



August 9, 2021

Emma Lewis
American Oversight
1030 15th Street NW, B255
Washington, DC 20005

RE: FDA FOIA Request 2020-2523;
American Oversight v. HHS et al., Civil No. 20-cv-01063

Dear Ms. Lewis:

This is in response to the Freedom of Information Act (FOIA) request number FDA-2020-2523 that is the subject of the Amended Complaint filed in *American Oversight v. HHS et al.*, Civil No. 20-cv- 01063, now pending in the U.S. District Court for the District of Columbia.

FDA's Center for Devices and Radiological Health (CDRH) sent records to the Department of Health and Human Services and the White House for further review and return to us. That consultation has been completed and the records, identified as FDA-CDRH-2020-2523-000001 through 000069, are enclosed. This production completes the number of pages that CDRH intends to process for FOIA request FDA-2020-2523.

We have withheld portions of these pages under the exemptions provided in 5 U.S.C. §§ 522(b)(4), (b)(5), and (b)(6) of FOIA, as delineated below:

Exemption (b)(4) permits the withholding of trade secrets and /or commercial or financial information that was obtained from a person and that is privileged or confidential.

Exemption (b)(5) permits the withholding of inter-agency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with the agency. This exemption includes communications records which are part of the deliberative process and pre-decisional. Disclosure of such material could inhibit the open and candid expression of opinions and diminish the quality of the decision-making process.

Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption (b)(6) consists of personal information, such as direct contact information, and conference and passcode numbers. In this case, it was determined that there is no countervailing public interest qualifying under the standard set forth under exemption (b)(6) to release the personal identifying information of certain third parties.

Please direct any questions regarding this response to Amy Powell of the U.S. Department of Justice, at (919) 856-4013 or Amy.Powell@usdoj.gov.

Sincerely,



Candace Boston
Division Director
Division of Information Disclosure
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

From: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
Sent: 3/25/2020 6:38:10 PM
To: Wainer, Andrea F [andrea.wainer@abbott.com]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Birx, Deborah L. EOP/NSC (b) (6) @nsc.eop.gov; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Ford, Robert B [Robert.Ford@abbott.com]
Subject: Re: Abbott COVID 3-25-20 Update

Thank you, Andrea.

Jeff

From: Wainer, Andrea F <andrea.wainer@abbott.com>
Date: March 25, 2020 at 6:31:47 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <(b) (6) @nsc.eop.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Ford, Robert B <Robert.Ford@abbott.com>
Subject: Abbott COVID 3-25-20 Update

From: Birx, Deborah L. EOP/NSC [(b) (6)]@nsc.eop.gov]
Sent: 4/3/2020 7:49:32 PM
To: Wainer, Andrea F [andrea.wainer@abbott.com]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Ford, Robert B [Robert.Ford@abbott.com]
Subject: Re: [EXTERNAL] FW: Today's Covid Data

Thank you so much. Of all your ID NOW equipment out there are these the only ones that requested tests? Deb

From: "Wainer, Andrea F" <andrea.wainer@abbott.com>
Date: Friday, April 3, 2020 at 7:24 PM
To: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Haddad, Carla (HHS/OASH)" <Carla.Haddad@hhs.gov>, "Birx, Deborah L. EOP/NSC" [(b) (6)]@nsc.eop.gov, "Shuren, Jeff (FDA/CDRH)" <Jeff.Shuren@fda.hhs.gov>, "Stenzel, Timothy (FDA/CDRH)" <Timothy.Stenzel@fda.hhs.gov>
Cc: "Ford, Robert B" <Robert.Ford@abbott.com>
Subject: [EXTERNAL] FW: Today's Covid Data

Good evening,

In addition to our daily shipment and testing report, I am including at the request of Tim, an outlook of our shipments in the US. In the supply outlook we only show what we will be shipping in the US for the next 5 weeks. Our ID now production is dedicated to the US. But for the m2000, our actual production is more than double what we will be sending to the US. Based on the forecast throughput of our machines, this outlook is what we expect to ship to US customers.

Here's today's data. We'll be reporting Saturdays and Sundays from here on out so look for an email tomorrow afternoon. The m2000 utilization is showing a pickup.

Please find attached Abbott's data as of April 2 for (1) ID NOW; and (2) m2000.

For m2000 test data, there are two types of data we have:

1. Information in our control such as the names and addresses of our customers and the number of tests we shipped to them cumulatively and this week.
2. Raw data we receive from a remote data link that is sent from the instruments at the customers to Abbott.
 - a. First, we only receive the remote data link from certain customers (on the spreadsheet, the customers we don't receive data from are in gray).

- b. Second, for those customers with the remote data link, we are providing raw data that has the number of tests run and the number of positives. Customers run their own required protocols to validate the accuracy of a test when a new test first becomes available. Those validation processes include negative and positive samples. The raw data we get from data link of the instrument cannot distinguish between validation samples and patient samples.
3. We do not have data regarding inventory at the labs.

For ID NOW test data:

1. We are reporting names, addresses, total cumulative tests shipped, and total tests shipped this week.
2. Unlike the m2000 instrument, we do not have any data on tests performed from the ID NOW instruments.



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From: Birx, Deborah L. EOP/NSC [(b) (6)]@nsc.eop.gov]
Sent: 4/2/2020 10:08:50 PM
To: Wainer, Andrea F [andrea.wainer@abbott.com]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Ford, Robert B [Robert.Ford@abbott.com]
Subject: Re: [EXTERNAL] Abbott COVID Data

Thank you so much for looking into this and working through this and understanding the issues. We stand ready to support. Deb

From: "Wainer, Andrea F" <andrea.wainer@abbott.com>
Date: Thursday, April 2, 2020 at 9:32 PM
To: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Haddad, Carla (HHS/OASH)" <Carla.Haddad@hhs.gov>, "Birx, Deborah L. EOP/NSC" <[(b) (6)]@nsc.eop.gov>, "Shuren, Jeff (FDA/CDRH)" <Jeff.Shuren@fda.hhs.gov>, "Stenzel, Timothy (FDA/CDRH)" <Timothy.Stenzel@fda.hhs.gov>
Cc: "Ford, Robert B" <Robert.Ford@abbott.com>
Subject: [EXTERNAL] Abbott COVID Data

Good evening,

Along with our daily report, we have done some research with our customers to understand where they are at with their COVID testing. Below is a snapshot of the customers who report to be running less than (b) (4) tests per day. I have asked for the list of customers reporting short staffing so stay tuned.

Here's today's data. Of note: (1) we have shipped m2000 tests to (b) (4) and (2) m2000 Prior Day Tests Performed rose (b) (4) from yesterday. Also (b) (4) of m2000 systems report through AbbottLink. (b) (4) on AbbottLink (b) (4) m2000 systems installed/installing.

Please find attached Abbott's data as of April 1 for (1) ID NOW tests; and (2) m2000 tests.

For m2000 test data, there are two types of data we have:

1. Information in our control such as the names and addresses of our customers and the number of tests we shipped to them cumulatively and this week.
2. Raw data we receive from a remote data link that is sent from the instruments at the customers to Abbott.
 - a. First, we only receive the remote data link from certain customers (on the spreadsheet, the customers we don't receive data from are in gray).
 - b. Second, for those customers with the remote data link, we are providing raw data that has the number of tests run and the number of positives. Customers run their own required protocols to validate the accuracy of a test when a new test first becomes available. Those validation processes include negative and positive samples. The raw data we get from data link of the instrument cannot distinguish between validation samples and patient samples.
 - c. Third, as requested, the raw data for the Prior Day Tests Performed and positive numbers and rates (columns J, K and L) are for the previous day only.

3. We do not have data regarding inventory at the labs.

For ID NOW test data:

1. We are reporting names, addresses, total cumulative tests shipped, and total tests shipped this week.
2. Unlike the m2000 instrument, we do not have any data on tests performed from the ID NOW instruments.

Best regards, Andrea

(b)(6)



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From: Birx, Deborah L. EOP/NSC [(b) (6)]@nsc.eop.gov]
Sent: 4/1/2020 5:15:56 AM
To: Wainer, Andrea F [andrea.wainer@abbott.com]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Ford, Robert B [Robert.Ford@abbott.com]
Subject: Re: [EXTERNAL] Abbott's daily COVID Data

Thank you so much and thank you for talking with the laboratories and seems things are picking up. If in your conversations you sense there is a issue with human capacity we can follow up with the sites. Den

From: "Wainer, Andrea F" <andrea.wainer@abbott.com>
Date: Tuesday, March 31, 2020 at 6:42 PM
To: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Haddad, Carla (HHS/OASH)" <Carla.Haddad@hhs.gov>, "Birx, Deborah L. EOP/NSC" <[(b) (6)]@nsc.eop.gov>, "Shuren, Jeff (FDA/CDRH)" <Jeff.Shuren@fda.hhs.gov>, "Stenzel, Timothy (FDA/CDRH)" <Timothy.Stenzel@fda.hhs.gov>
Cc: "Ford, Robert B" <Robert.Ford@abbott.com>
Subject: [EXTERNAL] Abbott's daily COVID Data

Good evening,

Attached are: (1) ID NOW's first report; and (2) m2000 US sites. Given this is our first inclusion of ID NOW data, I have revised the explanations below to include both sets of data and explained what we are and are not reporting on ID NOW. Given this is our first m2000 report with cumulative tests performed, positives and positive %, I have also added 2(d) below to note that we have added cumulative tests performed, etc (see last three columns in the report).

