
From: "Holland, Liam C. (CIV)" <Liam.C.Holland@usdoj.gov>
Date: Tuesday, December 5, 2023 at 10:34 PM
To: Emma Lewis <emma.lewis@americanoversight.org>
Subject: RE: American Oversight v. HHS/FDA; 20-cv-947 JSR Due

Hi Emma,

Please see attached for HHS's supplemental draft Vaughn index and associated bates-stamped records, which may include some removed redactions.

FDA is still working on their *Vaughn* for the entire set of records. I will circulate a draft JSR for your consideration before the due date.

Best,
Liam

From: Emma Lewis <emma.lewis@americanoversight.org>
Sent: Friday, December 1, 2023 11:50 AM
To: Holland, Liam C. (CIV) <Liam.C.Holland@usdoj.gov>
Subject: [EXTERNAL] Re: American Oversight v. HHS/FDA; 20-cv-947 JSR Due

Good morning Liam,

I hope you had a good Thanksgiving. In advance of our JSR next week, do you have any updates on the Vaughn indices from FDA and HHS?

Thanks very much,
Emma

From: "Holland, Liam C. (CIV)" <Liam.C.Holland@usdoj.gov>
Date: Friday, September 8, 2023 at 11:04 AM
To: Emma Lewis <emma.lewis@americanoversight.org>
Subject: RE: American Oversight v. HHS/FDA; 20-cv-947 JSR Due

Thanks Emma. You have a good weekend as well.

Best,
Liam

From: Emma Lewis <emma.lewis@americanoversight.org>
Sent: Friday, September 8, 2023 11:00 AM
To: Holland, Liam C. (CIV) <Liam.C.Holland@usdoj.gov>
Subject: [EXTERNAL] Re: American Oversight v. HHS/FDA; 20-cv-947 JSR Due

Good morning Liam,

We have no edits to the JSR, and you have my permission to file. Enjoy your weekend!

Best,
Emma

From: "Holland, Liam C. (CIV)" <Liam.C.Holland@usdoj.gov>
Date: Thursday, September 7, 2023 at 5:07 PM
To: Emma Lewis <emma.lewis@americanoversight.org>
Subject: American Oversight v. HHS/FDA; 20-cv-947 JSR Due

Hi Emma,

In this case, the Court ordered us to file the next JSR by this Sunday, September 10. I'm hoping we can get something on file tomorrow. Please see attached for a draft. Let me know if it is acceptable to file.

Thanks,
Liam

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



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Draft Vaughn Index

American Oversight v. HHS, 20-947

Table of Abbreviations

ASH	Assistant Secretary for Health
CDC	Centers for Disease Control and Prevention
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
QC	Quality Control
WH	White House

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Bates	Exemption(s) Invoked	Description of Withheld Material	Summary of Grounds for Withholding
AO-20-947-0001-0004	b(5)	Portions of emails between the ASH, an FDA employee and a CDC employee providing updates on tests, issues the agency is facing and ideas to address those issues, as well as unverified, preliminary numbers of tests that will be available	Exemption 5 – Deliberative Process Privilege: the material withheld pursuant to Exemption 5 is predecisional in that the discussions are prior to the final shipping decision and are deliberative in that they are trying to determine how many tests will be available as well as exchanging ideas about how to increase test production. Release of the withheld material would harm the agency’s decisionmaking process by inhibiting the agency from coordinating testing during a public health emergency as well as inhibiting agency employees’ freedom to discuss and develop ideas to address evolving issues with testing. Release of the withheld information could also cause public confusion by making the public think there are more or less tests available than what is actually available which could cause the public to attempt to hoard tests or wait to test.
AO-20-947-0005-0007	b(5)	Portions of emails between the ASH and an FDA employee preparing information on test numbers for a briefing with the Vice President	Exemption 5 – Deliberative Process Privilege: the withheld material consists of draft information to be considered for inclusion for the Vice President’s briefing before a call with governors. The withheld material is predecisional in that it is draft information being provided to the Vice President for his consideration and it is deliberative in that is a draft version still under review. Release of the withheld material would harm the agency’s decisionmaking process by inhibiting the agency from coordinating testing during a public health emergency as well as inhibiting agency employees’ freedom to discuss and develop ideas to address evolving issues with testing. Release of the withheld information could also cause public confusion by making the public think there are more or less tests available than what is actually available which could cause the public to attempt to hoard tests or wait to test.
AO-20-947-0008-0013, 0024-0028	b(5), b(6)	Portions of emails between the ASH and two FDA employees discussing potential new point of care tests and issues arising with some of those tests, as well as potential steps to address those issues	Exemption 5 – Deliberative Process Privilege: the material withheld pursuant to Exemption 5 consists of point of care testing candidates and discussions about those candidates. The material is predecisional in that the agency has not decided whether EUA’s should or need to be issued and deliberative in that they are discussing that issue and how to resolve it with respect to a handful of point of care testing facilities. Release of the withheld material would harm the agency’s decisionmaking

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			process by inhibiting the agency's ability to consider all potential testing candidates during a public health emergency and would reveal individual employees' honest assessments of those candidates. Exemption 6 – the material withheld pursuant to Exemption 6 consists of a mobile phone number; the privacy interest in the mobile phone number outweighs the public interest in that it is the mobile phone number of a person in private industry and does not reveal any workings of the government.
AO-20-947-0014-0017, 0029-0032, 0050-0062, 0074-0080, 0085-0096, 0097-0104, 0105-0117, 0123-0137, 0142-0155, 0159-0168, 0169-0177, 0178-0195, 0199-0215, 0219-0231, 0232-0241	b(5), b(6)	Portions of emails between the ASH, FDA and CDC coordinating shipping and approval of shipments for tests, timing for when tests are expected to arrive at CDC and when they can be shipped; deliberative discussions about how many patients could actually be tested with the number of tests shipped	Exemption 5 – Deliberative Process Privilege: the material withheld pursuant to Exemption 5 is predecisional in that the discussions are prior to the final shipping decision, as well as prior to final swab guidance and are deliberative in that they are trying to determine how many tests will be available and whether FDA should provide clarifying guidance on how many swabs should be used per patient as well as exchanging ideas about how to increase test production. Release of the withheld material would harm the agency's decisionmaking process by inhibiting the agency from coordinating testing during a public health emergency as well as inhibiting agency employees' freedom to discuss and develop ideas to address evolving issues with testing. Release would also harm the agency's decisionmaking process by preventing the agencies' involved to have full and frank conversations about testing policy prior to issuing any final guidance. Release of the withheld information could also cause public confusion by making the public think there are more or less tests available than what is actually available which could cause the public to attempt to hoard tests or wait to test. Exemption 6 – the material withheld pursuant to Exemption 6 consists of a mobile phone number; the privacy interest in the mobile phone number outweighs the public interest in even if the privacy interest in the number is low the number does not reveal any workings of the government.
AO-20-947-0018-0020	b(5)	Portions of emails between the ASH, an FDA employee, and a HHS deputy chief of staff discussing potential test kit manufacturers and issues arising with some of those companies, as well as potential steps to address those issues	Exemption 5 – Deliberative Process Privilege: the material withheld pursuant to Exemption 5 consists of test kit manufacturer candidates and discussions about those candidates. The material is predecisional in that the agency has not decided whether EUAs should or need to be issued and deliberative in that they are discussing that issue and how to resolve it with respect to a handful of test kit manufacturers. Release of the withheld material would harm the agency's decisionmaking process by inhibiting the agency's ability to consider all potential testing candidates during a public health emergency and would reveal individual

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			employees' honest assessments of those candidates. Agency employees would likely not feel comfortable sharing those honest assessments if they knew they would be made public.
AO-20-947-0021-0023 0063-0066	b(5), b(6)	Portions of emails between the ASH, FDA, and CDC discussing issues arising with QC testing and potential avenues to address those issues, the number of tests to pass QC testing and ideas on the order of priority of QC testing	Exemption 5 – Deliberative Process Privilege: the material withheld pursuant to Exemption 5 is predecisional in that it is prior to a final decision on priorities for testing and deliberative in that it is sharing the ASH's opinion on what the Secretary's priorities will be, as well as sharing preliminary numbers on the number of test kits that passed QC testing. Release of the withheld material would harm the agency's decisionmaking process by prematurely revealing individual's opinions, who do not have final decisionmaking authority, of what the agency's testing priorities are, which would deter the individual from offering their own opinions on testing options during a public health emergency. Release of the withheld information could also cause public confusion by making the public think there are more or less tests available than what is actually available which could cause the public to attempt to hoard tests or wait to test. Exemption 6 – the material withheld pursuant to Exemption 6 consists of a mobile phone number; the privacy interest in the mobile phone number outweighs the public interest in even if the privacy interest in the number is low the number does not reveal any workings of the government.
AO-20-947-0033-0035	b(4), b(5), b(6)	Portions of emails between Thermofisher and the agency, as well as internal emails between the ASH, CDC, and FDA discussing issues with the EUA process Thermofisher is facing	Exemption 4 – Confidential Commercial Information: the withheld section of this email chain contains communications between FDA and ThermoFisher regarding the disposition of material being used for their study. Not only is the withheld information confidential commercial information, but release of the information would cause foreseeable harm and it is protected by law, as required by the FOIA Improvement Act. The company has a commercial or financial interest in the withheld information that is held in confidence and was not otherwise disclosed to the public. Exemption 5 – Deliberative Process Privilege: the material withheld pursuant to Exemption 5 consists of testing manufacturer candidates and discussions about those candidates. The material is predecisional in that the agency has not decided whether EUAs should or need to be issued and deliberative in that they are discussing that issue and how to resolve it with respect to the manufacturers. Release of the withheld material would harm the agency's decisionmaking

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			process by inhibiting the agency's ability to consider all potential testing candidates during a public health emergency and would reveal individual employees' honest assessments of those candidates. Exemption 6 – the material withheld pursuant to Exemption 6 consists of a mobile phone number; the privacy interest in the mobile phone number outweighs the public interest in that it is the mobile phone number of a person in private industry and does not reveal any workings of the government.
AO-20-947-0036-0038	b(5)	Portions of emails between the ASH, FDA, and CDC discussing issues arising with QC testing and potential avenues to address those issues, the number of tests to pass QC testing	Exemption 5 – Deliberative Process Privilege: the material withheld pursuant to Exemption 5 is predecisional in that the discussions are prior to final decisions regarding QC testing and are deliberative in that they are trying to determine how many tests will be available and will be going through QC testing, how to address the issues with QC testing as well as exchanging ideas about how to increase test production. Release of the withheld material would harm the agency's decisionmaking process by inhibiting the agency from coordinating testing during a public health emergency as well as inhibiting agency employees' freedom to discuss and develop ideas to address evolving issues with testing. Release of the withheld information could also cause public confusion by making the public think there are more or less tests available than what is actually available which could cause the public to attempt to hoard tests or wait to test.
AO-20-947-0039-0041	b(5), b(6)	Portions of emails between the ASH and an FDA employee preparing information on test numbers for updates to the Hill	Exemption 5 – Deliberative Process Privilege: the withheld material consists of draft information to be considered for inclusion for providing to Congress. The withheld material is predecisional in that it is draft information being considered to provide to the Hill and it is deliberative in that is a draft version still under review. Release of the withheld material would harm the agency's decisionmaking process by inhibiting the agency from coordinating testing during a public health emergency as well as inhibiting agency employees' freedom to discuss and develop ideas to address evolving issues with testing and how to share that information outside of the Executive Branch. Release of the withheld information could also cause public confusion by making the public think there are more or less tests available than what is actually available which could cause the public to attempt to hoard tests or wait to test. Exemption 6 – the material withheld pursuant to Exemption 6 consists of a mobile phone number; the privacy interest in the mobile phone number

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			outweighs the public interest in even if the privacy interest in the number is low the number does not reveal any workings of the government.
AO-20-947-0042-0047	b(5), b(6)	Portions of emails preparing responses to inquiries from Congress including draft information, ideas for how the agency should respond, and discussions about who the best person to respond to the inquiry is	Exemption 5 – Deliberative Process Privilege: the withheld material consists of draft information to be considered for inclusion for providing to Congress. The withheld material is predecisional in that it is draft information being considered to provide to the Hill and it is deliberative in that is a draft version. Release of the withheld material would harm the agency’s decisionmaking process by inhibiting the agency from coordinating testing during a public health emergency as well as inhibiting agency employees’ freedom to discuss and develop ideas to address evolving issues with testing and how to share that information outside of the Executive Branch. Release of the withheld information could also cause public confusion by making the public think there are more or less tests available than what is actually available which could cause the public to attempt to hoard tests or wait to test. Exemption 6 – the material withheld pursuant to Exemption 6 consists of a mobile phone number; the privacy interest in the mobile phone number outweighs the public interest in even if the privacy interest in the number is low the number does not reveal any workings of the government.
AO-20-947-0067-0070, 0216-0218	b(5)	Portions of emails previewing potential actions by FDA, including draft guidance and policies to for consideration to include in a briefing to the Secretary	Exemption 5 – Deliberative Process Privilege: the withheld material consists of draft information on proposed FDA initiatives and draft guidance to be considered for inclusion for the Secretary’s briefing. The withheld material is predecisional in that it is draft information and summaries of proposed actions being provided to the Secretary for his consideration and it is deliberative in that it is a draft version still being reviewed and considered by a higher level decisionmaker. Release of the withheld material would harm the agency’s decisionmaking process by inhibiting the agency from coordinating draft policies and guidance. Release would also deter the agency from providing vital information to decisionmakers during a public health emergency. Release of the withheld information could also cause public confusion by prematurely revealing actions or guidance the agency did not take or issue.
AO-20-947-0071-0073, 0081-0084	b(5), b(6)	Emails preparing draft talking points on the testing kits for briefing the WH, as well as prepping for a meeting with the WH and lab association	Exemption 5 – Deliberative Process Privilege: the withheld material consists of draft information to be considered for inclusion for the WH. The withheld material is predecisional in that it is draft information being provided to the WH for their consideration and it is deliberative in that it is a draft version.

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			Release of the withheld material would harm the agency's decisionmaking process by inhibiting the agency from coordinating testing during a public health emergency as well as inhibiting agency employees' freedom to discuss and develop ideas to address evolving issues with testing. Release would also deter the agency from providing vital information to decisionmakers during a public health emergency. Release of the withheld information could also cause public confusion by making the public think there are more or less tests available than what is actually available which could cause the public to attempt to hoard tests or wait to test.
AO-20-947-0118-0121	b(5)	Portions of emails between the ASH, FDA, and CDC discussing questions about international testing, where those tests are coming from	Exemption 5 – Deliberative Process Privilege: the withheld material consists of questions related to where tests are coming from and how the agency could acquire more tests. This information is predecisional in that it is a series of initial questions and responses prior to the decision of where and how to acquire more tests and deliberative in that it consists of discussions about preliminary questions and considerations when determining how to acquire more tests. Release of the withheld material would harm the agency's decisionmaking process by inhibiting important preparatory discussions necessary to make sound decisions about how to acquire new tests during a public health emergency.
AO-20-947-0138-0141	b(4), b(5)	Internal discussions between FDA and the ASH regarding issues with Roche's EUA	Exemption 4 – Confidential Commercial Information: The withheld section of this email chain contains communications related to production volume and Roche's strategy for resolving the issue. Not only is the withheld information confidential commercial information, but release of the information would cause foreseeable harm and it is protected by law, as required by the FOIA Improvement Act. The company has a commercial or financial interest in the withheld information that is held in confidence and was not otherwise disclosed to the public. Exemption 5 – Deliberative Process Privilege: the material withheld pursuant to Exemption 5 consists of testing manufacturer candidates and discussions about those candidates. The material is predecisional in that the agency has not decided whether EUAs should or need to be issued and deliberative in that they are discussing that issue and how to resolve it with respect to the manufacturers. Release of the withheld material would harm the agency's decisionmaking process by inhibiting the agency's ability to consider all potential testing candidates during a public health emergency and would reveal individual employees' honest assessments of those candidates.

