 2-18-20.pptx; Diagnostics for Coronavirus Timeline Projection v4 clean.docx | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025610<br><br>Bates: 002532 – 002533<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the distribution of SARS-CoV-2 viral RNA to entities developing tests for COVID-19 and the landscape at the time for developing handheld, point-of-care diagnostic tests for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise |

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| 002535 | 002541 | 2/17/2020 | Rosemary Humes, M.S., M.T. (ASCP) | 2019-nCoV Diagnostics Landscape POC 2-18-20 | (b)(5) | FDA-CVD-STENZELT-00025610.0001<br>Attachment of FDA-CVD-STENZELT-00025610<br><br>Bates: 002535 – 002541<br>Deliberative Process Privilege: The redacted information in this email attachment is a draft slide deck with information about various entities' development of diagnostic assays for SARS-CoV-2, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002542 | 002544 | 2/17/2020 | Rosemary Humes, M.S., M.T. (ASCP) | Diagnostics for Coronavirus Timeline Projection | (b)(5) | FDA-CVD-STENZELT-00025610.0002<br>Attachment of FDA-CVD-STENZELT-00025610<br><br>Bates: 002542 – 002544<br>Deliberative Process Privilege: The redacted information in this email attachment is a draft document with information intended to supplement FDA's slide deck discussing its strategy for the development of point-of-care SARS-CoV-2 tests in non-public health laboratories, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 002545 | 002548 | 2/19/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Outcomes of FDA/CDC Discussion of Surveillance for Community Transmission | (b)(5) | FDA-CVD-STENZELT-00025625<br><br>Bates: 002545 – 002548<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the issuance of Emergency Use Authorization (EUA) for CDC's SARS-CoV-2 test so that it can be used for the surveillance of community transmission of COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002549 | 002551 | 2/18/2020 | Timothy Stenzel, M.D., Ph.D. | RE: CDC Coronavirus assay question | (b)(5) | FDA-CVD-STENZELT-00025629<br><br>Bates: 002549 – 002550<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the distribution of CDC's SARS-CoV-2 assay to clinical labs in light of governing regulatory requirements, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002552 | 002555 | 2/18/2020 | Timothy Stenzel, M.D., Ph.D. | RE: By noon tomorrow? | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025677<br><br>Bates: 002552 – 002555<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the distribution of CDC's assay for SARS-CoV-2 to clinical laboratories in light of the governing regulatory requirements, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise |

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| | | | | | | the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002555<br>Personal Privacy Information: The redacted information contains the private cell phone number of a Department of Health and Human Services (HHS) employee. |
| 002559 | 002563 | 2/22/2020 | Timothy Stenzel, M.D., Ph.D. | RE: Coronavirus and MERS culturing | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025683<br><br>Bates: 002562<br>Confidential Commercial Information: The redacted information contains confidential commercial information that relates to a submission of information from a potential developer of cultures of SARS-CoV-2 and MERS. The release of this information would inform competitors about this entity's operations and would lead to predictable harm.<br><br>Bates: 002562<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the pathogens FDA would like to see developers of tests for SARS-CoV-2 culture while they develop their diagnostic assays, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |
| 002564 | 002574 | 2/23/2020 | Timothy Stenzel, M.D., Ph.D. | RE: ACTION NEEDED: DRAFT CDC EUA Request for Sentinel Surveillance Activities | (b)(5) | FDA-CVD-STENZELT-00025713<br><br>Bates: 002567, 002569 – 002573<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the CDC's application for Emergency Use Authorization (EUA) of its test for SARS-CoV-2 for surveillance of community transmission of |

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| | | | | | | COVID-19, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002567, 002569 – 002573<br>Attorney-Client Privilege: The redacted information in this email exchange contains legal opinions and communications from the Office of the Chief Counsel (OCC) related to CDC's application for Emergency Use Authorization (EUA) for its test for SARS-CoV-2 for surveillance of community transmission of COVID-19. |
| 002575 | 002577 | 2/20/2020 | Timothy Stenzel, M.D., Ph.D. | DRAFT CDC Protocol EUA 2019-nCoV Letter of Authorization 2-20-20.doc | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025745<br><br>Bates: 002575<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about a draft Letter of Authorization for CDC's application for Emergency Use Authorization (EUA) for its SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002576<br>Personal Privacy Information: The redacted information contains a Webex meeting number (access code) and password. |
| 002578 | 002581 | 2/19/2020 | Timothy Stenzel, M.D., Ph.D. | RE: COVID_19 sentinel surveillance Feb 18 2020 to FDA.docx | (b)(4), (b)(5) | FDA-CVD-STENZELT-00025752<br><br>Bates: 002578 – 002579, 002581<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the potential of CDC submitting a new application for Emergency |

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| | | | | | | Use Authorization (EUA) for its SARS-CoV-2 test, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates 002578, 002579<br>Attorney-Client Privilege: The redacted information contains an embedded attorney-client legal opinion/advice from FDA's Office of the Chief Counsel (OCC) regarding the potential of CDC submitting a new application for Emergency Use Authorization (EUA) submission to FDA for its SARS-CoV-2 test.<br><br>Bates 002579 – 002581<br>Confidential Commercial Information: The withheld information contains confidential commercial information about a copyrighted article pertaining to CDC's plans for surveillance of community transmission of SARS-CoV-2. The release of this information would inform competitors about CDC's operations and would lead to predictable harm. |
| 002582 | 002585 | 2/18/2020 | Timothy Stenzel, M.D., Ph.D. | BY noon tomorrow | (b)(5), (b)(6) | FDA-CVD-STENZELT-00025765<br><br>Bates: 002583 – 002585<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the development of rapid and point-of-care tests for SARS-CoV-2 in light of the governing regulatory requirements and testing capacity more generally, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts. |

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| 002586 | 002587 | 2/27/2020 | Timothy Stenzel, M.D., Ph.D. | Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing | (b)(5), (b)(6) | FDA-CVD-STENZELT-00033616<br>Bates: 002586<br>Deliberative Process Privilege: The redacted information in this email exchange contains internal deliberations about the American Clinical Laboratories Association (ACLA) Annual Meeting, the release of which would cause foreseeable harm as it would reveal internal discussions and strategy and would compromise the agency's ability to receive candid and informed opinions and recommendations from its subject matter experts.<br><br>Bates: 002587<br>Personal Privacy Information: The redacted information contains the private cell phone number of an ACLA member. |

* Page prefix is FDACDRH-p2-AO
** Exemption codes refer to sections of the Freedom of Information Act, *see* 5 U.S.C. § 552(b).

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