Please find attached Abbott's data as of March 30 for (1) ID NOW tests; and (2) m2000 tests.

For m2000 test data, there are two types of data we have:

1. Information in our control such as the names and addresses of our customers and the number of tests we shipped to them cumulatively and this week.
2. Raw data we receive from a remote data link that is sent from the instruments at the customers to Abbott.
 - a. First, we only receive the remote data link from certain customers (on the spreadsheet, the customers we don't receive data from are in gray).
 - b. Second, for those customers with the remote data link, we are providing raw data that has the number of tests run and the number of positives. Customers run their own required protocols to validate the accuracy of a test when a new test first becomes available. Those

validation processes include negative and positive samples. The raw data we get from data link of the instrument cannot distinguish between validation samples and patient samples.

- c. Third, as requested, the raw data for the Prior Day Tests Performed and positive numbers and rates (columns J, K and L) are for the previous day only.
 - d. Fourth, we have added columns for Cumulative Tests Performed, Cumulative Positives, and Cumulative % Positive.
3. We do not have data regarding inventory at the labs.

For ID NOW test data:

1. We are reporting names, addresses, total cumulative tests shipped, and total tests shipped this week.
2. Unlike the m2000 instrument, we do not have any data on tests performed from the ID NOW instruments.

Best regards

Andrea

(b)(6)



Abbott

Andrea Wainer
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From: Birx, Deborah L. EOP/NSC [(b) (6)]@nsc.eop.gov]
Sent: 3/30/2020 8:11:50 PM
To: Wainer, Andrea F [andrea.wainer@abbott.com]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Ford, Robert B [Robert.Ford@abbott.com]
Subject: Re: [EXTERNAL] Abbott COVID-19 update

Thank you – do you have an idea why so few tests are run despite available test kits – are they reporting any issues?

From: "Wainer, Andrea F" <andrea.wainer@abbott.com>
Date: Monday, March 30, 2020 at 8:05 PM
To: "Hahn, Stephen" <sh1@fda.hhs.gov>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" <[(b) (6)]@nsc.eop.gov>, "Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov>
Cc: "Ford, Robert B" <Robert.Ford@abbott.com>
Subject: [EXTERNAL] Abbott COVID-19 update

Good evening,

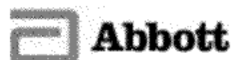
Please find attached Abbott's submission today for m2000 tests shipped through Friday. We have sent this information directly to FEMA. Please feel free to call with any questions. [(b)(6)]

Below is the guidance sent to FEMA along with our data.

1. Information in our control such as the names and addresses of our customers and the number of tests we shipped to them cumulatively and this week.
2. Raw data we receive from a remote data link that is sent from the instruments at the customers to Abbott.
 - a. First, we only receive the remote data link from certain customers (on the spreadsheet, the customers we don't receive data from are in gray).
 - b. Second, for those customers with the remote data link, we are providing raw data that has the number of tests run and the number of positives. Customers run their own required protocols to validate the accuracy of a test when a new test first becomes available. Those validation processes include negative and positive samples. The raw data we get from data link of the instrument cannot distinguish between validation samples and patient samples.
 - c. Third, as requested, the raw data for the Prior Day Tests Performed and positive numbers and rates (columns J, K and L) are for the previous day only.
3. We do not have data regarding inventory at the labs.
4. The cumulative shipping data from Friday's March 27 report is slightly higher as compared to today's March 30 report because of shipping reconciliation we performed over the weekend.

Please let me know if you need further explanation on the data provided or any other questions.

Best regards, Andrea



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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/14/2020 5:04:55 PM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Joe Grogan [(b)(6) who.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Follow up - samples needed for test developers

Bob,

Great to see you today. I just wanted to follow up regarding (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5) Jeff's team can provide you and your team with the appropriate contacts.

Thanks

Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/24/2020 6:28:49 PM
To: Wainer, Andrea F [andrea.wainer@abbott.com]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Birx, Deborah L. EOP/NSC [(b) (6) @nsc.eop.gov]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Ford, Robert B [Robert.Ford@abbott.com]
Subject: RE: [EXTERNAL] Re: Abbott Update

Thanks, Andrea.

Steve

From: Wainer, Andrea F <andrea.wainer@abbott.com>
Date: March 24, 2020 at 6:12:22 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <(b) (6) @nsc.eop.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Ford, Robert B <Robert.Ford@abbott.com>
Subject: RE: [EXTERNAL] Re: Abbott Update

Good evening,

As Robert mentioned, we have pulled together the data requested. Attached is the data Abbott has submitted to FEMA which is current as of yesterday. It does not include tests shipped or run today. I will continue to share the data we submit to FEMA on an ongoing basis.

I saw a couple of questions come through regarding gender and Dr. Birx, your question on single patient data that may not be addressed in the attached. We do not have data by gender. Also, while we cannot see if the data is single patient or in duplicate, but what we hear from labs so far is that they are running only single tests on patients and reporting positive results with one test.

Below is the guidance sent to FEMA along with our data.

1. Information in our control such as the names and addresses of our customers and the number of tests we shipped to them cumulatively and this week.
2. Raw data we receive from a remote data link that is sent from the instruments at the customers to Abbott.
 - a. First, we only receive the remote data link from certain customers (on the spreadsheet, the customers we don't receive data from are in gray).
 - b. Second, for those customers with the remote data link, we are providing raw data that has the number of tests run and the number of positives. Customers run their own required protocols to validate the accuracy of a test when a new test first becomes available. Those validation processes include negative and positive samples. The raw data we get from data link of the instrument cannot distinguish between validation samples and patient samples.
 - c. Third, as requested, the raw data for the Prior Day Tests Performed and positive numbers and rates (columns J, K and L) are for the previous day only.

HHS-FDA-20-0498-F-000012

FDA-CVD-SHURENJ-00008205

FDA-CDRH-2020-2523-000012

3. We do not have data regarding inventory at the labs.

Please let me know if you need further explanation on the data provided or any other questions. I can be reached at (b)(6)

Best regards, Andrea



Abbott

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From: Hahn, Stephen <SH1@fda.hhs.gov>

Sent: Tuesday, March 24, 2020 3:20 PM

To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Birx, Deborah L. EOP/NSC <(b)(6)@nsc.eop.gov>; Ford, Robert B <Robert.Ford@abbott.com>

Cc: Wainer, Andrea F <andrea.wainer@abbott.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: RE: [EXTERNAL] Re: Abbott Update

Robert,
Terrific work. Thank you.
Steve

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

Date: March 24, 2020 at 3:03:26 PM EDT

To: Birx, Deborah L. EOP/NSC <(b)(6)@nsc.eop.gov>; Ford, Robert B <Robert.Ford@abbott.com>

Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Wainer, Andrea F <andrea.wainer@abbott.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: RE: [EXTERNAL] Re: Abbott Update

Robert,

Many thanks for the update and the great work.

Jeff

From: Birx, Deborah L. EOP/NSC <(b)(6)@nsc.eop.gov>

Sent: Tuesday, March 24, 2020 2:13 PM

To: Ford, Robert B <Robert.Ford@abbott.com>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Wainer, Andrea F <andrea.wainer@abbott.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: Re: [EXTERNAL] Re: Abbott Update

Deeply grateful, We do need the site of the instrument and tests run and test positives as the individual level we also need to know if these are being submitted or run in duplicate or as single patients

From: "Ford, Robert B" <Robert.Ford@abbott.com>

Date: Tuesday, March 24, 2020 at 1:21 PM

To: "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>

Cc: "Hahn, Stephen" <SH1@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" <(b) (6)@nsc.eop.gov>, "Wainer, Andrea F" <andrea.wainer@abbott.com>, Timothy Stenzel <timothy.stenzel@fda.hhs.gov>

Subject: [EXTERNAL] Re: Abbott Update

Jeff,

I received a call from Senior Advisor for Domestic Policy requesting test data. FEMA has also send us a spreadsheet they want filled out. In a few hours we will be sending to you, Commissioner, Stenzel and Birx this spreadsheet & data on the testing.

Below however is a high level summary.

Our commitment was to (b) (4) tests upon approval. Make another (b) (4) And then in April (b) (4)

So far as of 3/22 we have made the (b) (4)

We have (b) (4) that have our analyzer. (b) (4) they will purchase tests, (b) (4) already placed a purchase order (b) (4) accounts have received tests and have began testing.

We did make the (b) (4) from yesterdays commitment and we will begin to ship those.

Robert B. Ford

(b)(6)

On Mar 23, 2020, at 4:54 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

Robert,

Thank you very much for the update. These are all great developments and we appreciate close collaboration.

We would be interested to see information on testing. In addition to the two of us please also include Tim Stenzel.

Best regards,

Jeff

From: Ford, Robert B <Robert.Ford@abbott.com>

Date: March 23, 2020 at 5:45:46 PM EDT

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

Subject: Abbott Update

Just wanted to provide a brief update on the Abbott testing platforms.