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AO-20-947-0156-0158	b(6)	Private individual's Gmail address	Exemption 6 – the material withheld pursuant to Exemption 6 consists of a Gmail address; the privacy interest in the Gmail address outweighs the public interest in that even if the privacy interest in the number is low the number does not reveal any workings of the government.
AO-20-947-0196-0198	b(5)	Portions of emails between the ASH and an FDA employee preparing information on test numbers for a briefing with the Vice President	Exemption 5 – Deliberative Process Privilege: the withheld material consists of draft information to be considered for inclusion for the Vice President. The withheld material is predecisional in that it is draft information being provided to the Vice President for their consideration and it is deliberative in that it is a draft version still under review. Release of the withheld material would harm the agency's decisionmaking process by inhibiting the agency from coordinating testing during a public health emergency as well as inhibiting agency employees' freedom to discuss and develop ideas to address evolving issues with testing. Release would also deter the agency from providing vital information to decisionmakers during a public health emergency. Release of the withheld information could also cause public confusion by making the public think there are more or less tests available than what is actually available which could cause the public to attempt to hoard tests or wait to test.

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
CC:	Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>
Subject:	RE: Any new news?
Date:	2020/03/10 10:22:00
Priority:	Normal
Type:	Note

copy

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 10:19 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <stm2@cdc.gov>
Subject: RE: Any new news?

(b)(5)

More updates to follow

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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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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Tuesday, March 10, 2020 9:05 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) <stm2@cdc.gov>
Subject: RE: Any new news?

No rush this morning, but I am always standing by for your updates.

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Monday, March 9, 2020 10:30 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: RE: Any new news?

Hi Admiral,

(b)(5)

I did not get information on how many tests shipped today.

(b)(5)

(b)(5)

I will have additional updates for other manufacturers in the AM.

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Monday, March 9, 2020 6:47 PM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: Any new news?

Cheers
BG

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>
Sent Date:	2020/03/10 10:22:29
Delivered Date:	2020/03/10 10:22:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject:	RE: Numbers
Date:	2020/03/09 10:47:00
Priority:	Normal
Type:	Note

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Monday, March 9, 2020 10:37 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Subject: RE: Numbers

(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

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Monday, March 9, 2020 10:33 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Numbers

I will provide.
Latest info:

(b)(5)

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Monday, March 9, 2020 10:30 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Numbers

(b)(5)

Much appreciated!
-Carly"

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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Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent Date:	2020/03/09 10:47:59
Delivered Date:	2020/03/09 10:47:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI,BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>
Subject:	RE: Developing of point-of-care test for COVID-19
Date:	2020/03/12 10:53:00
Priority:	Normal
Type:	Note

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>**Sent:** Thursday, March 12, 2020 10:50 AM**To:** Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>**Subject:** RE: Developing of point-of-care test for COVID-19

(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
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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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 12, 2020 10:32 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Developing of point-of-care test for COVID-19

(b)(5)

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 12, 2020 10:25 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Developing of point-of-care test for COVID-19

(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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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: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 12, 2020 10:01 AM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Developing of point-of-care test for COVID-19

I will forward to our review team to check to see if they have engaged us and if not we will reach out to them. I am not easily finding a product they have launched yet, need to 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
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 12, 2020 9:55 AM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: FW: Developing of point-of-care test for COVID-19

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>

Sent: Thursday, March 12, 2020 9:49 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Cc: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>

Subject: FW: Developing of point-of-care test for COVID-19

Hi Brett,

(b)(5)

John

From: Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>

Sent: Wednesday, March 11, 2020 3:10 PM

To: Dempsey, Donald A. <Donald.Dempsey@CVSHealth.com>

Cc: Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>

Subject: RE: Developing of point-of-care test for COVID-19

Yes. That'll be great!

Gary M. Beck
Office of the Secretary | Intergovernmental and External Affairs
U.S. Department of Health and Human Services

From: Dempsey, Donald A. <Donald.Dempsey@CVSHealth.com>
Sent: Wednesday, March 11, 2020 3:08 PM
To: Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>
Cc: Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>
Subject: RE: Developing of point-of-care test for COVID-19

Hi Gary,

We are having a call with our chief CMO and Joe Grogan and some of the White House team tomorrow at 10:30am – would you be able to join that? I can forward the invite.

Thanks,
Don

From: Beck, Gary (OS/IEA) [<mailto:Gary.Beck@hhs.gov>]
Sent: Tuesday, March 10, 2020 5:44 PM
To: Dempsey, Donald A. <Donald.Dempsey@CVSHealth.com>
Cc: Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>
Subject: [EXTERNAL] RE: Developing of point-of-care test for COVID-19

Hey Don – I’m actually very interested in speaking with them if they have time this week or next week.

Gary M. Beck
Office of the Secretary | Intergovernmental and External Affairs
U.S. Department of Health and Human Services

From: Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>
Sent: Tuesday, March 10, 2020 10:07 AM
To: Dempsey, Donald A. <Donald.Dempsey@CVSHealth.com>; Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>
Subject: RE: Developing of point-of-care test for COVID-19

Thanks Don – we will share with the team.

From: Dempsey, Donald A. <Donald.Dempsey@CVSHealth.com>
Sent: Tuesday, March 10, 2020 9:46 AM
To: Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>; Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>
Subject: Developing of point-of-care test for COVID-19
Importance: High

Hi Gary and John,

I wanted to make you aware of this effort and if you can please make the Secretary aware (as well as anyone else at HHS you thinks needs to know). CVS Health and Gates Foundation are investors in LumiraDx, which is a private company operated by executives with 30 years of experience in point of care testing.

LumiraDx currently offers a variety of point-of-care tests on their new platform.

In light of the COVID-19 pandemic, they are pivoting to development of a POC test (immediate result), totally portable, that will identify infection, as well as previous infection now in recovery

You can see the attached presentation for more information. We are happy to set up a call if you have questions about this effort.

Thanks,

Don

Donald Dempsey | Vice President, Policy and Regulatory Affairs

p 202-772-3534 | c (b)(6) | f 202-772-3535

CVS Health | 1275 Pennsylvania Avenue, NW, Suite 700, Washington, DC 20004

donald.dempsey@cvshhealth.com

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>
Sent Date:	2020/03/12 10:53:42
Delivered Date:	2020/03/12 10:53:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject:	RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/05 16:28:00
Priority:	Normal
Type:	Note

(b)(5)

Brett P. Giroir, MD
 ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:20 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

We approved them going.

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(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 <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:17 PM
To: Kuhnert-Tallman, Wendi L (CDC) (b)(6); Terrill, Roman <rterrill@idtdna.com>;
Lindstrom, Stephen (CDC) (b)(6); Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M (CDC) (b)(6); Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Schwartz,
Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B (CDC) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Roman,

FDA confirms you can ship lot ending 847 under CDC EUA today for N1, N2 and RP as discussed.

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: Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterrill@idtdna.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>;
Lindstrom, Stephen (CDC) (b)(6); Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M (CDC) (b)(6); Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Schwartz,
Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B (CDC) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
Office - 404-639-3103
Mobile - (b)(6)

From: Terrill, Roman <rterrill@idtdna.com>
Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6)
Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Recipient:	Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent Date:	2020/03/05 16:29:00
Delivered Date:	2020/03/05 16:28:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
CC:	Kellogg, Rachel (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=897ed8e8d85f4105b2bf0705fc476e32-Kellogg, Ra>
Subject:	RE: First New Kit Manufacturer
Date:	2020/03/12 10:57:00
Priority:	Normal
Type:	Note

Super great

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 12, 2020 10:54 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>
Subject: RE: First New Kit Manufacturer

Confidential

Will do. (b)(5)

(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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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 12, 2020 9:58 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Kellogg, Rachel (OS) <Rachel.Kellogg@hhs.gov>
Subject: FW: First New Kit Manufacturer

(b)(5)

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Sent: Thursday, March 12, 2020 9:55 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: FW: First New Kit Manufacturer

(b)(5)

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Wednesday, March 11, 2020 6:57 PM
To: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Subject: First New Kit Manufacturer

(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

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Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Kellogg, Rachel (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=897ed8e8d85f4105b2bf0705fc476e32-Kellogg, Ra>
Sent Date:	2020/03/12 10:57:38
Delivered Date:	2020/03/12 10:57:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
CC:	Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>
Subject:	RE: Order of priority of testing IDT QC lots (509 > 295)
Date:	2020/03/11 17:19:00
Priority:	Normal
Type:	Note

My thanks to CDC.

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Wednesday, March 11, 2020 4:11 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6)
Subject: FW: Order of priority of testing IDT QC lots (509 >295)

(b)(5)

Please see Wendi's comments 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

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From: Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6)
Sent: Wednesday, March 11, 2020 3:56 PM
To: Terrill, Roman <rterrill@idtdna.com>; Lindstrom, Stephen (CDC) (b)(6)
Cc: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Monroe, Stephan S (CDC) (b)(6)
Subject: RE: Order of priority of testing IDT QC lots (509 >295)

Roman, Please find attached the QC for the most recent lot from IDT. Please note that the lab worked very hard on this effort for the past 2 days. I would request that in the future we not expect same day testing. As you are aware we have many other ongoing QC needs and will always be happy to do this testing but would request that these not come with the expectation that they will be completed the same day that they are received.

We appreciate it if this could be shared with leadership as appropriate.

Thanks, wendi

Wendi Kuhnert-Tallman
Office - 404-639-3103
Mobile - (b)(6)

From: Terrill, Roman <rterrill@idtdna.com>
Sent: Tuesday, March 10, 2020 9:53 PM
To: Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6)
Cc: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Subject: Order of priority of testing IDT QC lots (509 >295)
Importance: High

Hello Wendi, Steve and Tim:

I wanted to add urgency and provide clarity on the order of priority for the QC of lots of IDT kits at CDC.

As we discussed today, QC test lot (507295, aka '295) arrived at CDC earlier this morning (Tuesday 3-10) from the last of our smaller scale builds. This lot will approve another ~700 kits or 350,000 tests. We used these smaller scale builds so that we always had sellable inventory available last week and early this week.

Tonight we are shipping an additional set of test kits from our scale up process. This new lot of QC samples (Lot # 507509, aka '509) will be arriving tomorrow at the CDC by 10:30am on FedEx Tracking 1707 6170 3009. This will release **4,000 kits (2 Million tests)**.

If we can urge CDC to prioritize the Wednesday receipt, **lot '509**, over the testing of the Tuesday receipt, lot '295, that would be very beneficial to our inventory. We are approaching stock-out levels, and the approval of the larger lot tomorrow Wednesday may be necessary to continue to provide "same day shipment" to testing labs nationwide.

Thank you in advance for your attention to this email, and for your cooperation.

Sincerely,

Roman Terrill
Senior Vice President
IDT

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Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>
Sent Date:	2020/03/11 17:19:25
Delivered Date:	2020/03/11 17:19:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>
Subject:	RE: Developing of point-of-care test for COVID-19
Date:	2020/03/12 10:59:00
Priority:	Normal
Type:	Note

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 12, 2020 10:25 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Developing of point-of-care test for COVID-19

(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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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 12, 2020 10:01 AM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Developing of point-of-care test for COVID-19

I will forward to our review team to check to see if they have engaged us and if not we will reach out to them. I am not easily finding a product they have launched yet, need to 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
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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=1900&S=E>

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 12, 2020 9:55 AM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: FW: Developing of point-of-care test for COVID-19

(b)(5)

Brett P. Giroir, MD
ADM, US Public Health Service

Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>
Sent: Thursday, March 12, 2020 9:49 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Subject: FW: Developing of point-of-care test for COVID-19

Hi Brett,

(b)(5)



John

From: Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>
Sent: Wednesday, March 11, 2020 3:10 PM
To: Dempsey, Donald A. <Donald.Dempsey@CVSHealth.com>
Cc: Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>
Subject: RE: Developing of point-of-care test for COVID-19

Yes. That'll be great!

Gary M. Beck
Office of the Secretary | Intergovernmental and External Affairs
U.S. Department of Health and Human Services

From: Dempsey, Donald A. <Donald.Dempsey@CVSHealth.com>
Sent: Wednesday, March 11, 2020 3:08 PM

To: Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>
Cc: Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>
Subject: RE: Developing of point-of-care test for COVID-19

Hi Gary,

We are having a call with our chief CMO and Joe Grogan and some of the White House team tomorrow at 10:30am – would you be able to join that? I can forward the invite.

Thanks,
Don

From: Beck, Gary (OS/IEA) [mailto:Gary.Beck@hhs.gov]
Sent: Tuesday, March 10, 2020 5:44 PM
To: Dempsey, Donald A. <Donald.Dempsey@CVSHealth.com>
Cc: Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>
Subject: [EXTERNAL] RE: Developing of point-of-care test for COVID-19

Hey Don – I'm actually very interested in speaking with them if they have time this week or next week.

Gary M. Beck
Office of the Secretary | Intergovernmental and External Affairs
U.S. Department of Health and Human Services

From: Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>
Sent: Tuesday, March 10, 2020 10:07 AM
To: Dempsey, Donald A. <Donald.Dempsey@CVSHealth.com>; Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>
Subject: RE: Developing of point-of-care test for COVID-19

Thanks Don – we will share with the team.

From: Dempsey, Donald A. <Donald.Dempsey@CVSHealth.com>
Sent: Tuesday, March 10, 2020 9:46 AM
To: Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>; Brooks, John (CMS/OA) <John.Brooks@cms.hhs.gov>
Subject: Developing of point-of-care test for COVID-19
Importance: High

Hi Gary and John,

I wanted to make you aware of this effort and if you can please make the Secretary aware (as well as anyone else at HHS you thinks needs to know). CVS Health and Gates Foundation are investors in LumiraDx, which is a private company operated by executives with 30 years of experience in point of care testing.

LumiraDx currently offers a variety of point-of-care tests on their new platform.

In light of the COVID-19 pandemic, they are pivoting to development of a POC test (immediate result), totally portable, that will identify infection, as well as previous infection now in recovery

You can see the attached presentation for more information. We are happy to set up a call if you have questions about this effort.