On the Point-of-Care platform (5 minute test) we (b) (4)

(b) (4)

(b) (4)



Best,

Robert B. Ford

(b)(6)



From: Birx, Deborah L. EOP/NSC [(b) (6)]@nsc.eop.gov]
Sent: 3/24/2020 2:12:40 PM
To: Ford, Robert B [Robert.Ford@abbott.com]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Wainer, Andrea F [andrea.wainer@abbott.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
Subject: Re: [EXTERNAL] Re: Abbott Update

Deeply grateful, We do need the site of the instrument and tests run and test positives as the individual level – we also need to know if these are being submitted or run in duplicate or as single patients

From: "Ford, Robert B" <Robert.Ford@abbott.com>
Date: Tuesday, March 24, 2020 at 1:21 PM
To: "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>
Cc: "Hahn, Stephen" <SH1@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" <[(b) (6)]@nsc.eop.gov>, "Wainer, Andrea F" <andrea.wainer@abbott.com>, Timothy Stenzel <timothy.stenzel@fda.hhs.gov>
Subject: [EXTERNAL] Re: Abbott Update

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 (b)(6)

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From: Ford, Robert B <Robert.Ford@abbott.com>

Date: March 23, 2020 at 5:45:46 PM EDT

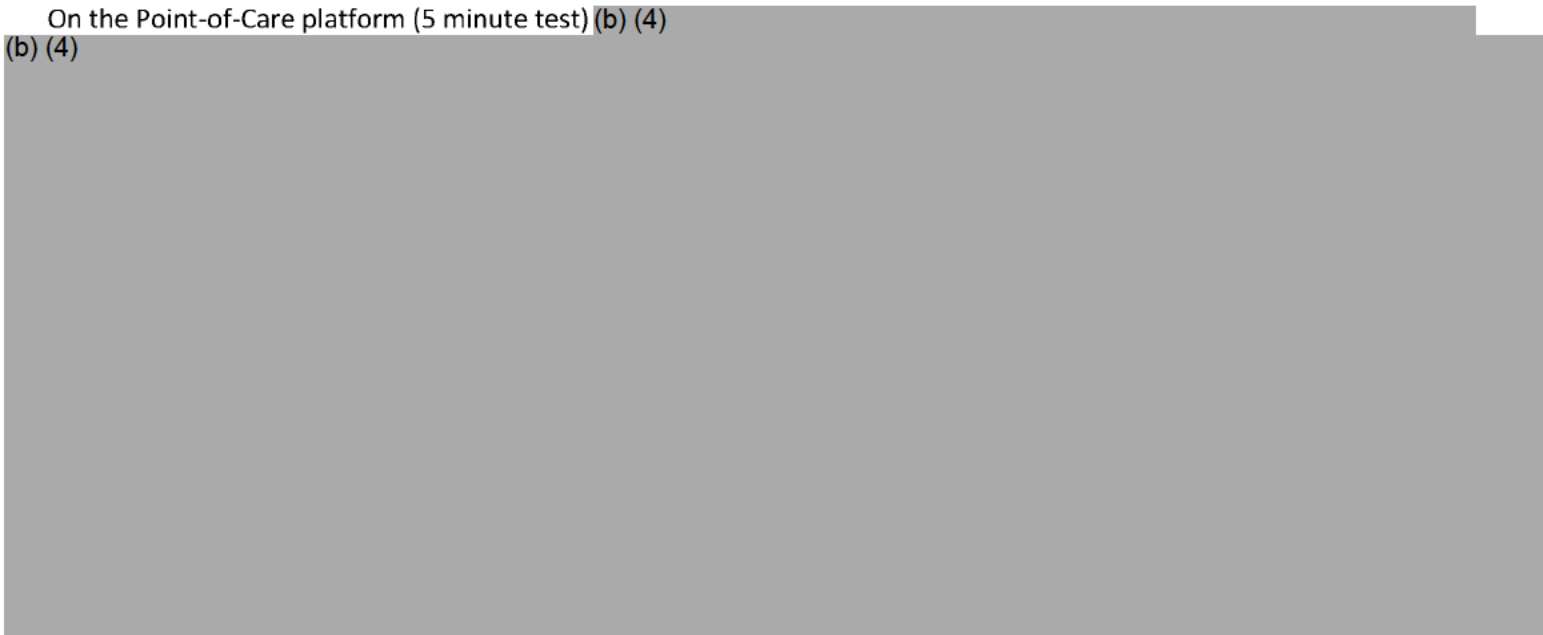
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Subject: Abbott Update

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On the Point-of-Care platform (5 minute test) (b) (4)

(b) (4)



Best,

Robert B. Ford

(b)(6)



From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/21/2020 7:43:09 AM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Birx, Deborah L. EOP/NSC [(b) (6)]@nsc.eop.gov; Gaynor, Pete [(b) (6)]@fema.dhs.gov]
Subject: RE: White House Coronavirus Task Force Meeting

Thx Jeff

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 21, 2020 at 7:41:14 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <[(b) (6)]@nsc.eop.gov>, Gaynor, Pete [(b) (6)]@fema.dhs.gov>
Subject: RE: White House Coronavirus Task Force Meeting

Attached is a list of CEOs of test makers, including the ones listed below, and their contact information.

Jeff

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, March 21, 2020 7:32 AM
To: Birx, Deborah L. EOP/NSC <[(b) (6)]@nsc.eop.gov>; Gaynor, Pete [(b) (6)]@fema.dhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Re: White House Coronavirus Task Force Meeting

Jeff or Admiral Giroir,
Good morning.
Can you all provide contacts for the vendors below?
Thx
Steve

From: Birx, Deborah L. EOP/NSC <[(b) (6)]@nsc.eop.gov>
Date: March 21, 2020 at 7:12:34 AM EDT
To: Gaynor, Pete [(b) (6)]@fema.dhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: White House Coronavirus Task Force Meeting

Steve
Can you send contacts

From: "Gaynor, Pete" [(b) (6)]@fema.dhs.gov>
Date: Saturday, March 21, 2020 at 7:10 AM
To: "Birx, Deborah L. EOP/NSC" <[(b) (6)]@nsc.eop.gov>
Subject: RE: White House Coronavirus Task Force Meeting

Thanks. Do you have POCs for each?

Pete Gaynor
Administrator

Office: (202) 212-5516 | Mobile: (b)(6)

(b)(6)@fema.dhs.gov

From: Birx, Deborah L. EOP/NSC (b)(6)@nsc.eop.gov>

Sent: Saturday, March 21, 2020 7:09 AM

To: Gaynor, Pete <(b)(6)@fema.dhs.gov>

Cc: Gastfriend, Daniel Z. EOP/OMB <(b)(6)@omb.eop.gov>

Subject: Re: White House Coronavirus Task Force Meeting

(b)(5)

From: "Gaynor, Pete" <(b)(6)@fema.dhs.gov>

Date: Saturday, March 21, 2020 at 6:59 AM

To: "Birx, Deborah L. EOP/NSC" <(b)(6)@nsc.eop.gov>

Subject: RE: White House Coronavirus Task Force Meeting

Ambassador,

Can you send me the information and names of vendor you want me to collect testing data from?

s/f

Pete

Pete Gaynor
Administrator

Office: (202) 212-5516 | Mobile: (b)(6)

(b)(6)@fema.dhs.gov

From: Birx, Deborah L. EOP/NSC (b)(6)@nsc.eop.gov>

Sent: Saturday, March 21, 2020 6:56 AM

To: Short, Marc T. EOP/OVP <(b)(6)@ovp.eop.gov>; Troye, Olivia (b)(6)@nsc.eop.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Pataki, Timothy (who.eop.gov) (b)(6)@who.eop.gov>; Goyer, James (who.eop.gov) (b)(6)@who.eop.gov>; Pottebaum, Nicholas (who.eop.gov) <(b)(6)@who.eop.gov>; Haddad, Carla (HHS/OASH) <Carla.Haddad@hhs.gov>; Hodgson, Christopher (ovp.eop.gov) (b)(6)@ovp.eop.gov>; Hoelscher, Douglas (who.eop.gov) (b)(6)@who.eop.gov>; Obenshain, Anne (ovp.eop.gov) <(b)(6)@ovp.eop.gov>; Nevins, Kristan K. EOP/WHO <(b)(6)@who.eop.gov>; Stuftt, Julie M. EOP/NSC <(b)(6)@nsc.eop.gov>; Davis, May M. EOP/WHO <(b)(6)@who.eop.gov>; Bonner, Maria K. EOP/WHO <(b)(6)@who.eop.gov>; Hudson, Renee R. EOP/WHO <(b)(6)@who.eop.gov>; O'Malley, Devin (treasury.gov) <Devin.O'Malley@treasury.gov>; Sheehan, Matthew J. EOP/OVP <(b)(6)@ovp.eop.gov>; Moore, Caroline E. EOP/WHO <(b)(6)@who.eop.gov>; Kushner, Jared C. EOP/WHO <(b)(6)@who.eop.gov>; Hicks, Hope C. EOP/WHO <(b)(6)@who.eop.gov>; Fisher, Garrett C. EOP/OVP <(b)(6)@ovp.eop.gov>; Kadlec, Robert <Robert.kadlec@hhs.gov>; Joel.Szabat@dot.gov; randal@mail.house.gov; Grogan, Joseph J. EOP/WHO <(b)(6)@who.eop.gov>; AMA2@HHS.GOV; stm77@treasury.gov; Kudlow, Larry A. EOP/WHO

HHS-FDA-20-0498-F-000019

<(b)(6)> who.eop.gov>; olx1@cdc.gov (b)(6) @niaid.nih.gov; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; BiegunSE@state.gov; sh1@fda.hhs.gov; AS1CFW (b)(6) @hq.dhs.gov>; SV1@cms.hhs.gov; rlw@va.gov; Pottinger, Matthew F. EOP/WHO (b)(6) @who.eop.gov>; Vought, Russell T. EOP/OMB <(b)(6) omb.eop.gov>; Miller, Katie R. (ovp.eop.gov) <(b)(6) ovp.eop.gov>; Liddell, Christopher P. EOP/WHO <(b)(6) who.eop.gov>; Grisham, Stephanie A. EOP/WHO (b)(6) @who.eop.gov>; Philbin, Patrick F. EOP/WHO <(b)(6) @who.eop.gov>; Miller, Stephen EOP/WHO (b)(6) @who.eop.gov>; Gaynor, Pete <p(b)(6) @fema.dhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Kate@mail.house.gov; DeValliere, Ian C. EOP/WHO <(b)(6) @who.eop.gov>; Campana, Alexandra D. EOP/WHO (b)(6) @who.eop.gov>; Zachary.McEntee@treasury.gov; shirley.gathers@treasury.gov; Andrew.Hughes@hud.gov; Jennifer.L.Naaden@hud.gov; Lin, Merry S. EOP/WHO <(b)(6) who.eop.gov>; Baker, Brittany G. EOP/WHO (b)(6) @who.eop.gov>; Olmem, Andrew J. EOP/WHO <(b)(6) @who.eop.gov>; veu4@cdc.gov (b)(6) nih.gov; Marston, Hilary (NIH/NIAID) [(b)(6) @nih.gov>; Dulaigh, Joel (HHS/OASH) <Joel.Dulaigh@hhs.gov>; Hurst, Natalie R. EOP/OVP <(b)(6) @ovp.eop.gov>; OVPSchedule <(b)(6) @OVP.eop.gov>; BurnettJD@state.gov; HattinghEF@state.gov; Janice.Sheehy@fda.hhs.gov; Colin.Rom@fda.hhs.gov; BRISTOL, JULIA <JULIA.BRISTOL@hq.dhs.gov>; Best, Natalia <Natalia.Best@hq.dhs.gov>; Thomas, Nkosi <Nkosi.Thomas@hq.dhs.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>; Good-Cohn, Meredith (CMS/OA) <Meredith.Good-Cohn@cms.hhs.gov>; Diana.Perez-Rivera@cms.hhs.gov; pamelapowers@va.gov; belinda.carrington@va.gov; jacqueline.colli@va.gov; Hennessey, Millicent S. EOP/NSC <(b)(6) nsc.eop.gov>; Conant, Ann M. EOP/OMB <(b)(6) omb.eop.gov>; beth.tignor@hhs.gov; Zachary.Dareshori@hhs.gov; Lair, Kate E. EOP/WHO <(b)(6) who.eop.gov>; Riggs, Charlotte R. EOP/WHO <(b)(6) who.eop.gov>; Murrell, Baxter R. EOP/WHO <(b)(6) who.eop.gov>; (b)(6) sd.mil; Rader, John N. EOP/NSC <(b)(6) nsc.eop.gov>; Haley, Vincent M. EOP/WHO <(b)(6) who.eop.gov>; Gabriel, Robert Jr. EOP/WHO <(b)(6) who.eop.gov>; Worthington, Ross P. EOP/WHO <(b)(6) who.eop.gov>; Baldwin, Brittany L. EOP/WHO <(b)(6) who.eop.gov>; Royer, Theodore M. EOP/WHO (b)(6) @who.eop.gov>; Bolduc, Brian J. EOP/OVP <(b)(6) @ovp.eop.gov>; Dumbauld, Cassidy M. EOP/WHO <(b)(6) who.eop.gov>; (b)(6) sd.mil; (b)(6) sd.mil; (b)(6) sd.mil; Cytryn, Jen B. EOP/WHO (b)(6) who.eop.gov>; McGuffee, Tyler A. EOP/OVP (b)(6) @ovp.eop.gov>; Hahn, Julia A. EOP/WHO <(b)(6) who.eop.gov>; Taylor, Elizabeth (who.eop.gov) (b)(6) @who.eop.gov>; DL WHO COMMS Speechwriters (b)(6) @whmo.mil>; Ford Barnes, Arwenithia <Arwenithia.FordBarnes@hhs.gov>; Brandy.Brunson@hhs.gov; donna.o'berry@dot.gov; amie.kalsbeek@dot.gov; Fischer, Lauren <lauren.fischer@fema.dhs.gov>; Deere, Judd P. EOP/WHO (b)(6) @who.eop.gov>; Bante, Katie (OS/OASH) <Katie.Bante@hhs.gov>; Victoria.Callahan@hhs.gov; Croghan, Mary E. EOP/WHO (b)(6) ry @who.eop.gov>; McBride, Emily J. EOP/WHO (b)(6) @who.eop.gov>; Cc: Hoosier Calendar <(b)(6) @OVP.eop.gov>; Bauer, Zachary C. EOP/OVP (b)(6) @ovp.eop.gov>; Cipollone, Pat A. EOP/WHO <(b)(6) who.eop.gov>

Subject: Re: White House Coronavirus Task Force Meeting

Electronic version of today's data summary – not for forwarding or public

From: "Hurst, Natalie R. EOP/OVP" <(b)(6) ovp.eop.gov> on behalf of "Short, Marc T. EOP/OVP" <(b)(6) ovp.eop.gov>

Date: Friday, March 20, 2020 at 9:58 PM

To: "Troye, Nsc" <(b)(6) nsc.eop.gov>, "Brian.Harrison@hhs.gov" <Brian.Harrison@hhs.gov>, "Pataki, Tim A. EOP/WHO" <(b)(6) @who.eop.gov>, "Goyer, Jim L. IV EOP/WHO"

<(b)(6) who.eop.gov>, "Pottebaum, Nic D. EOP/WHO" <(b)(6) who.eop.gov>, "Haddad, Carla (HHS/OASH)" <Carla.Haddad@hhs.gov>, "Hodgson, Christopher M. EOP/OVP"

(b)(6) @ovp.eop.gov>, "Hoelscher, Douglas L. EOP/WHO"

(b)(6) @who.eop.gov>, "Obenshain, Tucker T. EOP/OVP" <(b)(6) ovp.eop.gov>, "Nevins, Kristan K. EOP/WHO" <(b)(6) who.eop.gov>, "Stuftt, Julie M. EOP/NSC"

<(b)(6) nsc.eop.gov>, "Davis, May M. EOP/WHO" <(b)(6) who.eop.gov>, "Bonner, Maria K.

EOP/WHO" <(b)(6) who.eop.gov>, "Hudson, Renee R. EOP/WHO" <(b)(6) who.eop.gov>, "HHS (FDA-20-0498-F-000020" <(b)(6) hhs.gov>