Thanks,

Don

Donald Dempsey | Vice President, Policy and Regulatory Affairs

p 202-772-3534 | c (b)(6) | f 202-772-3535

CVS Health | 1275 Pennsylvania Avenue, NW, Suite 700, Washington, DC 20004

donald.dempsey@cvshealth.com

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>
Sent Date:	2020/03/12 10:59:21
Delivered Date:	2020/03/12 10:59:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject:	RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/05 16:46:00
Priority:	Normal
Type:	Note

awesome

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:40 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:24 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

The hour is late for them but they have (b)(5) test each for (b)(5) tests that are going to US customers only today and I asked to ship them to as many unique labs as possible to get tests out to as many labs as possible. (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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From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:17 PM
To: Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

From: Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:16 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

CDC released the IDT lot!

(b)(5)

this is great news for getting kits out this week.

THANK YOU!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD) <(b)(6)>
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterrell@idtdna.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC) <(b)(6)>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M (CDC) <(b)(6)>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B (CDC) <(b)(6)>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
Office - 404-639-3103
Mobile - (b)(6)

From: Terrill, Roman <rterill@idtdna.com>
Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent Date:	2020/03/05 16:46:25
Delivered Date:	2020/03/05 16:46:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>
Subject:	RE: Cross Reactivity Study for EUA
Date:	2020/03/09 11:36:00
Priority:	Normal
Type:	Note

Any update?

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Monday, March 9, 2020 8:41 AM
To: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6)
Cc: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: FW: Cross Reactivity Study for EUA

Hi Steve,

(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

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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From: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Sent: Sunday, March 8, 2020 11:15 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Cc: Fenton, Tim <tim.fenton@thermofisher.com>; Tanzella, Kelli <Kelli.Tanzella@thermofisher.com>
Subject: FW: Cross Reactivity Study for EUA

Colleagues,

We are making solid progress on our EUA. One bump has been the cross reactivity study materials. See below situation.

This is the last step in our EUA work. Can you work with CDC to get us permission to use this material? Thank you for your effort.

Best,
Peter

Peter E. Shearstone
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: +1 (781) 622-1333 | Mobile: (b)(6)
Internal extension 110-1333
peter.shearstone@thermofisher.com

From: Tanzella, Kelli <Kelli.Tanzella@thermofisher.com>
Sent: Sunday, March 8, 2020 9:30 PM
To: Tanner, Michael <michael.tanner@thermofisher.com>; Varma, Kamini H. <Kamini.Varma@thermofisher.com>
Cc: Fenton, Tim <tim.fenton@thermofisher.com>; Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Subject: RE: Cross Reactivity Study for EUA

Adding Peter for his awareness.

Mike,

Please confirm if the information below is correct and add in the any additional details I have left blank?

Date permit applied for:

Consignor: Institut für Virologie, Charité – Universitätsmedizin Berlin

Country of Origin: Germany

Date received:

Consignee: Thermo Fisher 180 Oyster Point S. San Francisco, CA 94080

Items ordered: SARSCoV-2 positive strand RNA and MERSCoV positive strand RNA

Items received:

When did we receive notice the permit was declined?

Tim,

Attached is the select agent application as well as the protocol which requires the RNA. This is the last test needed to complete all of the testing for the EUA. The detail above as well as the questions below can help facilitate the discussion with CDC

(b)(4)

Let me know if you need more information.

Kind regards,

Kelli

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>
Sent Date:	2020/03/09 11:36:48
Delivered Date:	2020/03/09 11:36:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>
CC:	McGowan, Robert (Kyle) (CDC/OD/OCS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2046e75239f48a28d2854bedbe5f899-robert.mcgo>
Subject:	RE: IDT
Date:	2020/03/11 08:11:00
Priority:	Normal
Type:	Note

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>**Sent:** Wednesday, March 11, 2020 8:10 AM**To:** Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Monroe, Steve (CDC/DDPHSS/OLSS/OD)**(b)(6)** Berger, Sherri (CDC/OCOO/OD) **(b)(6)****Cc:** McGowan, Robert (Kyle) (CDC/OD/OCS) **(b)(6)****Subject:** RE: IDTIDT has subsequently said the lot arriving **(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
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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Tuesday, March 10, 2020 10:27 PM
To: Monroe, Stephan S (CDC) (b)(6); Berger, Sherri (CDC) (b)(6)
Cc: McGowan, Robert K (CDC) (b)(6); Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: FW: IDT
Importance: High

Clarification please
Thank you
BG

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 9:19 PM
To: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6)
Cc: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: IDT
Importance: High

Hi Steve,

(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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Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; McGowan, Robert (Kyle) (CDC/OD/OCS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2046e75239f48a28d2854bedbe5f899-robert.mcgo>
Sent Date:	2020/03/11 08:11:57
Delivered Date:	2020/03/11 08:11:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject:	RE: Updated test numbers
Date:	2020/03/10 14:12:00
Priority:	Normal
Type:	Note

thanks

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Tuesday, March 10, 2020 2:08 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Paulos, Lauren (FDA/OC) <Lauren.Paulos@fda.hhs.gov>

Subject: RE: Updated test numbers

Just sent them to you Admiral.

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Tuesday, March 10, 2020 11:54 AM
To: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Updated test numbers

(b)(5)

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:51 AM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: RE: Updated test numbers

Thank you, Tim

Admiral Giroir - Please let me know if the below is still accurate or if there are any updates:

(b)(5)

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 10:12 AM
To: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Cc: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>
Subject: RE: Updated test numbers

I am waiting to hear from IDT and Biosearch today with their sales yesterday and will update the Admiral 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

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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: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

Sent: Tuesday, March 10, 2020 10:10 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: Updated test numbers

Hi Tim –

(b)(5)

Thank you!

Lauren

Lauren Paulos, MPH

Congressional Affairs Specialist

Office of Legislation**U.S. Food and Drug Administration**

Office: 301-796-8226

Mobile: (b)(6)

Lauren.Paulos@fda.hhs.gov



cid:image001.png@01D1C57E.DFA022A0

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy < Timothy.Stenzel@fda.hhs.gov >
Sent Date:	2020/03/10 14:12:17
Delivered Date:	2020/03/10 14:12:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>; Stenzel, Timothy (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cba7ee2d647d476fa35a0fb86a74514c-timothy.ste>
CC:	Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>
Subject:	RE: Rapid Input Requested: Talking Points Responsive to 3/6/2020 Letter from Reps. Schakowsky, Doggett, DeLauro on COVID-19 Testing Capacity
Date:	2020/03/09 20:30:00
Priority:	Normal
Type:	Note

Laura

(b)(5)

BG

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Sent: Monday, March 9, 2020 8:25 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>
Subject: RE: Rapid Input Requested: Talking Points Responsive to 3/6/2020 Letter from Reps. Schakowsky, Doggett, DeLauro on COVID-19 Testing Capacity

(b)(5)

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Monday, March 9, 2020 8:22 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Subject: RE: Rapid Input Requested: Talking Points Responsive to 3/6/2020 Letter from Reps. Schakowsky, Doggett, DeLauro on COVID-19 Testing Capacity

(b)(5)

BG

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Monday, March 9, 2020 7:58 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Cc: Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>

Subject: FW: Rapid Input Requested: Talking Points Responsive to 3/6/2020 Letter from Reps. Schakowsky, Doggett, DeLauro on COVID-19 Testing Capacity

Dear Admiral,

Today we have received the attached letter request from congress that includes asking for how kits have been shipped. And when will the (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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From: Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>
Sent: Monday, March 9, 2020 7:27 PM
To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Diamond, Matthew <Matthew.Diamond@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Rapid Input Requested: Talking Points Responsive to 3/6/2020 Letter from Reps. Schakowsky, Doggett, DeLauro on COVID-19 Testing Capacity

Sorry, actually including Jeff and Tim. There are questions in here about the number of tests shipped. My understanding is that Tim is under orders from Admiral Giroir to only share this info with the Admiral.

Any direction on the big picture questions would be appreciated too.

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

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=1960&S=E>.

From: Sauer, Robert
Sent: Monday, March 09, 2020 7:25 PM
To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Diamond, Matthew <Matthew.Diamond@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Subject: RE: Rapid Input Requested: Talking Points Responsive to 3/6/2020 Letter from Reps. Schakowsky, Doggett, DeLauro on COVID-19 Testing Capacity

+Jeff and Tim,

There are questions in here about the number of tests shipped. My understanding is that (b)(5)

(b)(5)

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

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=1960&S=E>.

From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Sent: Monday, March 09, 2020 4:29 PM
To: Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; Diamond, Matthew <Matthew.Diamond@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Subject: FW: Rapid Input Requested: Talking Points Responsive to 3/6/2020 Letter from Reps. Schakowsky, Doggett, DeLauro on COVID-19 Testing Capacity
Importance: High

Rob and Matthew,

(b)(5)

Many thanks for all of your help.

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)
jennifer.tomasello@fda.hhs.gov



cid:image002.png@01D4DB42.60832940

☐ cid:image004.jpg@01D4DB42.60832940 ☐ cid:image006.jpg@01D4DB42.60832940
☐ cid:image008.jpg@01D4DB42.60832940 ☐ cid:image010.jpg@01D4DB42.60832940
☐ cid:image012.jpg@01D4DB42.60832940

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<https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E>

From: Price, William <William.Price@fda.hhs.gov>

Sent: Monday, March 9, 2020 4:14 PM

To: OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Berkowitz, Lauren <Lauren.Berkowitz@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>

Cc: 2019-nCoV FDA IMG JIC <2019-nCoVDAIMGJIC@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Howard, Megan <Megan.Howard@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Roberts, Michelle <Michelle.Roberts1@fda.hhs.gov>

Subject: Rapid Input Requested: Talking Points Responsive to 3/6/2020 Letter from Reps. Schakowsky, Doggett, DeLauro on COVID-19 Testing Capacity

Importance: High

Hi all,

(b)(5)

(b)(5)

Thanks all,

Taylor

 Taylor Price
 Office of Congressional Appropriations
 U.S. Food and Drug Administration
William.Price@fda.hhs.gov
 Office: (240)-402-2640
 Cell: (b)(6)

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>; Stenzel, Timothy (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cba7ee2d647d476fa35a0fb86a74514c-timothy.ste>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>
Sent Date:	2020/03/09 20:30:50
Delivered Date:	2020/03/09 20:30:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
CC:	Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>
Subject:	RE: NYC call
Date:	2020/03/13 16:57:00
Priority:	Normal
Type:	Note

Steve,
Please alert cdc

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 13, 2020 3:53 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) <stm2@cdc.gov>
Subject: NYC call

Hi Admiral,

Just got off a call with NYC. See participants below. I was invited to the call but did not initiate it. They were expecting HHS and CDC participants. They said they were happy with the testing updates I gave them but were disappointed that HHS and CDC were not on the call to address their other concerns. They specifically had concerns with confusion about CDC guidances. Let me know if I can provide any additional information.

Alexandra Nudelman <anudelman@health.nyc.gov>; igacall <igacall@health.nyc.gov>; Maura Kennelly <mkenell@health.nyc.gov>; Kagan, Rebecca <rkagan@cityhall.nyc.gov>; Demetre Daskalakis <ddaskalakis@health.nyc.gov>; CPrice@cityhall.nyc.gov; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>;

Jennifer Rakeman-Cagno <jrakeman@health.nyc.gov>; David Starr <dstarr@health.nyc.gov>; Jacob Kraemer <jkraemer@health.nyc.gov>

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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CDRH | Food and Drug Administration
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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy < Timothy.Stenzel@fda.hhs.gov >; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bced884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>
Sent Date:	2020/03/13 16:57:20
Delivered Date:	2020/03/13 16:57:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <(b)(6)>; Delew, Nancy (HHS/ASPE) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f3de4322eea4acb9c69140630415f1b-Nancy Delew>
CC:	Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Schuchat, Anne MD (CDC/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e506fd4b204294906aa26f44d2f2c8-Schuchat, A>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Carla Haddad (HHS/OASH) (Carla.Haddad@hhs.gov) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>
Subject:	RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/06 15:20:00
Importance:	High
Priority:	Urgent
Type:	Note

(b)(5)

Brett P. Giroir, MD
 ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 10:48 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(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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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 10:44 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 10:41 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 10:21 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

One additional:

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 10:01 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Admiral,

Just received this email in green and followed up by call to confirm. IDT fulfilled all open orders to US

(b)(5)

From IDT email just now:

Here are the numbers, and there is potentially game-changing juice in here.

- As of Wednesday March 4, 2020, IDT has shipped kits sufficient to test (b)(5) individual for coronavirus.
- On Thursday March 5, IDT shipped kits sufficient to test an additional (b)(5) individuals for coronavirus.
- As of Friday March 6, at 10am Eastern, IDT has kits in inventory ready to ship to those labs in need, sufficient to test an additional (b)(5) individual for coronavirus. IDT is ready to ship on receipt until that inventory is consumed.

(b)(5)

Hope this helps correct the narrative.

Roman

(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
Jennifer.Campbell@fda.hhs.gov

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 9:02 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

Brett P. Giroir, MD
 ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 8:02 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Thank you Admiral for your help with the QC testing of lots that arrive today and tomorrow at the CDC. And more will be arriving next week.

I was a little tired last night when trying to update the math. In fact, for (b)(5) if we include the new lot of IDT reagents arriving at the CDC (b)(5) for QC testing and we include Biosearch's lot that arrives at the CDC (b)(5) for QC testing. The total (b)(5) will be (b)(5) tests (lots of (b)(5) plus (b)(5) plus (b)(5) from IDT and one lot of (b)(5) tests from Biosearch for a grand total of (b)(5) tests.

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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 U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 7:48 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK

By calculation, that would be 1.1 million since 100,000 plus 600,000 have already been shipped. I will work with Sherri on the receipt as well as the QC timeline.

V/r
BG

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 7:00 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5)
 (b)(5) We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by (b)(5) ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5) I will keep the pressure on. We are grateful for the lot release testing reported (b)(5) by 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

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From: Stenzel, Timothy

Sent: Thursday, March 5, 2020 5:56 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;

Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for (b)(5) tests according to what the companies are telling me.

Best,
Tim

Timothy T. Stenzel, MD, PhD

Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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Timothy.Stenzel@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=1900&S=E>

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 5, 2020 5:46 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;

Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further, (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

Best,
Tim

Timothy T. Stenzel, MD, PhD

*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Thursday, March 5, 2020 5:31 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6); Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make a (b)(5)).

Is that Monday?

And are we still no track for (b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201

Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6); Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Redfield, Robert R. (CDC/OD) (b)(6) Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 4:18 PM
To: Berger, Sherri (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Redfield, Robert R (CDC) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

(b)(5)

Brett P. Giroir, MD
 ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterill@idtdna.com>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6)

Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
Office - 404-639-3103
Mobile - (b)(6)

From: Terrill, Roman <rterill@idtdna.com>

Sent: Thursday, March 5, 2020 3:58 PM

To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)

Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6); Delew, Nancy (HHS/ASPE) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f3de4322eea4acb9c69140630415f1b-Nancy Delew>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Schuchat, Anne MD (CDC/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e506fd4b204294906aa26f44d2f2c8-Schuchat, A>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bced884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Carla Haddad (HHS/OASH) (Carla.Haddad@hhs.gov) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>
Sent Date:	2020/03/06 15:20:42
Delivered Date:	2020/03/06 15:20:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
CC:	Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>
Subject:	RE: Order of priority of testing IDT QC lots (509 > 295)
Date:	2020/03/11 08:58:00
Priority:	Normal
Type:	Note

COpy

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Wednesday, March 11, 2020 8:58 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6)
Subject: RE: Order of priority of testing IDT QC lots (509 > 295)

The IDT lot that was qualified just now has (b)(5) tests. The IDT lot arriving today at the CDC for QC has (b)(5) tests.