"Devin.O'Malley@treasury.gov" <Devin.O'Malley@treasury.gov>, "Sheehan, Matthew J. EOP/OVP" <(b)(6)@ovp.eop.gov>, "Moore, Caroline E. EOP/WHO" <(b)(6)@who.eop.gov>, "Kushner, Jared C. EOP/WHO" <(b)(6)@who.eop.gov>, "Hicks, Hope C. EOP/WHO" <(b)(6)@who.eop.gov>, "Fisher, Garrett C. EOP/OVP" <(b)(6)@ovp.eop.gov>, "Robert.Kadlec@hhs.gov" <Robert.Kadlec@hhs.gov>, "Joel.Szabat@dot.gov" <Joel.Szabat@dot.gov>, "(b)(6)@mail.house.gov" <(b)(6)@mail.house.gov>, "Grogan, Joseph J. EOP/WHO" <(b)(6)@who.eop.gov>, "AMA2@HHS.GOV" <AMA2@HHS.GOV>, "stm77@treasury.gov" <stm77@treasury.gov>, "Kudlow, Larry A. EOP/WHO" <(b)(6)@who.eop.gov>, "olx1@cdc.gov" <olx1@cdc.gov>, "(b)(6)@niaid.nih.gov" <(b)(6)@niaid.nih.gov>, "Jerome.Adams@hhs.gov" <Jerome.Adams@hhs.gov>, "BiegunSE@state.gov" <BiegunSE@state.gov>, "sh1@fda.hhs.gov" <sh1@fda.hhs.gov>, "as1cfw@hq.dhs.gov" <as1cfw@hq.dhs.gov>, "Birx, Deborah L. EOP/NSC" <(b)(6)@nsc.eop.gov>, "SV1@cms.hhs.gov" <SV1@cms.hhs.gov>, "rlw@va.gov" <rlw@va.gov>, "Pottinger, Matthew F. EOP/WHO" <(b)(6)@eop.gov>, "Vought, Russell T. EOP/OMB" <(b)(6)@omb.eop.gov>, "Miller, Ovp" <(b)(6)@ovp.eop.gov>, "Liddell, Christopher P. EOP/WHO" <(b)(6)@who.eop.gov>, "Grisham, Stephanie A. EOP/WHO" <(b)(6)@who.eop.gov>, "Philbin, Patrick F. EOP/WHO" <(b)(6)@who.eop.gov>, "Miller, Stephen EOP/WHO" <(b)(6)@who.eop.gov>, "(b)(6)@fema.dhs.gov" <(b)(6)@fema.dhs.gov>, "Brett.Giroir@hhs.gov" <Brett.Giroir@hhs.gov>, "Kate@mail.house.gov" <Kate@mail.house.gov>, "DeValliere, Ian C. EOP/WHO" <(b)(6)@who.eop.gov>, "Campana, Alexandra D. EOP/WHO" <(b)(6)@who.eop.gov>, "Zachary.McEntee@treasury.gov" <Zachary.McEntee@treasury.gov>, "shirley.gathers@treasury.gov" <shirley.gathers@treasury.gov>, "Andrew.Hughes@hud.gov" <Andrew.Hughes@hud.gov>, "Jennifer.L.Naaden@hud.gov" <Jennifer.L.Naaden@hud.gov>, "Lin, Merry S. EOP/WHO" <(b)(6)@who.eop.gov>, "Baker, Brittany G. EOP/WHO" <(b)(6)@who.eop.gov>, "Olmem, Andrew J. EOP/WHO" <(b)(6)@who.eop.gov>, "veu4@cdc.gov" <veu4@cdc.gov>, "(b)(6)@niaid.nih.gov" <(b)(6)@niaid.nih.gov>, "(b)(6)@nih.gov" <(b)(6)@nih.gov>, "(b)(6)@nih.gov" <(b)(6)@nih.gov>, "Joel.Dulaigh@hhs.gov" <Joel.Dulaigh@hhs.gov>, "Hurst, Natalie R. EOP/OVP" <(b)(6)@ovp.eop.gov>, "OVPSchedule" <(b)(6)@OVP.eop.gov>, "BurnettJD@state.gov" <BurnettJD@state.gov>, "HattinghEF@state.gov" <HattinghEF@state.gov>, "Janice.Sheehy@fda.hhs.gov" <Janice.Sheehy@fda.hhs.gov>, "Colin.Rom@fda.hhs.gov" <Colin.Rom@fda.hhs.gov>, "julia.bristol@hq.dhs.gov" <julia.bristol@hq.dhs.gov>, "natalia.best@hq.dhs.gov" <natalia.best@hq.dhs.gov>, "Nkosi.thomas@hq.dhs.gov" <Nkosi.thomas@hq.dhs.gov>, "Brady.Brookes@CMS.HHS.GOV" <Brady.Brookes@CMS.HHS.GOV>, "meredith.good-cohn@cms.hhs.gov" <meredith.good-cohn@cms.hhs.gov>, "Diana.Perez-Rivera@cms.hhs.gov" <Diana.Perez-Rivera@cms.hhs.gov>, "pamela.powers@va.gov" <pamela.powers@va.gov>, "belinda.carrington@va.gov" <belinda.carrington@va.gov>, "jacqueline.colli@va.gov" <jacqueline.colli@va.gov>, "Hennessey, Millicent S. EOP/NSC" <(b)(6)@nsc.eop.gov>, "Conant, Ann M. EOP/OMB" <(b)(6)@omb.eop.gov>, "beth.tignor@hhs.gov" <beth.tignor@hhs.gov>, "Zachary.Dareshori@hhs.gov" <Zachary.Dareshori@hhs.gov>, "Lair, Kate E. EOP/WHO" <(b)(6)@who.eop.gov>, "Riggs, Charlotte R. EOP/WHO" <(b)(6)@who.eop.gov>, "Murrell, Baxter R. EOP/WHO" <(b)(6)@who.eop.gov>, "(b)(6)@sd.mil" <(b)(6)@sd.mil>, "Rader, John N. EOP/NSC" <(b)(6)@nsc.eop.gov>, "Haley, Vincent M. EOP/WHO" <(b)(6)@who.eop.gov>, "Gabriel, Robert Jr. EOP/WHO" <(b)(6)@who.eop.gov>, "Worthington, Ross P. EOP/WHO" <(b)(6)@who.eop.gov>, "Baldwin, Brittany L. EOP/WHO" <(b)(6)@who.eop.gov>, "Royer, Theodore M. EOP/WHO" <(b)(6)@who.eop.gov>, "Bolduc, Brian J. EOP/OVP" <(b)(6)@ovp.eop.gov>, "Dumbauld, Cassidy M. EOP/WHO" <(b)(6)@who.eop.gov>, "(b)(6)@sd.mil" <(b)(6)@sd.mil>, "(b)(6)@sd.mil" <(b)(6)@sd.mil>, "(b)(6)@sd.mil" <(b)(6)@sd.mil>, "Cytryn, Jen B. EOP/WHO" <(b)(6)@who.eop.gov>, "McGuffee, Tyler A. EOP/OVP" <(b)(6)@ovp.eop.gov>, "Hahn Julia A. EOP/WHO" <(b)(6)@who.eop.gov>, "Taylor, Elizabeth A.HHS" <A.HHS>

<(b)(6) [REDACTED]@who.eop.gov>, DL WHO COMMS Speechwriters
 <(b)(6) [REDACTED]@hmo.mil>, "Arwenthia.FordBarnes@hhs.gov"
 <Arwenthia.FordBarnes@hhs.gov>, "Brandy.Brunson@hhs.gov" <Brandy.Brunson@hhs.gov>,
 "donna.o'berry@dot.gov" <donna.o'berry@dot.gov>, "amie.kalsbeek@dot.gov" <amie.kalsbeek@dot.gov>,
 (b)(6) [REDACTED]@fema.dhs.gov" (b)(6) [REDACTED]@fema.dhs.gov>, "Deere, Judd P. EOP/WHO"
 (b)(6) [REDACTED]@who.eop.gov>, "Bante, Katie (OS/OASH)" <Katie.Bante@hhs.gov>,
 "Victoria.Callahan@hhs.gov" <Victoria.Callahan@hhs.gov>, "Croghan, Mary E. EOP/WHO"
 (b)(6) [REDACTED]@who.eop.gov>, "McBride, Emily J. EOP/WHO" <(b)(6) [REDACTED]@who.eop.gov>
 Cc: Hoosier Calendar <(b)(6) [REDACTED]@ovp.eop.gov>, "Bauer, Zachary C. EOP/OVP"
 <(b)(6) [REDACTED]@ovp.eop.gov>, "Cipollone, Pat A. EOP/WHO" <(b)(6) [REDACTED]@who.eop.gov>
Subject: White House Coronavirus Task Force Meeting

All -

There will be a **White House Coronavirus Task Force Meeting** on **Saturday, March 21, 2020 at 10:00am**.
 Seating chart and agenda attached.

Thank you,

Natalie Hurst

Operations Coordinator, White House Coronavirus Task Force
 Executive Assistant to the Chief of Staff
 The Office of the Vice President
 (b)(6) [REDACTED]

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/13/2020 1:18:47 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Debi Birx [(b) (6) @nsc.eop.gov]
Subject: Re: Swabs/ Viral Transport Media Tubes

Jeff
 Thx. Copying Dr. Birx. There are additional questions.
 Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 13, 2020 at 12:38:13 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Swabs/ Viral Transport Media Tubes

New FAQ just posted on our website that should help relieve some of the strains on specimen collection swab/tube availability and more under consideration,

Q: I am having trouble obtaining viral transport media/ universal transport media (VTM/UTM) to collect and transport patient samples. Are there alternatives that I can use?

A: While VTM/UTM remains the preferred transport media, FDA believes that the following alternative transport media could be used to collect and transport patient samples for molecular RT-PCR SARS-CoV-2 assays in a manner that will stabilize the RNA without meaningful degradation:

- Liquid Amies-based transport media.
 - Supplies:
 - E-Swab by Copan (Catalogue # 481C and 482C) with regular or flex minitip applicator
 - Opti-Swab by Puritan (Catalogue # LA-117), swab included in kit (Catalog#3317-H).
 - Storage: Up to 72 hours at 4°C, or frozen for longer storage.

If the above are not available, FDA believes that the following could be used to collect and transport samples for molecular RT-PCR SARS-CoV-2 assays:

- Dry swab in saline
 - Supplies:
 - Puritan: 25-3317-H, 25-3316-U, 25-3316-H, 25-3317-U, 25-3318-U, 25-3318-H, 3316-U, 3317-U, 3318-U, 25-3319-H, 3316-H, 3318-H, 25-3320-U, 25-3320-U EMB 100MM, 25-3320-U EMB 80MM, 25-3320-H and 25-3320-H EMB 80MM
 - Copan: 501CS01, 503CS01, 516CS01, 518CS01 and 534CS01
 - Storage: Up to 72 hours at 4°C, or frozen for longer storage.

Please be aware that the CDC does **not** recommend use of calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.