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Wednesday, March 11, 2020 8:56 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6)
Subject: RE: Order of priority of testing IDT QC lots (509 >295)

(b)(5)

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Wednesday, March 11, 2020 8:54 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6)
Subject: FW: Order of priority of testing IDT QC lots (509 >295)

IDT's lot received by the CDC yesterday has received QC approval

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: Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6)
Sent: Wednesday, March 11, 2020 8:48 AM
To: Terrill, Roman <rterrill@idtdna.com>; Lindstrom, Stephen (CDC) (b)(6)
Cc: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Monroe, Stephan S (CDC) (b)(6)
Subject: RE: Order of priority of testing IDT QC lots (509 >295)

Roman, please see attached for the QC approval for the lot that we received yesterday.

Thanks, wendi

Wendi Kuhnert-Tallman
 Office - 404-639-3103
 Mobile - (b)(6)

From: Terrill, Roman <rterrill@idtdna.com>
Sent: Tuesday, March 10, 2020 9:53 PM
To: Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6)
Cc: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Subject: Order of priority of testing IDT QC lots (509 >295)
Importance: High

Hello Wendi, Steve and Tim:

I wanted to add urgency and provide clarity on the order of priority for the QC of lots of IDT kits at CDC.

As we discussed today, QC test lot (507295, aka '295) arrived at CDC earlier this morning (Tuesday 3-10) from the last of our smaller scale builds. This lot will approve another ~700 kits or 350,000 tests. We used these smaller scale builds so that we always had sellable inventory available last week and early this week.

Tonight we are shipping an additional set of test kits from our scale up process. This new lot of QC samples (Lot # 507509, aka '509) will be arriving tomorrow at the CDC by 10:30am on FedEx Tracking 1707 6170 3009. This will release **4,000 kits (2 Million tests)**.

If we can urge CDC to prioritize the Wednesday receipt, **lot '509**, over the testing of the Tuesday receipt, lot '295, that would be very beneficial to our inventory. We are approaching stock-out levels, and the approval of the larger lot tomorrow Wednesday may be necessary to continue to provide "same day shipment" to testing labs nationwide.

Thank you in advance for your attention to this email, and for your cooperation.

Sincerely,

Roman Terrill

Senior Vice President
IDT

Please be advised that this email may contain confidential information. If you are not the intended recipient, please notify us by email by replying to the sender and delete this message. The sender disclaims that the content of this email constitutes an offer to enter into, or the acceptance of, any agreement; provided that the foregoing does not invalidate the binding effect of any digital or other electronic reproduction of a manual signature that is included in any attachment.

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>
Sent Date:	2020/03/11 08:58:29
Delivered Date:	2020/03/11 08:58:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>
Subject:	RE: FDA Heads Up for HHS NN - 3/13/19
Date:	2020/03/12 22:54:00
Priority:	Normal
Type:	Note

Thank you

Do you need me to flag?

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>
Sent: Thursday, March 12, 2020 10:04 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Fwd: FDA Heads Up for HHS NN - 3/13/19

(b)(5)

Danielle Steele
Senior Adviser, IOS, HHS

Sent from my iPhone

Begin forwarded message:

From: "McWilliams, Carly" <Carly.McWilliams@fda.hhs.gov>
Date: March 12, 2020 at 9:05:59 PM EDT
To: "Rebello, Heidi" <Heidi.Rebello@fda.hhs.gov>, "Steele, Danielle (OS)" <Danielle.Steele@hhs.gov>, "Dareshori, Zachary (OS)" <Zachary.Dareshori@hhs.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Roth, Lauren" <Lauren.Roth@fda.hhs.gov>, "Amin, Stacy" <Stacy.Amin@fda.hhs.gov>, "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>, "Beshara, Nicholas" <Nicholas.Beshara@fda.hhs.gov>, "Franklin, Joseph" <Joseph.Franklin@fda.hhs.gov>, "Beardsley, Sara" <Sara.Beardsley@fda.hhs.gov>, "Anderson, Erika" <Erika.Anderson@fda.hhs.gov>, "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>, "Raza, Mark" <Mark.Raza@fda.hhs.gov>, "Flahive, James" <James.Flahive@fda.hhs.gov>, "Tobias, Lindsay" <Lindsay.Tobias@fda.hhs.gov>, "Giroir, Brett (OS)" <Brett.Giroir@hhs.gov>
Subject: RE: FDA Heads Up for HHS NN - 3/13/19

(b)(5)

confidential

From: McWilliams, Carly
Sent: Thursday, March 12, 2020 2:28 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Dareshori, Zachary (OS) <Zachary.Dareshori@hhs.gov>; 'Hahn, Stephen'
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Beshara, Nicholas <Nicholas.Beshara@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Beardsley, Sara

<Sara.Beardsley@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>

Subject: RE: FDA Heads Up for HHS NN - 3/13/19

(b)(5)

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>
Sent Date:	2020/03/12 22:54:44
Delivered Date:	2020/03/12 22:54:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Berger, Sherri (CDC/OCOO/OD) (b)(6)
CC:	Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>
Subject:	RE: Update w/ test #s from this morning
Date:	2020/03/03 17:34:00
Priority:	Normal
Type:	Note

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Tuesday, March 3, 2020 5:23 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: Update w/ test #s from this morning

From: Berger, Sherri (CDC/OCOO/OD)
Sent: Tuesday, March 3, 2020 9:31 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McGowan, Robert (Kyle) (CDC/OD) (b)(6)
Subject: RE: Test kit TPs

(b)(5)

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Sent: Tuesday, March 3, 2020 9:29 AM

To: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <(b)(6)>

Subject: Re: Test kit TPs

(b)(5)

Sent from my iPhone

On Mar 3, 2020, at 9:24 AM, Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov> wrote:



Thanks. Let me try to massage it a little bit and then loop back to see if it's ok before using it.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Sent: Tuesday, March 3, 2020 9:16 AM

To: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>

Subject: RE: Test kit TPs

(b)(5)

From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>
Sent: Tuesday, March 3, 2020 9:01 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Test kit TPs

(b)(5)

William Hall

Deputy Assistant Secretary for Public Affairs (Public Health)
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health & Human Services
Washington, DC
Direct: 202-690-6344
Mobile: (b)(6)
Email: bill.hall@hhs.gov
www.hhs.gov



Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Berger, Sherri (CDC/OCOO/OD) (b)(6) Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>
Sent Date:	2020/03/03 17:34:08
Delivered Date:	2020/03/03 17:34:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>
Subject:	FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/06 07:13:00
Priority:	Normal
Type:	Note

Let's discuss

I don't want CDC thrown under bus. You have QC'd in less than 24 hours.

Heads up though. I would create a simple spreadsheet about receipt and release.

Share with me please.

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 7:45 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Fwd: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

Sent from my iPhone

Begin forwarded message:

From: "Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov>
Date: March 5, 2020 at 6:59:37 PM EST
To: "Giroir, Brett (OS)" <Brett.Giroir@hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Berger, Sherri (CDC)" (b)(6)
Cc: "Monroe, Stephan S (CDC)" (b)(6), "Schuchat, Anne (CDC)" (b)(6), "Schwartz, Suzanne" <Suzanne.Schwartz@fda.hhs.gov>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC

(b)(5) We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by (b)(5) ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5)

We are grateful for the lot release testing reported (b)(5) by 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

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: Stenzel, Timothy

Sent: Thursday, March 5, 2020 5:56 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6)

Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff

<Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for next week: (b)(5) tests according to what the companies are telling 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

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

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: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 5, 2020 5:46 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6)

Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff

<Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially

count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week (b)(5)

Further, (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Thursday, March 5, 2020 5:31 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC)

(b)(6); Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make a million).
Is that Monday?

And are we still no track for (b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6); Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Redfield, Robert R. (CDC/OD) (b)(6) Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 4:18 PM
To: Berger, Sherri (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Redfield, Robert R (CDC) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterrill@idtdna.com>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
Office - 404-639-3103
Mobile - (b)(6)

From: Terrill, Roman <rterrill@idtdna.com>
Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

Please be advised that this email may contain confidential information. If you are not the intended recipient, please notify us by email by replying to the sender and delete this message. The sender disclaims that the content of this email constitutes an offer to enter into, or the acceptance of, any agreement; provided that the foregoing does not invalidate the binding effect of any digital or other electronic reproduction of a manual signature that is included in any attachment.

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>
Sent Date:	2020/03/06 07:13:40
Delivered Date:	2020/03/06 07:13:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Berger, Sherri (CDC/OCOO/OD) (b)(6)
CC:	Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>
Subject:	RE: Update w/ test #s from this morning
Date:	2020/03/03 17:38:00
Priority:	Normal
Type:	Note

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Tuesday, March 3, 2020 5:37 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Update w/ test #s from this morning

(b)(5)

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Tuesday, March 3, 2020 5:33 PM
To: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Update w/ test #s from this morning
Importance: High

(b)(5)

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Tuesday, March 3, 2020 5:23 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: Update w/ test #s from this morning

From: Berger, Sherri (CDC/OCOO/OD)
Sent: Tuesday, March 3, 2020 9:31 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; McGowan, Robert (Kyle) (CDC/OD) (b)(6)
Subject: RE: Test kit TPs

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Sent: Tuesday, March 3, 2020 9:29 AM

To: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)

Subject: Re: Test kit TPs

Ok. Adding Sherri because she has some numbers and nuance to the talkers.

Sent from my iPhone

On Mar 3, 2020, at 9:24 AM, Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov> wrote:

☐

Thanks. Let me try to massage it a little bit and then loop back to see if it's ok before using it.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Sent: Tuesday, March 3, 2020 9:16 AM

To: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>

Subject: RE: Test kit TPs

(b)(5)

From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>

Sent: Tuesday, March 3, 2020 9:01 AM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: Test kit TPs

(b)(5)

(b)(5)

William Hall

Deputy Assistant Secretary for Public Affairs (Public Health)
 Office of the Assistant Secretary for Public Affairs
 U.S. Department of Health & Human Services
 Washington, DC
 Direct: 202-690-6344
 Mobile: (b)(6)
 Email: bill.hall@hhs.gov
www.hhs.gov



Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Berger, Sherri (CDC/OCOO/OD) (b)(6); Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>
Sent Date:	2020/03/03 17:38:14
Delivered Date:	2020/03/03 17:38:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject:	RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/06 17:43:00
Priority:	Normal
Type:	Note

Wonderful
Thanks

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 5:42 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 5:32 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Standing by.

If they can ship tonight or tomorrow, it will really rock and the Boss will be pleased

Brett P. Giroir, MD

ADM, US Public Health Service
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 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 5:10 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne MD (CDC/OD) (b)(6)
 Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

QC results came in. The new IDT lot passed QC with (b)(5) tests, (b)(5) patients. I will now contact to see how many tests they could ship (b)(5) and will report back.

Best,
Tim

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 5:05 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Schuchat, Anne (CDC) (b)(6) Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

My thoughts, I just reread the entire summary of data from the CDC. (b)(5)

(b)(5)

(b)(5)

Apologies for not being more helpful.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 4:13 PM

To: Schuchat, Anne (CDC) (b)(6); Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK high priority.

Either way we need to know. If the advice is one swab, we double test.

If that is NOT the right recommendation, no issue.

Looked like NP was far superior on the limited data we saw

Brett P. Giroir, MD

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Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Schuchat, Anne MD (CDC/OD) (b)(6)
Sent: Friday, March 6, 2020 3:48 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: Re: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Tim. You may want Steve Monroe to provide some info on specimen site results as from various populations one vs the other site is positive. Not saying this isn't a good idea but np and op not providing perfect concordance. I don't have data right now but believe it can be looked at.

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 3:23:31 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

I previously checked with my team and checked the CDC's package insert and it is correct. One sample per patient is sufficient. This is what is commonly done with all molecular testing not just for this virus. One test per patient is the norm.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 9:32 AM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Contacted IDT by voice and they are working on getting me the numbers. They will recontact me soon.

Best,
Tim

Timothy T. Stenzel, MD, PhD
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 9:02 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(4); (b)(5) tests were shipped yesterday, to be specific. Not (b)(4); (b)(5)

Please verify and be certain

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 8:02 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Thank you Admiral for your help with the QC testing of lots that arrive today and tomorrow at the CDC. And more will be arriving next week.

I was a little tired last night when trying to update the math. In fact, for (b)(5) if we include the new lot of IDT reagents arriving at the CDC (b)(5) for QC testing and we include Biosearch's lot that arrives at the CDC (b)(5) for QC testing. The total (b)(5) will be (b)(5) tests (lots of (b)(5) plus (b)(5) plus (b)(5) from IDT and one lot of (b)(5) tests from Biosearch for a grand total of (b)(5) tests.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 7:48 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK

By calculation, that would be 1.1 million since 100,000 plus 600,000 have already been shipped. I will work with Sherri on the receipt as well as the QC timeline.

V/r
 BG

Brett P. Giroir, MD
 ADM, US Public Health Service
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 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 7:00 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5). We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is

reported to be (b)(5) tests by (b)(5) ThermoFisher's shipments this week could add to the total. I will update as soon as I get them.

(b)(5) We are grateful for the lot release testing reported (b)(5) by the CDC.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Stenzel, Timothy

Sent: Thursday, March 5, 2020 5:56 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;

Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for next week: (b)(5) tests according to what the companies are telling me.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 5, 2020 5:46 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;

Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

Best,
Tim

Timothy T. Stenzel, MD, PhD

Director, OHT7: Office of *In Vitro* Diagnostics and Radiological Health
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 5:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6); Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make (b)(5)).
 Is that Monday?

And are we still no track for (b)(5) tests next week?

Brett P. Giroir, MD
 ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
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 Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6); Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Redfield, Robert R. (CDC/OD) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 4:18 PM
To: Berger, Sherri (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Redfield, Robert R (CDC) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterill@idtdna.com>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
Office - 404-639-3103

Mobile - (b)(6)

From: Terrill, Roman <rterrill@idtdna.com>
Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6) Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6) Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6) Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent Date:	2020/03/06 17:43:09
Delivered Date:	2020/03/06 17:43:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Berger, Sherri (CDC/OCOO/OD) (b)(6)
Subject:	RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/06 07:53:00
Priority:	Normal
Type:	Note

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Friday, March 6, 2020 7:49 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Re: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

On it

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 7:43:06 AM
To: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Sherri,

(b)(5)

BG

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW

Washington, DC 20201
Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 7:45 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Fwd: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

Sent from my iPhone

Begin forwarded message:

From: "Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov>
Date: March 5, 2020 at 6:59:37 PM EST
To: "Giroir, Brett (OS)" <Brett.Giroir@hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Berger, Sherri (CDC)" (b)(6)
Cc: "Monroe, Stephan S (CDC)" (b)(6), "Schuchat, Anne (CDC)" (b)(6), "Schwartz, Suzanne" <Suzanne.Schwartz@fda.hhs.gov>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5) We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by (b)(5) ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5)

We are grateful for the lot release testing reported (b)(5) by 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

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: Stenzel, Timothy

Sent: Thursday, March 5, 2020 5:56 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)

Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff

<Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for next week: (b)(5) tests according to what the companies are telling me.

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

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 5, 2020 5:46 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6)

Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff

<Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further, (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Thursday, March 5, 2020 5:31 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC)

(b)(6); Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Sent: Thursday, March 5, 2020 4:19 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD)

(b)(6); Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Redfield, Robert R. (CDC/OD) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Thursday, March 5, 2020 4:18 PM

To: Berger, Sherri (CDC) (b)(6); Lenihan, Keagan
<Keagan.Lenihan@fda.hhs.gov>

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)

Redfield, Robert R (CDC) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Importance: High

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service

Assistant Secretary for Health (ASH)

200 Independence Avenue, SW

Washington, DC 20201

Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)

Sent: Thursday, March 5, 2020 4:13 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD
(CDC/OD) (b)(6)

Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)

Sent: Thursday, March 5, 2020 4:13 PM

To: Terrill, Roman <rterrell@idtdna.com>; Stenzel, Timothy (FDA/CDRH)
<Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD)

(b)(6) Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen
(FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH)
<Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)

(b)(6)

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
Office - 404-639-3103
Mobile - (b)(6)

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Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <(b)(6)>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) <(b)(6)>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <(b)(6)>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <(b)(6)>
Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

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I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Recipient:	Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent Date:	2020/03/06 07:53:11
Delivered Date:	2020/03/06 07:53:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Kellogg, Rachel (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=897ed8e8d85f4105b2bf0705fc476e32-Kellogg, Ra>
Subject:	Re: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/07 10:26:50
Priority:	Normal
Type:	Note

i think i am up to date!

From: Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>
Sent: Saturday, March 7, 2020 10:26 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Re: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

Sent from my iPhone

On Mar 6, 2020, at 5:27 PM, Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov> wrote:

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) <(b)(6)>
Sent: Friday, March 6, 2020 5:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Schuchat, Anne MD (CDC/OD) <(b)(6)>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <(b)(6)>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>
Subject: Re: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

May I ask that we wait for CDC to weigh in. This isn't my area of expertise. Steve and Anne are in the midst of the visit. Thank you

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 5:10:39 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Schuchat, Anne MD (CDC/OD) (b)(6); Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

You are helpful

We – that is HHS/CDC – need to recommend to clinicians how to sample and how many times to sample.

Over to CDC and will discuss this afternoon

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 5:05 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne MD (CDC/OD) (b)(6); Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

My thoughts, I just reread the entire summary of data from the CDC. (b)(5)

(b)(5)

(b)(5)

Apologies for not being more helpful.

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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<https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E>

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 4:13 PM

To: Schuchat, Anne (CDC) (b)(6) Stenzel, Timothy

<Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schwartz, Suzanne

<Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK high priority.

Either way we need to know. If the advice is one swab, we double test.

If that is NOT the right recommendation, no issue.

Looked like NP was far superior on the limited data we saw

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Schuchat, Anne MD (CDC/OD) (b)(6)
Sent: Friday, March 6, 2020 3:48 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: Re: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Tim. You may want Steve Monroe to provide some info on specimen site results as from various populations one vs the other site is positive. Not saying this isn't a good idea but np and op not providing perfect concordance. I don't have data right now but believe it can be looked at.

Get Outlook for iOS

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 3:23:31 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

I previously checked with my team and checked the CDC's package insert and it is correct. One sample per patient is sufficient. This is what is commonly done with all molecular testing not just for this virus. One test per patient is the norm.

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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 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, March 6, 2020 9:32 AM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Contacted IDT by voice and they are working on getting me the numbers. They will recontact me 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
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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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 9:02 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5) tests were shipped yesterday, to be specific. Not (b)(5)
Please verify and be certain

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 8:02 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD)

(b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schuchat, Anne MD (CDC/OD) (b)(6) Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Thank you Admiral for your help with the QC testing of lots that arrive today and tomorrow at the CDC. And more will be arriving next week.

I was a little tired last night when trying to update the math. In fact, for (b)(5) if we include the new lot of IDT reagents arriving at the CDC (b)(5) for QC testing and we include Biosearch's lot that arrives at the CDC (b)(5) for QC testing. The total this week will be (b)(5) tests (lots of (b)(5) plus (b)(5) plus (b)(5) from IDT and one lot of (b)(5) tests from Biosearch for a grand total of (b)(5) tests.

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 7:48 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK

By calculation, that would be (b)(5) since (b)(5) plus (b)(5) have already been shipped.

I will work with Sherri on the receipt as well as the QC timeline.

V/r
 BG

Brett P. Giroir, MD
 ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 7:00 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5) We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of this (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by (b)(5) ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5)

(b)(5) We are grateful for the lot release testing reported (b)(5) by 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

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From: Stenzel, Timothy

Sent: Thursday, March 5, 2020 5:56 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC)

(b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren,

Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for (b)(5) tests according to what the companies are telling 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

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Ph: 301-796-7692

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 5, 2020 5:46 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC)

(b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren,

Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the

CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

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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<https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E>

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Thursday, March 5, 2020 5:31 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC)

(b)(6) Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC)

(b)(6)

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make (b)(5)).
Is that Monday?

And are we still no track for (b)(5) tests (b)(5)?

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Sent: Thursday, March 5, 2020 4:19 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6); Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Redfield, Robert R. (CDC/OD) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Thursday, March 5, 2020 4:18 PM

To: Berger, Sherri (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Monroe, Stephen S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Redfield, Robert R (CDC) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Importance: High

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)

200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterrill@idtdna.com>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
 Office - 404-639-3103
 Mobile - (b)(6)

From: Terrill, Roman <rterrill@idtdna.com>
Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen

(FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)

(b)(6)

Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Kellogg, Rachel (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=897ed8e8d85f4105b2bf0705fc476e32-Kellogg, Ra>
Sent Date:	2020/03/07 10:26:50

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bced884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>; Hahn, Stephen <SH1@fda.hhs.gov>
CC:	Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea51e17a084644918dbec2d9b4db2a0f-Jernigan, D>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eac7af7ae9754d4290d7aa8cdb537078-Rosenstein>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>
Subject:	RE: Questions
Date:	2020/03/06 08:49:00
Priority:	Normal
Type:	Note

(b)(5)

Thanks
Brett

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>**Sent:** Friday, March 6, 2020 8:45 AM**To:** Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>**CC:** Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6); Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b)(6)

Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>

Subject: RE: Questions

Hi Admiral,

(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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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 8:41 AM

To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Jernigan, Daniel B (CDC) (b)(6)

Messonnier, Nancy E (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>

Subject: RE: Questions

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Sent: Friday, March 6, 2020 8:20 AM

To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Giroir, Brett (HHS/OASH)

<Brett.Giroir@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>

Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Jernigan, Daniel B.

(CDC/DDID/NCIRD/ID) (b)(6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b)(6)

Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schwartz, Suzanne (FDA/CDRH)

<Suzanne.Schwartz@fda.hhs.gov>

Subject: RE: Questions

No new updates. (b)(5)

Jeff

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Date: March 6, 2020 at 8:13:36 AM EST

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Jernigan, Daniel B (CDC)

(b)(6), Messonnier, Nancy E (CDC) (b)(6), Giroir, Brett (OS)

<Brett.Giroir@hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Schwartz, Suzanne

<Suzanne.Schwartz@fda.hhs.gov>

Subject: RE: Questions

Dear Admiral,

(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

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 7:52 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Jernigan, Daniel B (CDC) (b)(6)

Messonnier, Nancy E (CDC) (b)(6) Giroir, Brett (OS) <Brett.Giroir@hhs.gov>

Subject: Questions

(b)(5)

Many thanks

Brett P. Giroir, MD

ADM, US Public Health Service

Assistant Secretary for Health (ASH)

200 Independence Avenue, SW

Washington, DC 20201

Office Phone: 202-690-7694

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy < Timothy.Stenzel@fda.hhs.gov >; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bced884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>; Hahn, Stephen < SH1@fda.hhs.gov >; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea51e17a084644918db2d9b4db2a0f-Jernigan, D>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eac7af7ae9754d4290d7aa8cdb537078-Rosenstein>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>
Sent Date:	2020/03/06 08:49:12
Delivered Date:	2020/03/06 08:49:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Schuchat, Anne MD (CDC/OD) (b)(6) Stenzel, Timothy (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cba7ee2d647d476fa35a0fb86a74514c-timothy.ste>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>
CC:	Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>; Caccamo, Stephanie (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b415b3f6cff4b18980c5f723fad2ce0-stephanie.c>; Hillebrenner, Elizabeth J (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89aeb441cc0a424a86650c712c5e9312-elizabeth.h>; Flannery, Ellen (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d385c2cd6b21462282edba876e750319-ellen.flann>
Subject:	RE: update from fda and cdc
Date:	2020/03/08 10:46:00
Priority:	Normal
Type:	Note

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Schuchat, Anne MD (CDC/OD) (b)(6)
Sent: Sunday, March 8, 2020 10:46 AM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Hillebrenner, Elizabeth J (FDA/CDRH) <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
Subject: update from fda and cdc

(b)(5)

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Sunday, March 8, 2020 10:42 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne MD (CDC/OD) (b)(6)
 Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Hillebrenner, Elizabeth J (FDA/CDRH) <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Today's update. Will continue to update through the day when new information becomes available. Focus on first table in document which is new this 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

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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, March 6, 2020 8:01 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Schuchat, Anne (CDC) (b)(6) Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

News from Biosearch. See below. Their kits have (b)(5) tests per kit and their yield was increased by (b)(5) tests to (b)(5) tests. Attached updated table with these additional changes in green as well.

From Biosearch:

Attached is our invoice (b)(5) for the shipment of the (b)(5) kits from our initial production batch.

This batch total's (b)(5) kits.

The Fed Ex tracking # for this order is (b)(5)
(b)(5) early AM delivery – air bill label attached.

If you have any questions please let me know

I look forward to the feedback

Regards

Russell

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Stenzel, Timothy

Sent: Friday, March 6, 2020 7:53 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne (CDC) (b)(6) Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Elizabeth J Hillebrenner (Elizabeth.Hillebrenner@fda.hhs.gov) <Elizabeth.Hillebrenner@fda.hhs.gov>; Ellen Flannery (Ellen.Flannery@fda.hhs.gov) <Ellen.Flannery@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi,

See attached updated table. Updates are in green. IDT was able to ship (b)(5) tests (b)(5). An additional (b)(5) tests are available to ship on (b)(5)

Still awaiting confirmation from Biosearch that they have shipped kits for QC to CDC for (b)(5) delivery.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 5:11 PM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schuchat, Anne (CDC) <(b)(6)>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) <(b)(6)>

Cc: Monroe, Stephan S (CDC) <(b)(6)>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

awesome

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 5:10 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne MD (CDC/OD) (b)(6)
 Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD)
 (b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH)
 <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

QC results came in. The new IDT lot passed QC with (b)(5) tests/(b)(5) patients. I will now contact to see how many tests they could ship (b)(5) and will report back.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 5:05 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Schuchat, Anne (CDC) (b)(6); Lenihan, Keagan
 <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>;
 Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

My thoughts, I just reread the entire summary of data from the CDC. (b)(5)

(b)(5)

(b)(5)

Apologies for not being more helpful.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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Office of Product Evaluation and Quality

**Center for Devices and Radiological Health
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 4:13 PM

To: Schuchat, Anne (CDC) <(b)(6)>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) <(b)(6)>

Cc: Monroe, Stephan S (CDC) <(b)(6)>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK high priority.

Either way we need to know. If the advice is one swab, we double test.

If that is NOT the right recommendation, no issue.

Looked like NP was far superior on the limited data we saw

Brett P. Giroir, MD

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Assistant Secretary for Health (ASH)
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Washington, DC 20201
Office Phone: 202-690-7694

From: Schuchat, Anne MD (CDC/OD) <(b)(6)>

Sent: Friday, March 6, 2020 3:48 PM

To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <(b)(6)>

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <(b)(6)>; Schwartz, Suzanne (FDA/CDRH)

<Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: Re: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Tim. You may want Steve Monroe to provide some info on specimen site results as from various populations one vs the other site is positive. Not saying this isn't a good idea but np and op not providing perfect concordance. I don't have data right now but believe it can be looked at.

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 3:23:31 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC)

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD)

(b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

I previously checked with my team and checked the CDC's package insert and it is correct. One sample per patient is sufficient. This is what is commonly done with all molecular testing not just for this virus. One test per patient is the norm.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 9:32 AM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;

Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6); Schwartz,

Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Contacted IDT by voice and they are working on getting me the numbers. They will recontact me soon.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 9:02 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz,

Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5) tests were shipped yesterday, to be specific. Not (b)(5)

Please verify and be certain

Brett P. Giroir, MD

ADM, US Public Health Service

Assistant Secretary for Health (ASH)

200 Independence Avenue, SW

Washington, DC 20201

Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 8:02 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC)

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schuchat, Anne MD (CDC/OD) (b)(6) Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Thank you Admiral for your help with the QC testing of lots that arrive today and tomorrow at the CDC. And more will be arriving next week.

I was a little tired last night when trying to update the math. In fact, for (b)(5) if we include the new lot of IDT reagents arriving at the CDC (b)(5) for QC testing and we include Biosearch's lot that arrives at the CDC (b)(5) for QC testing. The total (b)(5) will be (b)(5) tests (lots of (b)(5) plus (b)(5) plus (b)(5) from IDT and one lot of (b)(5) tests from Biosearch for a grand total of (b)(5) tests.

Best,
Tim

Timothy T. Stenzel, MD, PhD

*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 7:48 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK

By calculation, that would be (b)(5) since (b)(5) plus (b)(5) have already been shipped. I will work with Sherri on the receipt as well as the QC timeline.

V/r
BG

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 5, 2020 7:00 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC)

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD)

(b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5)

(b)(5) We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5)

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by (b)(5) ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5)

We are grateful for the lot release testing reported (b)(5) by the CDC.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Stenzel, Timothy
Sent: Thursday, March 5, 2020 5:56 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for next week: (b)(5) tests according to what the companies are telling 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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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 5:46 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until (b)(5)

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further, (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

Best,
Tim

Timothy T. Stenzel, MD, PhD

*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Thursday, March 5, 2020 5:31 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) <(b)(6)> Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) <(b)(6)> Schuchat, Anne (CDC) <(b)(6)>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make (b)(5)).
 Is that (b)(5)?

And are we still no track for (b)(5) tests next week?

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <(b)(6)>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <(b)(6)>; Schuchat, Anne MD (CDC/OD) <(b)(6)>; Redfield, Robert R. (CDC/OD) <(b)(6)> Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 4:18 PM
To: Berger, Sherri (CDC) <(b)(6)>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) <(b)(6)>; Schuchat, Anne (CDC) <(b)(6)> Redfield, Robert R (CDC) <(b)(6)>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service

Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schuchat, Anne MD (CDC/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterrill@idtdna.com>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6) Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
 Office - 404-639-3103
 Mobile - (b)(6)

From: Terrill, Roman <rterrill@idtdna.com>
Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6) Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Schuchat, Anne MD (CDC/OD) (b)(6) Stenzel, Timothy (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cba7ee2d647d476fa35a0fb86a74514c-timothy.ste>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>; Caccamo, Stephanie (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b415b3f6cff4b18980c5f723fad2ce0-stephanie.c>; Hillebrenner, Elizabeth J (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89aeb441cc0a424a86650c712c5e9312-elizabeth.h>; Flannery, Ellen (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d385c2cd6b21462282edba876e750319-ellen.flann>
Sent Date:	2020/03/08 10:46:26
Delivered Date:	2020/03/08 10:46:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Hahn, Stephen <SH1@fda.hhs.gov>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
CC:	Shah, Anand (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=129795075b3f41c196fd261203d673e2-anand.shah.>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>
Subject:	RE: Roche
Date:	2020/03/16 16:44:00
Priority:	Normal
Type:	Note

roger

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, March 16, 2020 4:24 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Cc: Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: Roche

FYI.