We are continuing to evaluate other options for specimen collection supplies, and we will update this list accordingly as this information becomes available.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/8/2020 9:13:31 PM
To: Grogan, Joseph J. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>; Droegemeier, Kelvin K. EOP/OSTP [(b)(6)]<[redacted]@ostp.eop.gov>
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbddd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Pottinger, Matthew F. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Kratsios, Michael J. EOP/OSTP [(b)(6)]<[redacted]@ostp.eop.gov>; Bonner, Maria K. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>; Campana, Alexandra D. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>; Caro Rivera, Juan A. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>; Watson, Ian D. EOP/OSTP [(b)(6)]<[redacted]@ostp.eop.gov>; Waterman, Paige E. EOP/OSTP [(b)(6)]<[redacted]@ostp.eop.gov>; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
Subject: Re: Devices for surface testing

Very good question. We'll investigate.
 Steve

From: Grogan, Joseph J. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>
Date: March 7, 2020 at 8:20:04 PM EST
To: Droegemeier, Kelvin K. EOP/OSTP [(b)(6)]<[redacted]@ostp.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Redfield, Robert R (CDC) <olx1@cdc.gov>, McGowan, Robert K (CDC) <omc2@cdc.gov>, Pottinger, Matthew F. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Kratsios, Michael J. EOP/OSTP [(b)(6)]<[redacted]@ostp.eop.gov>, Bonner, Maria K. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>, Campana, Alexandra D. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>, Caro Rivera, Juan A. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>, Watson, Ian D. EOP/OSTP [(b)(6)]<[redacted]@ostp.eop.gov>, Waterman, Paige E. EOP/OSTP [(b)(6)]<[redacted]@ostp.eop.gov>
Subject: Re: Devices for surface testing

With Steve Hahn from FDA

Sent from my iPhone

> On Mar 7, 2020, at 8:17 PM, Droegemeier, Kelvin K. EOP/OSTP [(b)(6)]<[redacted]@ostp.eop.gov> wrote:
 >
 > I'm copying Ian and Paige at OSTP to get their thoughts. We also can engage our new National Academy committee.
 >
 > Kelvin
 >
 >
 >> On Mar 7, 2020, at 8:08 PM, Grogan, Joseph J. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov> wrote:
 >>
 >> Can we ramp up devices for surface testing for coronavirus?
 >>
 >> [(b)(5)]

simple.

>>

(b) (5)



>> Joe

>>

>> Sent from my iPhone

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/13/2020 7:45:13 AM
To: Wainer, Andrea F [andrea.wainer@abbott.com]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]; Deborah Birx (b) (6) [redacted]@nsc.eop.gov [deborah.l.birx@nsc.eop.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Ford, Robert B [Robert.Ford@abbott.com]
Subject: Re: Abbott's Covid Data

Thank you, Andrea.
 Steve

From: Wainer, Andrea F <andrea.wainer@abbott.com>
Date: April 12, 2020 at 6:37:18 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>, Deborah Birx (b) (6) [redacted]@nsc.eop.gov <deborah.l.birx@nsc.eop.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Ford, Robert B <Robert.Ford@abbott.com>
Subject: Abbott's Covid Data

Good evening, Commissioner Hahn and Adm Giroir, I will be sending the pooling data as per our previous email tonight. Confirming it is in process and coming.

Please find attached Abbott's data as of April 11 for (1) ID NOW; and (2) m2000.

For m2000 test data, there are two types of data we have:

1. Information in our control such as the names and addresses of our customers and the number of tests we shipped to them cumulatively and this week (Sunday to Saturday shipments).
2. Raw data we receive from a remote data link that is sent from the instruments at the customers to Abbott.
 - a. We only receive the remote data link from certain customers (on the spreadsheet, the customers we don't receive data from are in gray).
 - b. For those customers with the remote data link, we are providing raw data that has the number of tests run and the number of positives. Customers run their own required protocols to validate the accuracy of a test when a new test first becomes available. Those

validation processes include negative and positive samples. The raw data we get from data link of the instrument cannot distinguish between validation samples and patient samples.

3. We do not have data regarding inventory at the labs.

For ID NOW test data:

1. We are reporting names, addresses, total cumulative tests shipped, and total tests shipped this week (Monday to Sunday shipments).
2. Unlike the m2000 instrument, we do not have any data on tests performed from the ID NOW instruments.

Best Regards,

Andrea

(b)(6)



Abbott

Andrea Wainer
Executive Vice President
Rapid & Molecular Diagnostics

Abbott
100 Abbott Park Road
Building AP6C-2
Abbott Park, IL 60064

O: +1 224-668-9155
andrea.wainer@abbott.com

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From: Birx, Deborah L. EOP/NSC [(b) (6)]@nsc.eop.gov]
Sent: 4/12/2020 6:38:14 PM
To: Wainer, Andrea F [andrea.wainer@abbott.com]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Ford, Robert B [Robert.Ford@abbott.com]
Subject: Re: [EXTERNAL] Abbott's Covid Data

Thank you. Deb

From: "Wainer, Andrea F" <andrea.wainer@abbott.com>
Date: Sunday, April 12, 2020 at 6:37 PM
To: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Haddad, Carla (HHS/OASH)" <Carla.Haddad@hhs.gov>, "Birx, Deborah L. EOP/NSC" [(b) (6)]@nsc.eop.gov, "Shuren, Jeff (FDA/CDRH)" <Jeff.Shuren@fda.hhs.gov>, "Stenzel, Timothy (FDA/CDRH)" <Timothy.Stenzel@fda.hhs.gov>
Cc: "Ford, Robert B" <Robert.Ford@abbott.com>
Subject: [EXTERNAL] Abbott's Covid Data

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Best Regards,

Andrea

(b)(6)



Abbott

Andrea Wainer
Executive Vice President
Rapid & Molecular Diagnostics

Abbott
100 Abbott Park Road
Building AP6C-2
Abbott Park, IL 60064

O: +1 224-668-9155
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From: Birx, Deborah L. EOP/NSC (b) (6) @nsc.eop.gov]
Sent: 4/6/2020 1:49:32 PM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Grogan, Joseph J. EOP/WHO (b) (6) who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Call with serology test CEOs

Just a few comments

(b) (5)

Deb

From: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>
Date: Monday, April 6, 2020 at 1:34 PM
To: "Adams, Jerome (HHS/OASH)" <Jerome.Adams@hhs.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" (b) (6) @nsc.eop.gov>, "Verma, Seema (CMS/OA)" <Seema.Verma@cms.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" (b) (6) @niaid.nih.gov>, "Grogan, Joseph J. EOP/WHO" (b) (6) who.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>
Cc: "Shah, Anand (FDA/OC)" <Anand.Shah@fda.hhs.gov>, "Shuren, Jeff (FDA/CDRH)" <Jeff.Shuren@fda.hhs.gov>, "Lenihan, Keagan (FDA/OC)" <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Call with serology test CEOs

Yes

We are on it.

And I am the accountable person working with FDA, CDC, NIH, etc

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: Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>

Sent: Monday, April 6, 2020 1:08 PM

To: Hahn, Stephen <SH1@fda.hhs.gov>; Debi Birx <(b) (6)@nsc.eop.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Joe Grogan <(b)(6)@who.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Cc: Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Call with serology test CEOs

(b)(5)

Jerome

VADM Jerome Adams, MD, MPH
 20th U.S. Surgeon General

From: Hahn, Stephen <SH1@fda.hhs.gov>

Sent: Monday, April 6, 2020 1:02 PM

To: Debi Birx <(b) (6)@nsc.eop.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Joe Grogan <(b)(6)@who.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>

Cc: Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>

Subject: Call with serology test CEOs

Colleagues,

Great call today with the CEOs.

A couple of issues were flagged that I wanted to bring to your attention.

1. Obtaining plasma samples and antigen remains a critical stumbling block to test development. FDA will review and provide some information re: sources but if any of you could be of help here, I'll be happy to pass along that information to the CEOs.
2. The CEO's would like us to consider issuing task force guidance regarding how serology tests would be used in a 'back to work' algorithm. This information would provide more guidance during their test development process. I did provide a high level overview of our current plans.
3. The CEO's wanted to know if CMS would be issuing a specific and distinct CPT code and reimbursement rate for serology tests.
4. They had many questions about the technical aspects of test development. Dr. Shuren and his team provided good information and will do so on an ongoing basis.

Any help you could provide, particularly with the first 3 items would be appreciated. I can be the point of contact with the (b) (4) group.

Best
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/6/2020 5:36:52 PM
To: CMS SV1 [SV1@cms.hhs.gov]; Good-Cohn, Meredith (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e06154b83bb4cb8a7b01816905e1300-HHS-Meredith]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Debi Birx [(b) (6) @nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Joe Grogan [(b) (6) who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Call with serology test CEOs

Thanks, Seema

From: CMS SV1 <SV1@cms.hhs.gov>
Date: April 6, 2020 at 5:34:26 PM EDT
To: Good-Cohn, Meredith (CMS) <Meredith.Good-Cohn@cms.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Adams, Jerome (OS) <Jerome.Adams@hhs.gov>, Debi Birx [(b) (6) @nsc.eop.gov], Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Fauci, Anthony S (NIH) [(b) (6) @niaid.nih.gov], Joe Grogan <[(b) (6) who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Call with serology test CEOs

CMS can work on the code/payment for the test.