(b)(5)

Steve

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 16, 2020 at 4:11:55 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: Roche

(b)(5)

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Monday, March 16, 2020 4:10 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Roche

Latest from Roche:

From: Cline, Richeal <richeal.cline@roche.com>
Sent: Monday, March 16, 2020 4:06 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Matt Sause <matt.sause@roche.com>; Miller, Danelle <danelle.miller@roche.com>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>
Subject: Re: Increasing Assay Production Volumes per week

Dear Tim

(b)(4)

Best regards
Richeal

Kind regards
Richeal

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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Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

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From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 16, 2020 2:58 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: Re: Roche

Thanks Tim.

Sent from my iPhone

On Mar 16, 2020, at 2:30 PM, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov> wrote:

(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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Timothy.Stenzel@fda.hhs.gov

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From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 16, 2020 2:11 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Roche

Thanks Tim.

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Monday, March 16, 2020 2:10 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Roche

I will check and get back

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

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From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Sent: Monday, March 16, 2020 2:05 PM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: Roche

(b)(5)

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Hahn, Stephen <SH1@fda.hhs.gov>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Shah, Anand (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=129795075b3f41c196fd261203d673e2-anand.shah.>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>
Sent Date:	2020/03/16 16:44:10
Delivered Date:	2020/03/16 16:44:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cba7ee2d647d476fa35a0fb86a74514c-timothy.ste>
Subject:	Re: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/06 20:27:52
Priority:	Normal
Type:	Note

Well I said they shipped all of them. We were close. Since they will ship soon I am keeping this the same

Sent from my iPhone

On Mar 6, 2020, at 7:53 PM, Stenzel, Timothy
<Timothy.Stenzel@fda.hhs.gov>wrote:

□

Hi,

See attached updated table. Updates are in green. IDT was able to ship (b)(5) tests
(b)(5) An additional (b)(5) tests are available to ship on Monday.

Still awaiting confirmation from Biosearch that they have shipped kits for QC to CDC for
(b)(5) delivery.

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

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 5:11 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schuchat, Anne (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

awesome

Brett P. Giroir, MD
 ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 5:10 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne MD (CDC/OD) (b)(6); Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

QC results came in. The new IDT lot passed QC with (b)(5) tests/(b)(5) patients. I will now contact to see how many tests they could ship (b)(5) and will report back.

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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U.S. Food and Drug Administration
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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 5:05 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Schuchat, Anne (CDC) (b)(6)
 Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne
 <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

My thoughts, I just reread the entire summary of data from the CDC. (b)(5)

(b)(5)

(b)(5) Apologies for not being more helpful.

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 4:13 PM
To: Schuchat, Anne (CDC) (b)(6); Stenzel, Timothy

<Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;
 Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne
 <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause
 likely!!!

OK high priority.

Either way we need to know. If the advice is one swab, we double test.

If that is NOT the right recommendation, no issue.

Looked like NP was far superior on the limited data we saw

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Schuchat, Anne MD (CDC/OD) (b)(6)
Sent: Friday, March 6, 2020 3:48 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Giroir, Brett
 (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC)
 <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne
 (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH)
 <Jeff.Shuren@fda.hhs.gov>
Subject: Re: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause
 likely!!!

Tim. You may want Steve Monroe to provide some info on specimen site results as
 from various populations one vs the other site is positive. Not saying this isn't a
 good idea but np and op not providing perfect concordance. I don't have data right
 now but believe it can be looked at.

Get [Outlook for iOS](#)

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 3:23:31 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC)
 <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD
 (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH)
 <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause
 likely!!!

I previously checked with my team and checked the CDC's package insert and it is correct. One sample per patient is sufficient. This is what is commonly done with all molecular testing not just for this virus. One test per patient is the norm.

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 <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 9:32 AM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)

Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff

<Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Contacted IDT by voice and they are working on getting me the numbers. They will recontact me soon.

Best,
Tim

Timothy T. Stenzel, MD, PhD

*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 9:02 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5) tests were shipped (b)(5) to be specific. Not (b)(5)
Please verify and be certain

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 8:02 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Thank you Admiral for your help with the QC testing of lots that arrive today and tomorrow at the CDC. And more will be arriving next week.

I was a little tired last night when trying to update the math. In fact, for (b)(5) if we include the new lot of IDT reagents arriving at the CDC (b)(5) for QC testing and we include Biosearch's lot that arrives at the CDC (b)(5) for QC testing. The total (b)(5) will be

(b)(5) (lots of (b)(5) plus (b)(5) plus (b)(5) from IDT and one lot of (b)(5) tests from Biosearch for a grand total of (b)(5) tests.

Best,
Tim

Timothy T. Stenzel, MD, PhD

*Director, 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=1900&S=E>

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 7:48 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6)

Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff

<Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK

By calculation, that would be (b)(5) since (b)(5) plus (b)(5) have already been shipped.

I will work with Sherri on the receipt as well as the QC timeline.

V/r

BG

Brett P. Giroir, MD

ADM, US Public Health Service

Assistant Secretary for Health (ASH)

200 Independence Avenue, SW

Washington, DC 20201

Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 7:00 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5). We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by (b)(5). ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5) We are grateful for the lot release testing reported (b)(5) by the CDC.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Stenzel, Timothy
Sent: Thursday, March 5, 2020 5:56 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6)
 Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for next week (b)(5) tests according to what the companies are telling me.

Best,
 Tim

Timothy T. Stenzel, MD, PhD

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 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=1900&S=E>

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 5:46 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6)
 Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff

<Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further, (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

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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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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 5:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6); Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make (b)(5)).
 Is that (b)(5)?

And are we still no track for (b)(5) tests (b)(5)?

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
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 Washington, DC 20201
 Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6); Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Redfield, Robert R. (CDC/OD) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 4:18 PM
To: Berger, Sherri (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Redfield, Robert R (CDC) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

(b)(5)

Copying Director and Commissioner on this one

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterill@idtdna.com>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
Office - 404-639-3103
Mobile - (b)(6)

From: Terrill, Roman <rterrill@idtdna.com>
Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6) Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6) Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6) Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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<LAB TESTING UPDATE 3.6.20 V2 UPDATED Tim 1900 hours
6MAR2020.docx>

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cba7ee2d647d476fa35a0fb86a74514c-timothy.ste>

Sent Date:	2020/03/06 20:27:51
Delivered Date:	2020/03/06 20:27:52

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI,BRE>
To:	Amin, Stacy <Stacy.Amin@fda.hhs.gov>
CC:	Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Fischmann, Elizabeth (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba724288e27f40f3a6b498cc17a140e4-Fischmann,>
Subject:	RE: Providing advice to HHS and White House
Date:	2020/03/16 16:50:00
Priority:	Normal
Type:	Note

She was really helpful to the team yesterday.
I will stand by

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Monday, March 16, 2020 3:51 PM
To: Lauren Silvis (b)(6); Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Boehler, Adam <Adam.Boehler@dfc.gov>; Smith, Brad (CMS/OA) <Brad.Smith@cms.hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Akbari, Asim (FDA/OC) <Asim.Akbari@fda.hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Fischmann, Elizabeth (HHS/OGC) <Elizabeth.Fischmann@hhs.gov>
Subject: RE: Providing advice to HHS and White House

+ Bob Charrow, HHS GC. Our ethics office is handling this and they have a call with Scott Gast in WHCO this afternoon. Apologies for the delay, we are working as fast as we can to get Lauren's status worked out.

From: Lauren Silvis (b)(6)
Sent: Monday, March 16, 2020 3:17 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Boehler, Adam <Adam.Boehler@dfc.gov>; Smith, Brad (CMS) <Brad.Smith@cms.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Akbari, Asim <Asim.Akbari@fda.hhs.gov>
Subject: Fwd: Providing advice to HHS and White House

Dear Brett, Brad, and Adam,

I am writing to give you an update on my status and to be removed from all email chains for the time being. As you know, I was asked to provide expert advice to HHS and White House employees on a personal volunteer basis on certain coronavirus crisis response issues. Because I am a former FDA employee, I asked HHS/FDA lawyers to review the proposed scope of my activity to ensure compliance with all applicable post-government employment rules governing my contact with the FDA. Until I receive guidance from the lawyers, I am going to hold off on communications with any FDA employees. I am happy to communicate directly with you if there are particular questions I can answer for HHS or the White House but I am not going to participate in any group calls, meetings or emails pending future guidance.

Lauren

----- Forwarded message -----

From: **Lauren Silvis** (b)(6)
 Date: Sun, Mar 15, 2020 at 8:28 PM
 Subject: Providing advice to HHS and White House
 To: <stacy.amin@fda.hhs.gov>, (b)(6) Keagan Lenihan
 <keagan.lenihan@fda.hhs.gov>, <anand.shah@fda.hhs.gov>, Akbari, Asim <Asim.Akbari@fda.hhs.gov>, Boehler, Adam <Adam.Boehler@dfc.gov>, Leslie Kiernan <lkiernan@kiernanfirm.com>

Stacy,

This is to follow up on our recent telephone conversation in which I advised you that I have been asked to provide expert advice to HHS and White House employees on a volunteer basis regarding certain matters related to the coronavirus crisis response. Specifically, I have been asked to provide advice on diagnostic testing supply chain and validation issues in an emergency use authorization situation. I understand that they have reached out to me because of my prior experience and expertise on these issues and that I will be serving as an independent consultant and not as a special government employee.

I expect to provide purely advisory services in my personal capacity and not on behalf of my current employer, Tempus Labs, Inc. While I believe that this activity will primarily involve communications with HHS and White House personnel, it is possible that it could also involve communications with personnel from the FDA, my former agency. It is my understanding that my performing this work for HHS and the White House is legally permissible and consistent with all applicable post-employment restrictions -- even if I communicate with FDA personnel -- since I am doing this work at the request of the government and am not representing my current employer or any third

party with respect to this activity. Moreover, I have been advised that there is an exception to the restrictions of 18 U.S.C. 207 if the activities are performed on behalf of the United States pursuant to an agreement. See 5 C.F.R. 2641.301 (a)(2)(ii)(A)(1).

Please let me know if you have any concerns regarding the activities outlined above and also whether FDA believes a written agreement is necessary under these circumstances. I have also copied my attorney Leslie Kiernan here.

Lauren

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Fischmann, Elizabeth (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba724288e27f40f3a6b498cc17a140e4-Fischmann,>
Sent Date:	2020/03/16 16:50:58
Delivered Date:	2020/03/16 16:50:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schuchat, Anne MD (CDC/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e506fd4b204294906aa26f44d2f2c8-Schuchat, A>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>
CC:	Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>
Subject:	RE: Coordinating information about IDT
Date:	2020/03/06 09:23:00
Importance:	High
Priority:	Urgent
Type:	Note

Tim et al.,

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 9:15 AM

To: Schuchat, Anne MD (CDC/OD) (b)(6) Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>;
Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD)

(b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Coordinating information about IDT

Yes, Sir, I will increase my daily contact with manufacturers going forward.

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: Schuchat, Anne MD (CDC/OD) (b)(6)
Sent: Friday, March 6, 2020 9:08 AM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Coordinating information about IDT

Thanks for asking for the clarification. We all need to be using the same information.

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 9:02 AM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5) tests were shipped (b)(5) to be specific. Not (b)(5)
Please verify and be certain

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201

Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 8:02 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schuchat, Anne MD (CDC/OD) (b)(6) Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Thank you Admiral for your help with the QC testing of lots that arrive today and tomorrow at the CDC. And more will be arriving next week.

I was a little tired last night when trying to update the math. In fact, for (b)(5) if we include the new lot of IDT reagents arriving at the CDC (b)(5) for QC testing and we include Biosearch's lot that arrives at the CDC (b)(5) for QC testing. The total (b)(5) will be (b)(5) tests (lots of (b)(5) plus (b)(5) plus (b)(5) from IDT and one lot of (b)(5) tests from Biosearch for a grand total of (b)(5) tests.

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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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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 7:48 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK

By calculation, that would be (b)(5) since (b)(5) plus (b)(5) have already been shipped. I will work with Sherri on the receipt as well as the QC timeline.

V/r
BG

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 5, 2020 7:00 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC)

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <(b)(6)>

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <(b)(6)>; Schuchat, Anne MD (CDC/OD) <(b)(6)>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5). We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by (b)(5). ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5) We are grateful for the lot release testing reported (b)(5) by 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

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Jennifer.Campbell@fda.hhs.gov

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From: Stenzel, Timothy

Sent: Thursday, March 5, 2020 5:56 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;

Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for next week: (b)(5) tests according to what the companies are telling 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

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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: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 5:46 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further, (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

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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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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 5:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6) Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make (b)(5)).
 Is that (b)(5)?

And are we still no track for (b)(5) tests (b)(5)?

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6) Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Redfield, Robert R. (CDC/OD) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 4:18 PM
To: Berger, Sherri (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Redfield, Robert R (CDC) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

(b)(5)

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterrill@idtdna.com>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
 Office - 404-639-3103
 Mobile - (b)(6)

From: Terrill, Roman <rterrill@idtdna.com>
Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6)

Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)

Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schuchat, Anne MD (CDC/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e506fd4b204294906aa26f44d2f2c8-Schuchat, A>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>
Sent Date:	2020/03/06 09:23:40

Delivered Date:	2020/03/06 09:23:00
------------------------	---------------------

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>
CC:	Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Schuchat, Anne MD (CDC/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e506fd4b204294906aa26f44d2f2c8-Schuchat, A>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bced884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>
Subject:	RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/06 09:33:00
Priority:	Normal
Type:	Note

Standing by

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 9:32 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Contacted IDT by voice and they are working on getting me the numbers. They will recontact me 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
 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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 9:02 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5) tests were shipped (b)(5) to be specific. Not (b)(5)
 Please verify and be certain

Brett P. Giroir, MD
 ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 8:02 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Thank you Admiral for your help with the QC testing of lots that arrive today and tomorrow at the CDC. And more will be arriving next week.

I was a little tired last night when trying to update the math. In fact, for (b)(5) if we include the new lot of IDT reagents arriving at the CDC (b)(5) for QC testing and we include Biosearch's lot that arrives at

the CDC (b)(5) for QC testing. The total (b)(5) will be (b)(5) tests (lots of (b)(5) plus (b)(5) plus (b)(5) from IDT and one lot of (b)(5) tests from Biosearch for a grand total of (b)(5) tests.

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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U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 7:48 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK

By calculation, that would be (b)(5) since (b)(5) plus (b)(5) have already been shipped. I will work with Sherri on the receipt as well as the QC timeline.

V/r
BG

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 5, 2020 7:00 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5)
 (b)(5) We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by Saturday, March 14. ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5)

We are grateful for the lot release testing reported (b)(5) by 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

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Jennifer Campbell

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From: Stenzel, Timothy

Sent: Thursday, March 5, 2020 5:56 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;

Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for (b)(5) tests according to what the companies are telling 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

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 5, 2020 5:46 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;

Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of

which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further, (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Thursday, March 5, 2020 5:31 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6) Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make (b)(5)).

Is that (b)(5)?

And are we still no track for (b)(5) tests (b)(5) ?

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6); Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Redfield, Robert R. (CDC/OD) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 4:18 PM
To: Berger, Sherri (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Redfield, Robert R (CDC) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD)

(b)(6)

Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)

Sent: Thursday, March 5, 2020 4:13 PM

To: Terrill, Roman <rterill@idtdna.com>; Stenzel, Timothy (FDA/CDRH)

<Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6)

Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH)

<Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>;

Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman

Office - 404-639-3103

Mobile - (b)(6)

From: Terrill, Roman <rterill@idtdna.com>

Sent: Thursday, March 5, 2020 3:58 PM

To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi

(CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6)

Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH)

<Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>;

Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)

Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Schuchat, Anne MD (CDC/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e506fd4b204294906aa26f44d2f2c8-Schuchat, A>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>
Sent Date:	2020/03/06 09:33:48
Delivered Date:	2020/03/06 09:33:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject:	RE: Lab Testing
Date:	2020/03/08 11:19:00
Priority:	Normal
Type:	Note

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Sunday, March 8, 2020 11:08 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: RE: Lab Testing

Will do. I believe the numbers I have sent today are probably as much as I can get you before 2 pm. Will update daily by 2 pm and with any significant 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**
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Jennifer Campbell
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Sunday, March 8, 2020 11:05 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Lab Testing

(b)(5)

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Sunday, March 8, 2020 11:02 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: RE: Lab Testing

Perfect it works for me. How often do you want me to update it? And by what time each day?

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
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Sunday, March 8, 2020 11:00 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>
Subject: RE: Lab Testing

OK

(b)(5)

Best
Brett

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Sunday, March 8, 2020 10:49 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne MD (CDC/OD) <(b)(6)>
 Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <(b)(6)>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <(b)(6)>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Hillebrenner, Elizabeth J (FDA/CDRH) <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
Subject: RE: Lab Testing

Yes, sir.

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Sunday, March 8, 2020 10:47 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schuchat, Anne (CDC) (b)(6) Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>

Subject: Lab Testing

Great

Our emails passed each other.

Tim:

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service

Assistant Secretary for Health (ASH)

200 Independence Avenue, SW

Washington, DC 20201

Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Sunday, March 8, 2020 10:42 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne MD (CDC/OD) (b)(6) Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD)

(b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Hillebrenner, Elizabeth J (FDA/CDRH) <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Today's update. Will continue to update through the day when new information becomes available. Focus on first table in document which is new this 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
 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, March 6, 2020 8:01 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Schuchat, Anne (CDC) (b)(6) Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

News from Biosearch. See below. Their kits have (b)(5) tests per kit and their yield was increased by (b)(5) tests to (b)(5) tests. Attached updated table with these additional changes in green as well.

From Biosearch:

Attached is our invoice (b)(5) for the shipment of the (b)(5) kits from our initial production batch.

This batch total's (b)(5) kits.

The Fed Ex tracking # for this order is (b)(6)
 (b)(5) early AM delivery – air bill label attached.

If you have any questions please let me know

I look forward to the feedback

Regards

Russell

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

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From: Stenzel, Timothy

Sent: Friday, March 6, 2020 7:53 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Elizabeth J Hillebrenner (Elizabeth.Hillebrenner@fda.hhs.gov) <Elizabeth.Hillebrenner@fda.hhs.gov>; Ellen Flannery (Ellen.Flannery@fda.hhs.gov) <Ellen.Flannery@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi,

See attached updated table. Updates are in green. IDT was able to ship (b)(5) tests (b)(5) An additional (b)(5) tests are available to ship on (b)(5)

Still awaiting confirmation from Biosearch that they have shipped kits for QC to CDC for (b)(5) delivery.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 5:11 PM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schuchat, Anne (CDC) <(b)(6)>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) <(b)(6)>

Cc: Monroe, Stephan S (CDC) <(b)(6)>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

awesome

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 5:10 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne MD (CDC/OD) <(b)(6)>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <(b)(6)>

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <(b)(6)>; Schwartz, Suzanne (FDA/CDRH)

<Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

QC results came in. The new IDT lot passed QC with (b)(5) tests/(b)(5) patients. I will now contact to see how many tests they could ship (b)(5) and will report back.

Best,
Tim

Timothy T. Stenzel, MD, PhD

*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 5:05 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Schuchat, Anne (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

My thoughts, I just reread the entire summary of data from the CDC. (b)(5)

(b)(5)

(b)(5) Apologies for not being more helpful.

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
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 4:13 PM
To: Schuchat, Anne (CDC) (b)(6); Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Schuchat, Anne MD (CDC/OD) (b)(6)
Sent: Friday, March 6, 2020 3:48 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: Re: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 3:23:31 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

I previously checked with my team and checked the CDC's package insert and it is correct. One sample per patient is sufficient. This is what is commonly done with all molecular testing not just for this virus. One test per patient is the norm.

Best,
Tim

Timothy T. Stenzel, MD, PhD
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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 9:32 AM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Contacted IDT by voice and they are working on getting me the numbers. They will recontact me soon.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 9:02 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5) tests were shipped (b)(5) to be specific. Not (b)(5)
Please verify and be certain

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 8:02 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Thank you Admiral for your help with the QC testing of lots that arrive today and tomorrow at the CDC. And more will be arriving next week.

I was a little tired last night when trying to update the math. In fact, for (b)(5) if we include the new lot of IDT reagents arriving at the CDC (b)(5) for QC testing and we include Biosearch's lot that arrives at the CDC (b)(5) for QC testing. The total (b)(5) will be (b)(5) (lots of (b)(5) plus (b)(5) plus (b)(5) from IDT and one lot of (b)(5) tests from Biosearch for a grand total of (b)(5) tests.

Best,
Tim

Timothy T. Stenzel, MD, PhD

Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 7:48 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6) Schwartz,

Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK

By calculation, that would be (b)(5) since (b)(5) plus (b)(5) have already been shipped. I will work with Sherri on the receipt as well as the QC timeline.

V/r
BG

Brett P. Giroir, MD

ADM, US Public Health Service

Assistant Secretary for Health (ASH)

200 Independence Avenue, SW

Washington, DC 20201

Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 7:00 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5). We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by Saturday, March 14. ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5)

We are grateful for the lot release testing reported (b)(5) by the CDC.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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Center for Devices and Radiological Health

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From: Stenzel, Timothy
Sent: Thursday, March 5, 2020 5:56 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for next week: (b)(5) tests according to what the companies are telling me.

Best,
Tim

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 5:46 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further, (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Thursday, March 5, 2020 5:31 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) <(b)(6)> Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Cc: Monroe, Stephan S (CDC) <(b)(6)> Schuchat, Anne (CDC) <(b)(6)>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make (b)(5)).
Is that (b)(5)?

And are we still no track for (b)(5) tests (b)(5)

Brett P. Giroir, MD

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Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6); Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Redfield, Robert R. (CDC/OD) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 4:18 PM
To: Berger, Sherri (CDC) <sob8@cdc.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) <stm2@cdc.gov>; Schuchat, Anne (CDC) <acs1@cdc.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schuchat, Anne MD (CDC/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterrill@idtdna.com>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6) Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
Office - 404-639-3103
Mobile - (b)(6)

From: Terrill, Roman <rterrill@idtdna.com>
Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team

will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

Please be advised that this email may contain confidential information. If you are not the intended recipient, please notify us by email by replying to the sender and delete this message. The sender disclaims that the content of this email constitutes an offer to enter into, or the acceptance of, any agreement; provided that the foregoing does not invalidate the binding effect of any digital or other electronic reproduction of a manual signature that is included in any attachment.

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent Date:	2020/03/08 11:19:07
Delivered Date:	2020/03/08 11:19:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Rom, Colin (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc623491d95f47e2af2204b37b4d6c6c-colin.rom.f>
CC:	Stenzel, Timothy (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cba7ee2d647d476fa35a0fb86a74514c-timothy.ste>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; McWilliams, Carly (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d245578c83ab4d72a104c6bc1641d0e5-carlyle.mcw>
Subject:	Re: Updated diagnostics numbers for VPOTUS
Date:	2020/03/17 10:42:31
Priority:	Normal
Type:	Note

And please. All diagnostic info needs to flow to me in addition to the Commissioner.

Sent from my iPhone

On Mar 17, 2020, at 10:35 AM, Rom, Colin
<Colin.Rom@fda.hhs.gov>wrote:

□

Thank you sir

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Date: March 17, 2020 at 10:34:17 AM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>, Giroir, Brett (OS)
 <Brett.Giroir@hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McWilliams, Carly
 <Carly.McWilliams@fda.hhs.gov>
Subject: RE: Updated diagnostics numbers for VPOTUS

I will do my best. 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

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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: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 10:24 AM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: Updated diagnostics numbers for VPOTUS
Importance: High

Admiral Giroir and Tim—

Hope you are both surviving these busy days!

(b)(5)

(b)(5)

Please let me know if that is doable?

Thank you and apologies for the last minute request!

Best,
Colin

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI,BRE>
Recipient:	Stenzel, Timothy (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cba7ee2d647d476fa35a0fb86a74514c-timothy.ste>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; McWilliams, Carly (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d245578c83ab4d72a104c6bc1641d0e5-carlyle.mcw>; Rom, Colin (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc623491d95f47e2af2204b37b4d6c6c-colin.rom.f>
Sent Date:	2020/03/17 10:42:30
Delivered Date:	2020/03/17 10:42:31

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>
Subject:	RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/06 21:34:00
Priority:	Normal
Type:	Note

GOT it

THANK YOU

Go to sleep

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 9:33 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Great. Please note that (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

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 9:29 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Got it
That is what I am going with that

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 9:24 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

Best,
Tim

Timothy T. Stenzel, MD, PhD
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 9:17 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

Sorry but important
Happy to get on a call

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
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Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 9:15 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hopefully I can clarify. (b)(5)

Best,
Tim

Timothy T. Stenzel, MD, PhD

*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 9:07 PM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan
<Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

I am also happy to get on the phone with IDT to clarify where we are.
Again, number do matter

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
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Office Phone: 202-690-7694

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 9:01 PM

To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan (FDA/OC)
<Keagan.Lenihan@fda.hhs.gov>

Cc: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 7:53 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne MD (CDC/OD) (b)(6)
 Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>; Hillebrenner, Elizabeth J (FDA/CDRH) <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi,

See attached updated table. Updates are in green. IDT was able to ship (b)(5) tests (b)(5). An additional (b)(5) tests are available to ship on (b)(5).

Still awaiting confirmation from Biosearch that they have shipped kits for QC to CDC for (b)(5) delivery.

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 5:11 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schuchat, Anne (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

awesome

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 5:10 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Schuchat, Anne MD (CDC/OD) (b)(6);
Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD)
(b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH)
<Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

QC results came in. The new IDT lot passed QC with (b)(5) tests/(b)(5) patients. I will now contact to see how many tests they could ship (b)(5) and will report back.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 5:05 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Schuchat, Anne (CDC) (b)(6) Lenihan, Keagan
<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>;
Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

My thoughts, I just reread the entire summary of data from the CDC. (b)(5)

(b)(5)

(b)(5)

Apologies for not being more helpful.

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 4:13 PM

To: Schuchat, Anne (CDC) (b)(6); Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK high priority.

Either way we need to know. If the advice is one swab, we double test.

If that is NOT the right recommendation, no issue.

Looked like NP was far superior on the limited data we saw

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Schuchat, Anne MD (CDC/OD) <(b)(6)>
Sent: Friday, March 6, 2020 3:48 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <(b)(6)>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <(b)(6)>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: Re: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Tim. You may want Steve Monroe to provide some info on specimen site results as from various populations one vs the other site is positive. Not saying this isn't a good idea but np and op not providing perfect concordance. I don't have data right now but believe it can be looked at.

Get Outlook for iOS

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 3:23:31 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <(b)(6)>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <(b)(6)>; Schuchat, Anne MD (CDC/OD) <(b)(6)>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

I previously checked with my team and checked the CDC's package insert and it is correct. One sample per patient is sufficient. This is what is commonly done with all molecular testing not just for this virus. One test per patient is the norm.

Best,
Tim

Timothy T. Stenzel, MD, PhD

*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 9:32 AM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Contacted IDT by voice and they are working on getting me the numbers. They will recontact me 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
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Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 9:02 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5) tests were shipped (b)(5) to be specific. Not (b)(5)
Please verify and be certain

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201

Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 8:02 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Thank you Admiral for your help with the QC testing of lots that arrive today and tomorrow at the CDC. And more will be arriving next week.

I was a little tired last night when trying to update the math. In fact, for (b)(5) if we include the new lot of IDT reagents arriving at the CDC (b)(5) for QC testing and we include Biosearch's lot that arrives at the CDC (b)(5) for QC testing. The total (b)(5) will be (b)(5) tests (lots of (b)(5) plus (b)(5) plus (b)(5) from IDT and one lot of (b)(5) tests from Biosearch for a grand total of (b)(5) tests.

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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 Jennifer.Campbell@fda.hhs.gov

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 7:48 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK

By calculation, that would be 1.1 million since 100,000 plus 600,000 have already been shipped. I will work with Sherri on the receipt as well as the QC timeline.

V/r
BG

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
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Washington, DC 20201
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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 7:00 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schuchat, Anne MD (CDC/OD) (b)(6) Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5). We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by Saturday, March 14. ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5)

We are grateful for the lot release testing reported (b)(5) by the CDC.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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U.S. Food and Drug Administration

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From: Stenzel, Timothy

Sent: Thursday, March 5, 2020 5:56 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;

Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for next week: (b)(5) tests according to what the companies are telling me.

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 5:46 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

Best,
Tim

Timothy T. Stenzel, MD, PhD
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 Office of Product Evaluation and Quality*

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 5:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6) Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make (b)(5)).
 Is that (b)(5)?

And are we still no track for (b)(5) tests (b)(5)?