From: Good-Cohn, Meredith (CMS/OA)
Sent: Monday, April 6, 2020 1:47 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Debi Birx <[(b) (6) @nsc.eop.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] [(b) (6) @niaid.nih.gov]; Joe Grogan <[(b) (6) who.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; CMS SV1 <SV1@cms.hhs.gov>
Cc: Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Call with serology test CEOs

+Adm Verma's correct email address – SV1@cms.hhs.gov. Thank you.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, April 6, 2020 1:35 PM
To: Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Debi Birx [(b) (6) @nsc.eop.gov]; Giroir, Brett

(HHS/OASH) <Brett.Giroir@hhs.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] (b) (6) @niaid.nih.gov>; Joe Grogan <(b)(6)@who.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>

Cc: Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Call with serology test CEOs

(b)(5)

From: Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>

Date: April 6, 2020 at 1:08:18 PM EDT

To: Hahn, Stephen <SH1@fda.hhs.gov>, Debi Birx (b) (6) @nsc.eop.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Fauci, Anthony S (NIH) (b) (6) @niaid.nih.gov>, Joe Grogan <Joseph.J.Grogan@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>

Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Call with serology test CEOs

(b)(5)

Jerome

VADM Jerome Adams, MD, MPH
20th U.S. Surgeon General

From: Hahn, Stephen <SH1@fda.hhs.gov>

Sent: Monday, April 6, 2020 1:02 PM

To: Debi Birx <(b) (6) @nsc.eop.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] (b) (6) @niaid.nih.gov>; Joe Grogan <(b)(6)@who.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>

Cc: Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>

Subject: Call with serology test CEOs

Colleagues,

Great call today with the CEOs.

A couple of issues were flagged that I wanted to bring to your attention.

1. Obtaining plasma samples and antigen remains a critical stumbling block to test development. FDA will review and provide some information re: sources but if any of you could be of help here, I'll be happy to pass along that information to the CEOs.
2. The CEO's would like us to consider issuing task force guidance regarding how serology tests would be used in a 'back to work' algorithm. This information would provide more guidance during their test development process. I did provide a high level overview of our current plans.
3. The CEO's wanted to know if CMS would be issuing a specific and distinct CPT code and reimbursement rate for serology tests.
4. They had many questions about the technical aspects of test development. Dr. Shuren and his team provided good information and will do so on an ongoing basis.

Any help you could provide, particularly with the first 3 items would be appreciated. I can be the point of contact with the (b) (4) group.

Best
Steve

From: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
Sent: 4/15/2020 1:40:26 PM
To: McGowan, Robert (Kyle) (CDC/OD/OCS) [omc2@cdc.gov]; Grogan, Joseph J. EOP/WHO [(b)(6) who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: COVID-19 positive serum

Thank you.

Jeff

From: McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>
Sent: Wednesday, April 15, 2020 1:35 PM
To: Grogan, Joseph J. EOP/WHO <(b)(6) who.eop.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: COVID-19 positive serum

Following up on the email yesterday about the need for more access to COVID-19 positive serum. These are three companies that have been selling positive serum for COVID-19. CDC also just put out an RFI for a collection of serum samples from patients infected with COVID-19. We have already received samples from Cantor BioConnect.

Cantor BioConnect

<http://www.cantorbioconnect.com/>

Stem Express

<https://www.stemexpress.com/>

Boca Bio

<https://www.bocabio.com/>

From: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
Sent: 3/25/2020 6:38:01 PM
To: Wainer, Andrea F [andrea.wainer@abbott.com]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Birx, Deborah L. EOP/NSC (b) (6) @nsc.eop.gov; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Ford, Robert B [Robert.Ford@abbott.com]
Subject: Re: Abbott COVID 3-25-20 Update

Thank you, Andrea.

Jeff

From: Wainer, Andrea F <andrea.wainer@abbott.com>
Date: March 25, 2020 at 6:31:47 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <(b) (6) @nsc.eop.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Ford, Robert B <Robert.Ford@abbott.com>
Subject: Abbott COVID 3-25-20 Update

Good evening,

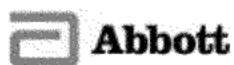
Please find attached Abbott's submission today for tests shipped through yesterday. We have sent this information directly to FEMA. You will see we have shipped (b) (4) to labs across the US. Please feel free to call with any questions. (b)(6)

Guidance included in our update to FEMA included:

1. Information in our control such as the names and addresses of our customers and the number of tests we shipped to them cumulatively and this week.
2. Raw data we receive from a remote data link that is sent from the instruments at the customers to Abbott.
 - a. First, we only receive the remote data link from certain customers (on the spreadsheet, the customers we don't receive data from are in gray).
 - b. Second, for those customers with the remote data link, we are providing raw data that has the number of tests run and the number of positives. Customers run their own required protocols to validate the accuracy of a test when a new test first becomes available. Those validation processes include negative and positive samples. The raw data we get from data link of the instrument cannot distinguish between validation samples and patient samples.
 - c. Third, as requested, the raw data for the Prior Day Tests Performed and positive numbers and rates (columns J, K and L) are for the previous day only.

3. We do not have data regarding inventory at the labs.
4. Of the (b)(4) tests shipped this week in column H, there were approximately (b)(4) tests that we expected to ship yesterday that did not ship until today.

Best Regards,
Andrea



Andrea Wainer
Executive Vice President
Rapid & Molecular Diagnostics

Abbott
100 Abbott Park Road
Building AP6C-2
Abbott Park, IL 60064

O: +1 224-668-9155
andrea.wainer@abbott.com

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From: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
Sent: 3/24/2020 11:53:39 AM
To: Grogan, Joseph J. EOP/WHO (b)(6) @who.eop.gov]
Subject: RE: Do you have the number for the ceo of hologic?

Steve MacMillan's cell phone number is (b)(6)

Jeff

-----Original Message-----

From: Grogan, Joseph J. EOP/WHO (b)(6) who.eop.gov>
Sent: Tuesday, March 24, 2020 11:38 AM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Do you have the number for the ceo of hologic?

Sent from my iPhone

From: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
Sent: 3/20/2020 11:43:17 AM
To: Grogan, Joseph J. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>
CC: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Campana, Alexandra D. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>; Bonner, Maria K. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: "Serology test"?? COVID-19

Got it. For the list of tests below, we don't have either any or any great data to draw a conclusion as to whether or not they are promising. That said, as a general matter, the antigen tests are likely to be promising. Those are all the tests in the list below that are identified as a Ag versus Ab or otherwise described.

Jeff

From: Grogan, Joseph J. EOP/WHO <[(b)(6)]@who.eop.gov>
Date: March 20, 2020 at 10:51:01 AM EDT
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Campana, Alexandra D. EOP/WHO <[(b)(6)]@who.eop.gov>, Bonner, Maria K. EOP/WHO <[(b)(6)]@who.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: "Serology test"?? COVID-19

(b) (5)

Sent from my iPhone

On Mar 20, 2020, at 7:59 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

Joe,

I wanted to give you an update on where we are at present. We received notifications and pre-EUAs for four of the tests, all CE marked according to the email you sent. We received notifications, but no pre-EUA, for two of the tests. We received pre-EUAs only for five of the tests. Two of the companies have provided neither a notification nor a pre-EUA but from which we have received a submission since 2011 for other in vitro diagnostics. Finally, one of the companies has not been in touch with us regarding the test identified in your email but we do have another test for which they have a pre-EUA.

The team is reviewing the list to see if we have any data for any of these tests to give you some idea as to whether or not we can determine if they look promising. I anticipate we won't have much information.

If you let me know what in particular you are looking for or how you would like to use the information, we can better tailor our search and review to best meet your needs.

Jeff

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 19, 2020 at 4:16:00 PM EDT
To: Grogan, Joseph J. EOP/WHO (b)(6)@who.eop.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Campana, Alexandra D. EOP/WHO (b)(6)@who.eop.gov>, Bonner, Maria K. EOP/WHO (b)(6)@who.eop.gov>
Subject: RE: "Serology test"?? COVID-19

Joe,

Yes, we'll take a look and get back to you. Happy to do so.

Jeff

From: Grogan, Joseph J. EOP/WHO (b)(6)@who.eop.gov>
Sent: Thursday, March 19, 2020 3:31 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Campana, Alexandra D. EOP/WHO (b)(6)@who.eop.gov>; Bonner, Maria K. EOP/WHO (b)(6)@who.eop.gov>
Subject: FW: "Serology test"?? COVID-19

Hey Jeff, can you guys take a look at this list of diagnostics and see if it matches up with promising diagnostics you are tracking? Are there any we are missing? I'd like to work to sync up and have 1 agreed upon list once a day if possible.

From: Birx, Deborah L. EOP/NSC (b)(6)@nsc.eop.gov>
Sent: Wednesday, March 18, 2020 3:19 PM
To: Grogan, Joseph J. EOP/WHO (b)(6)@who.eop.gov>
Subject: Fwd: "Serology test"?? COVID-19

Who can we get on this to track each of these down. Ensure this is a full list.

Sent from my iPhone

Begin forwarded message:

From: "Zaidi, Irum F" <ZaidiIF@state.gov>
Date: March 18, 2020 at 2:22:28 PM EDT
To: "Birx, Deborah L" <BirxDL@state.gov>, "Birx, Deborah L. EOP/NSC" (b)(6)@nsc.eop.gov>
Subject: FW: "Serology test"?? COVID-19

FYI.....