Brett P. Giroir, MD

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 Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6); Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Redfield, Robert R. (CDC/OD) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 4:18 PM
To: Berger, Sherri (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Redfield, Robert R (CDC) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

(b)(5)

(b)(5)

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 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schuchat, Anne MD (CDC/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterrill@idtdna.com>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6) Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
 Office - 404-639-3103
 Mobile - (b)(6)

From: Terrill, Roman <rterrill@idtdna.com>
Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6)

Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6) Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)

Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>
Sent Date:	2020/03/06 21:34:06
Delivered Date:	2020/03/06 21:34:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Heck, Mia (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70dbe2065d644b8dadbfa56c5d63553d-Heck, Mia>
CC:	Broido, Tara (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c3cd5c5afe049b6a8b48c25324c7465-Broido, Tar>
Subject:	RE: FDA Heads Up for HHS NN - 2/6/20
Date:	2020/02/05 21:13:00
Priority:	Normal
Type:	Note

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
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200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>
Sent: Wednesday, February 5, 2020 8:56 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>
Subject: Re: FDA Heads Up for HHS NN - 2/6/20

(b)(5)

Sent from my iPhone

On Feb 5, 2020, at 6:26 PM, Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov> wrote:

Any word on the Op Ed

Brett P. Giroir, MD

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From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 4:10 PM
To: Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Abernethy, Amy (FDA/OC) <Amy.Abernethy@fda.hhs.gov>; Beshara, Nicholas (FDA/OC) <Nicholas.Beshara@fda.hhs.gov>; Franklin, Joseph (FDA/OC) <Joseph.Franklin@fda.hhs.gov>; Beardsley, Sara (FDA/OC) <Sara.Beardsley@fda.hhs.gov>; Anderson, Erika (FDA/OC) <Erika.Anderson@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark (FDA/OC) <Mark.Raza@fda.hhs.gov>; Watters, Sam (HHS/IOS) <Sam.Watters@hhs.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>
Subject: FDA Heads Up for HHS NN - 2/6/20

(b)(5)

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Heck, Mia (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70dbe2065d644b8dadbf56c5d63553d-Heck, Mia>; Broido, Tara (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c3cd5c5afe049b6a8b48c25324c7465-Broido, Tar>
Sent Date:	2020/02/05 21:13:37
Delivered Date:	2020/02/05 21:13:00

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Stenzel, Timothy (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cba7ee2d647d476fa35a0fb86a74514c-timothy.ste>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea51e17a084644918dbee2d9b4db2a0f-Jernigan, D>; Delew, Nancy (HHS/ASPE) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f3de4322eea4acb9c69140630415f1b-Nancy Delew>
CC:	Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Schuchat, Anne MD (CDC/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e506fd4b204294906aa26f44d2f2c8-Schuchat, A>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bced884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Haddad, Carla (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>
Subject:	RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/06 15:20:45
Importance:	High
Priority:	Urgent
Type:	Note

Whooooa.....

(b)(5)

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 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 10:48 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC)

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <(b)(6)>

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <(b)(6)>; Schuchat, Anne MD (CDC/OD)

<(b)(6)>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

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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Administrative Assistant

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 10:44 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) <(b)(6)>

Cc: Monroe, Stephan S (CDC) <(b)(6)>; Schuchat, Anne (CDC) <(b)(6)>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

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Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 10:41 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC)

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD)

(b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff

(FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5)

Also, IDT confirmed receipt by CDC already this morning of the new lot of reagents. Neither IDT nor I have received word of this from the CDC. IDT is sending me the tracking info.

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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 10:21 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6) Schwartz,
 Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

One additional:

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 10:01 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC)
 <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schuchat, Anne MD (CDC/OD)
 (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff
 (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Admiral,

Just received this email in green and followed up by call to confirm. IDT fulfilled all open orders to US
 labs yesterday following lot QC release. (b)(5)

(b)(5)

From IDT email just now:

Here are the numbers, and there is potentially game-changing juice in here.

- • As of Wednesday March 4, 2020, IDT has shipped kits sufficient to test (b)(5)
 individual for coronavirus.
- • On Thursday March 5, IDT shipped kits sufficient to test an additional (b)(5)
 individuals for coronavirus.
- • As of Friday March 6, at 10am Eastern, IDT has kits in inventory ready to ship to
 those labs in need, sufficient to test an additional (b)(5) individual for
 coronavirus. IDT is ready to ship on receipt until that inventory is consumed.

- Pending approval anticipated later today by CDC of an additional lot of IDT kits, IDT will have kits sufficient to test an additional 400,000 individuals for coronavirus ready to ship on Monday, March 9th 2020.

Hope this helps correct the narrative.

Roman

(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**

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Jennifer Campbell

Administrative Assistant

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 9:02 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5) tests were shipped (b)(5) to be specific. Not (b)(5)
 Please verify and be certain

Brett P. Giroir, MD
 ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 8:02 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Thank you Admiral for your help with the QC testing of lots that arrive today and tomorrow at the CDC. And more will be arriving next week.

I was a little tired last night when trying to update the math. In fact, for (b)(5) if we include the new lot of IDT reagents arriving at the CDC (b)(5) for QC testing and we include Biosearch's lot that arrives at the CDC (b)(5) for QC testing. The total (b)(5) will be (b)(5) tests (lots of (b)(5) plus (b)(5) plus (b)(5) from IDT and one lot of (b)(5) tests from Biosearch for a grand total of (b)(5) tests.

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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 U.S. Food and Drug Administration
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 7:48 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK

By calculation, that would be 1.1 million since 100,000 plus 600,000 have already been shipped. I will work with Sherri on the receipt as well as the QC timeline.

V/r
BG

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Thursday, March 5, 2020 7:00 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Schuchat, Anne MD (CDC/OD) (b)(6) Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5)
 (b)(5) We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by (b)(5) ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5)

We are grateful for the lot release testing reported (b)(5) by 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

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From: Stenzel, Timothy

Sent: Thursday, March 5, 2020 5:56 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;

Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz,

Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for next week (b)(5) tests according to what the companies are telling me.

Best,
Tim

Timothy T. Stenzel, MD, PhD

Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov

Jennifer Campbell
Administrative Assistant

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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=1900&S=E>

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 5, 2020 5:46 PM

To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;

Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

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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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: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Thursday, March 5, 2020 5:31 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6) Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6)

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make (b)(5)

Is that (b)(5)

And are we still no track for (b)(5) tests (b)(5)?

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201

Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6); Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Redfield, Robert R. (CDC/OD) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 4:18 PM
To: Berger, Sherri (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Redfield, Robert R (CDC) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterill@idtdna.com>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6);

Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
Office - 404-639-3103
Mobile - (b)(6)

From: Terrill, Roman <rterill@idtdna.com>

Sent: Thursday, March 5, 2020 3:58 PM

To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)

Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Stenzel, Timothy (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cba7ee2d647d476fa35a0fb86a74514c-timothy.ste>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea51e17a084644918dbec2d9b4db2a0f-Jernigan, D>; Delew, Nancy (HHS/ASPE) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f3de4322eea4acb9c69140630415f1b-Nancy Delew>; Monroe, Steve (CDC/DDPHSS/OLSS/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dd524133eb4ac99724fc5456424b0b-Monroe, Ste>; Schuchat, Anne MD (CDC/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e506fd4b204294906aa26f44d2f2c8-Schuchat, A>; Schwartz, Suzanne (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bce62c458594ca8b15ecc04fe792094-suzanne.sch>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bced884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Haddad, Carla (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>
Sent Date:	2020/03/06 15:20:42
Delivered Date:	2020/03/06 15:20:45

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Haddad, Carla (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>; Gray, Oneika (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7c446d71dac4354a8218c8e08bffd51-Gray, Oneik>
Subject:	FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Date:	2020/03/06 10:22:07
Importance:	High
Priority:	Urgent
Type:	Note

Can you set up an 1100 call for 15 min?

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Giroir, Brett (HHS/OASH)
Sent: Friday, March 6, 2020 10:19 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <(b)(6)>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <(b)(6)>; Schuchat, Anne MD (CDC/OD) <(b)(6)>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

Can we have a call at 1100 for 15 minutes please???

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Friday, March 6, 2020 10:01 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC)

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) <(b)(6)>

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) <(b)(6)> Schuchat, Anne MD (CDC/OD)

<(b)(6)> Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Admiral,

Just received this email in green and followed up by call to confirm. IDT fulfilled all open orders to US labs yesterday following lot QC release. (b)(5)

(b)(5)

From IDT email just now:

Here are the numbers, and there is potentially game-changing juice in here.

- As of Wednesday March 4, 2020, IDT has shipped kits sufficient to test (b)(5) individual for coronavirus.
- On Thursday March 5, IDT shipped kits sufficient to test an additional (b)(5) individuals for coronavirus.
- **As of Friday March 6, at 10am Eastern, IDT has kits in inventory ready to ship to those labs in need, sufficient to test an additional (b)(5) individual for coronavirus. IDT is ready to ship on receipt until that inventory is consumed.**
- Pending approval anticipated later today by CDC of an additional lot of IDT kits, IDT will have kits sufficient to test an additional (b)(5) individuals for coronavirus ready to ship on Monday, March 9th 2020.

Hope this helps correct the narrative.

Roman

(b)(5)

(b)(5)

Best,
Tim

Timothy T. Stenzel, MD, PhD

*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>

Sent: Friday, March 6, 2020 9:02 AM

To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)

Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

(b)(5) tests were shipped (b)(5) to be specific. Not (b)(5)
Please verify and be certain

Brett P. Giroir, MD

ADM, US Public Health Service

Assistant Secretary for Health (ASH)

200 Independence Avenue, SW

Washington, DC 20201

Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Friday, March 6, 2020 8:02 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Thank you Admiral for your help with the QC testing of lots that arrive today and tomorrow at the CDC. And more will be arriving next week.

I was a little tired last night when trying to update the math. In fact, for (b)(5) if we include the new lot of IDT reagents arriving at the CDC (b)(5) for QC testing and we include Biosearch's lot that arrives at the CDC (b)(5) for QC testing. The total (b)(5) will be (b)(5) tests (lots of (b)(5) plus (b)(5) plus (b)(5) from IDT and one lot of (b)(5) tests from Biosearch for a grand total of (b)(5) tests.

Best,
Tim

Timothy T. Stenzel, MD, PhD

Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 6, 2020 7:48 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6); Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

OK

By calculation, that would be 1.1 million since 100,000 plus 600,000 have already been shipped.

I will work with Sherri on the receipt as well as the QC timeline.

V/r
BG

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Thursday, March 5, 2020 7:00 PM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Lenihan, Keagan (FDA/OC)

<Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6)

Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD)

(b)(6); Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Dear Admiral,

I just got a new update from IDT. A new lot of kits for QC testing will arrive at CDC (b)(5). We need QC testing right away and reporting back to IDT and FDA right away. They report this lot will have (b)(5) kits/(b)(5) reactions.

But, unfortunately, because of (b)(5)

(b)(5)

I am sorry to deliver these revised lower numbers to you. However, it looks like if all lots pass QC we will have (b)(5) tests available to ship by the end of (b)(5) and (b)(5) total so far is reported to be (b)(5) tests by (b)(5) ThermoFisher's shipments (b)(5) could add to the total. I will update as soon as I get them.

(b)(5)

We are grateful for the lot release testing reported (b)(5) by the CDC.

Best,
Tim

Timothy T. Stenzel, MD, PhD

Director, OHT7: Office of In Vitro Diagnostics and Radiological Health

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From: Stenzel, Timothy
Sent: Thursday, March 5, 2020 5:56 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6) Schuchat, Anne (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

And by the end of (b)(5) according to my industry contacts, ThermoFisher should have another (b)(5) tests to ship; IDT another (b)(5) tests to ship; and Biosearch will have another (b)(5) to ship.

Total for next week: (b)(5) tests according to what the companies are telling me.

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: Thursday, March 5, 2020 5:46 PM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6)
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6) Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Hi Admiral,

If the CDC immediately QC tests lots from either IDT or Biosearch upon receipt, this process will go more quickly. Not counting CDC's shipping of kits this week to PHLs, IDT shipped (b)(5) tests earlier this week and is shipping (b)(5) tests today. Biosearch has a lot of (b)(5) tests, a sampling of which will arrive at the CDC on Saturday for QC testing. If the CDC can test Saturday and give results Saturday we can potentially count those (b)(5) tests this week, though they probably wouldn't ship out until Monday.

In addition, ThermoFisher is finishing their EUA application on Monday which we will turn around quickly. They have (b)(5) tests in inventory and we gave them permission to preposition them in labs this week. I have just asked them how many tests they have shipped so far this week and how many they expect to ship yet this week. I will get those numbers to you as soon as I receive them.

Updated total this week, not counting ThermoFishers shipments which I am waiting on and counting Biosearch's tests this week: (b)(5)

Further (b)(5)

(b)(5)

Feel free to call anytime. My cell is (b)(6)

Best,
Tim

Timothy T. Stenzel, MD, PhD

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From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 5:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Berger, Sherri (CDC) (b)(6); Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Wonderful

I am still looking for the extra (b)(5) tests (to make (b)(5)).
 Is that (b)(5)?

And are we still no track for (b)(5) tests (b)(5)?

Brett P. Giroir, MD

ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:19 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Berger, Sherri (CDC/OCOO/OD) (b)(6); Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) <(b)(6)>; Redfield, Robert R. (CDC/OD) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

+ Tim

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Thursday, March 5, 2020 4:18 PM
To: Berger, Sherri (CDC) (b)(6); Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Monroe, Stephan S (CDC) (b)(6); Schuchat, Anne (CDC) <(b)(6)>; Redfield, Robert R (CDC) (b)(6); Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!
Importance: High

(b)(5)

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Berger, Sherri (CDC/OCOO/OD) (b)(6)
Sent: Thursday, March 5, 2020 4:13 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6); Schuchat, Anne MD (CDC/OD) (b)(6)
Subject: FW: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, March 5, 2020 4:13 PM
To: Terrill, Roman <rterill@idtdna.com>; Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)
Subject: RE: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

Roman and others, I have spoken with CDC leadership. CDC has performed QC on N1, N2 and RP for this lot of material. CDC is allowing IDT to sell these reagents under the CDC EUA.

We would appreciate it if we could renegotiate the shared document that outlines the process for this going forward. We can set up a meeting to do this tmrw if helpful.

Thanks, wendi

Wendi Kuhnert-Tallman
Office - 404-639-3103
Mobile - (b)(6)

From: Terrill, Roman <rterill@idtdna.com>
Sent: Thursday, March 5, 2020 3:58 PM
To: Stenzel, Timothy (FDA/CDRH) <Timothy.Stenzel@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) (b)(6); Lindstrom, Stephen (CDC/DDID/NCIRD/DVD) (b)(6); Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) (b)(6); Flannery, Ellen (FDA/CDRH) <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>;

Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) (b)(6)

Subject: Urgent 40 minute warning from IDT on ability to ship tests-3 day pause likely!!!

To my friends at FDA and CDC, and elsewhere within HHS:

Just to raise to your attention of the urgency of the time and the matter.

If IDT receives confirmation of IDT's permission to ship kits from lot '594 (which was QC'd yesterday, and that several people have suggested likely passed) **by 4:30pm Eastern (the next 40 minutes)**, IDT's team will be able to fill orders for hundreds of kits, representing thousands of tests to hundreds of institutions worldwide, for delivery and receipt on Friday (tomorrow), which ensures continuous testing capability throughout the weekend.

If does not receive said confirmation of its permission to ship kits from lot '594, then the earliest receipt of said products will be Monday morning of next week, as FedEx and UPS only do Saturday shipments by special arrangement, and we as a nation we will likely lose 3 calendar days of possible testing (FRI-SAT-SUN).

I'm not prone to the dramatic, but the circumstances warrant it.

Please advise ASAP.

Thanks,

Roman

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Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Haddad, Carla (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>; Gray, Oneika (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7c446d71dac4354a8218c8e08bffd51-Gray, Oneik>
Sent Date:	2020/03/06 10:22:06
Delivered Date:	2020/03/06 10:22:07