From: Parekh, Bharat (CDC/DDPHSIS/CGH/DGHT) <bsp1@cdc.gov>
Sent: Wednesday, March 18, 2020 1:16 PM
To: Yen Pottinger (b)(6) [REDACTED] Zaidi, Irum F <ZaidiIF@state.gov>
Subject: FW: "Serology test"?? COVID-19

FYI

From: Scheel, Christina M. (CDC/DDPHSIS/CGH/OD) <zsr3@cdc.gov>
Sent: Friday, March 13, 2020 12:19 PM
To: Rosario, Hilda (CDC/DDPHSIS/CGH/DGHT) <wlx5@cdc.gov>; Kohatsu, Luciana (CDC/DDPHSIS/CGH/DGHT) <iee2@cdc.gov>
Cc: Bonilla, Luis (CDC/DDPHSIS/CGH/DGHT) <wlx6@cdc.gov>; Hurlston, Mackenzie (CDC/DDPHSIS/CGH/DGHT) <wpd9@cdc.gov>
Subject: RE: "Serology test"?? COVID-19

Hi Hilda,

These are the tests that are commercially available for immune detection. Some are research only (RUO), some are approved in Europe (CE-IVD) and some are approved by the USA under FDA EUA. I do not see the test you are showing here, so no information about it.

I cannot recommend any antibody tests but am sharing the information that I have:

Manual or automated immunoassays

- Boditech Med, Inc. Contact
 - AFIAS COVID-19, Viral Antigen (automated; RUO)
 - AFIAS COVID-19 Ab, IgM/IgG (automated; RUO)
 - Ichroma COVID-19, viral antigen (manual; RUO)
 - Ichromia COVID-19 Ab, IgM/IgG (manual; RUO)
- Epitope Diagnostics, Inc. Contact
 - EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit (CE-IVD)
 - EDI™ Novel Coronavirus COVID-19 IgM ELISA Kit (CE-IVD)
- EUROIMMUN AG Contact
 - Anti-SARS-CoV-2 ELISA (IgA) (manual; automated; RUO)
 - Anti-SARS-CoV-2 ELISA (IgG) (manual; automated; RUO)
- Guangzhou Darui Biotechnology Co., Ltd Contact
 - 2019 Novel Coronavirus (2019-nCoV) IgM Antibody Detection Kit (ELISA Method) (RUO)
 - 2019 Novel Coronavirus (2019-nCoV) IgG Antibody Detection Kit (ELISA Method) (RUO)
 - Novel Coronavirus 2019-nCoV IgM Antibody Detection Kit (Colloidal Gold Method) (RUO)
 - Novel Coronavirus 2019-nCoV IgG Antibody Detection Kit (Colloidal Gold Method) (RUO)
- Guangzhou Wondfo Biotech Co., Ltd, Finecare SARS-CoV-2 Antibody Test (manual; RUO) Contact
- Liming Bio-Products Co., Ltd, COVID-19 Antigen Rapid Test Device (CE-IVD) Contact
- SD BIOSENSOR, Inc., STANDARD F COVID-19 Ag FIA (manual; CE-IVD) Contact
- Shenzhen Yhlo Biotech Co. Ltd Contact
 - iFlash-SARS-CoV-2 IgM (CE-IVD)
 - iFlash-SARS-CoV-2 IgG (CE-IVD)
- Taizhou ZECEN Biotech Co., Ltd., Contact
 - SARS-CoV-2 IgM (CE-IVD)
 - SARS-CoV-2 IgG (CE-IVD)
- Sugentech, Inc. (manual, RUO) Contact
 - SGTi-flex COVID-19 IgM/IgG

- SGTi-flex COVID-19 IgM
- SGTi-flex COVID-19 IgG

Rapid diagnostic tests

- Beijing Kewei Clinical Diagnostic Reagent Inc. Contact
 - Kewei COVID-19 IgM ELISA Test Kit (CE-IVD)
 - Kewei COVID-19 IgG ELISA Test Kit (CE-IVD)
 - Kewei COVID-19 IgG/IgM Fluorescence Rapid Test Kit (CE-IVD)
 - Kewei COVID-19 Antigen ELISA Test Kit (Nasal/Throat Swab) (CE-IVD)
 - Kewei COVID-19 Antigen Fluorescence Rapid Test Kit (Nasal/Throat Swab) (CE-IVD)
- BioMedomics, Inc. COVID-19 IgM-IgG Dual Antibody Rapid Test (CE-IVD) Contact
- Dynamiker Biotechnology (Tianjin) Co., Ltd., 2019 nCoV IgG/IgM Rapid Test (CE-IVD) Contact
- Getein Biotech, Inc., One Step Test for Novel Coronavirus(2019-nCoV) IgM/IgG antibody (Colloidal Gold) (CE-IVD)

Contact

- Genbody, Inc. GenBody COVID-19 IgM/IgG DUO (RUO) Contact
- Guangzhou Wondfo Biotech Co., Ltd, Wondfo SARS-CoV-2 Antibody Test (lateral flow method) (Chinese FDA-EUA; CE-IVD) Contact

- Guangzhou Fenghua Bioengineering Co. LTD, Combined Detection Kit for Novel Coronavirus (2019-nCoV) IgM/IgG Antibody (RUO) Contact

- Hangzhou AllTest Biotech Co. Ltd., 2019-nCoV IgG/IgM Rapid Test Cassette (CE-IVD) Contact
- Humasis, Humasis COVID-19 IgG/IgM Test (RUO) Contact
- Intec Products, Inc., (RUO) Contact-1; Contact-2
 - Rapid SARS-CoV-2 Antibody (IgM/IgG) Test
 - Rapid SARS-CoV-2 Antibody Test
- Jiangsu Bioperfectus Technologies Co. Ltd (RUO) Contact
 - PerfectPOC Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit
 - PerfectPOC Novel Corona Virus (SARS-CoV-2) IgM/IgG Rapid Test Kit
- Liming Bio-Products Co., Ltd, COVID-19 IgG/IgM Combo Rapid Test Device (CE-IVD) Contact
- MedicalSystem Biotechnology Co., Ltd., COVID-19 IgM/IgG Rapid Test Cassette (CE-IVD) Contact
- Nantong Egens Biotechnology Co., LTD, EGENS COVID-19 IgG/IgM Rapid Test Kit (CE-IVD; RUO) Contact
- SD BIOSENSOR, Inc. Contact
 - STANDARD Q COVID-19 IgM/IgG Duo Test (CE-IVD)
 - STANDARD Q COVID-19 Ag Test (RUO)
- servoprax GmbH, Cleartest Corona, Covid-19 (CE-IVD) Contact-1; Contact-2
- Shenzhen Bioeasy Biotechnology Co., Ltd. (CE-IVD) Contact
 - Novel Coronavirus (2019-nCoV) Fluorescence Antigen Rapid Test
 - Novel Coronavirus (2019-nCoV) Colloidal Gold Antigen Rapid Test
 - Novel Coronavirus (2019-nCoV) IgG/IgM detection kit (colloidal gold immunochromatography)
- Sugentech, Inc. (RUO) Contact
 - SGTi-flex COVID-19 IgM/IgG
 - SGTi-flex COVID-19 IgM
 - SGTi-flex COVID-19 IgG
- VivaChek Biotech (Hangzhou) Co., Ltd, VivaDiaq COVID-19 IgM/IgG Rapid Test (CE-IVD) Contact
- Wuhan EasyDiagnosis Biomedicine Co.,Ltd Contact
 - Novel Coronavirus IgM antibody test kit (colloidal gold method) (CE-IVD)
 - Novel Coronavirus IgG antibody test kit (colloidal gold method) (CE-IVD)
- Xiamen Biotime Biotechnology Co., Ltd., SARS-CoV-2 IgG/IgM Rapid Qualitative Test Kit (RUO) Contact

Abrazos,
Chris

From: Rosario, Hilda (CDC/DDPHSIS/CGH/DGHT) <wlx5@cdc.gov>

Sent: Friday, March 13, 2020 9:30 AM

HHS-FDA-20-0498-F-000043

FDA-CVD-SHURENJ-00033029

FDA-CDRH-2020-2523-000043

To: Scheel, Christina M. (CDC/DDPHSIS/CGH/OD) <zsr3@cdc.gov>; Kohatsu, Luciana (CDC/DDPHSIS/CGH/DGHT) <iee2@cdc.gov>

Cc: Bonilla, Luis (CDC/DDPHSIS/CGH/DGHT) <wlx6@cdc.gov>

Subject: "Serology test"?? COVID-19

Dear colleagues,

What do you know about this test? Is it approved as serology test already?

It is possible this is circulating in DR.

Please I need your advice ASAP how to proceed.

Thanks in advance.

Hilda Rosario

Laboratory Specialist

Centers for Disease Control and Prevention (CDC)

Dominican Republic

Office phone: 809-368-7028

Mobile phone: (b)(6)

From: Shuren, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44335A0C2F834535BC8713DFD643905E-JEFF.SHUREN]
Sent: 3/21/2020 7:41:13 AM
To: 'Hahn, Stephen' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Birx, Deborah L. EOP/NSC (b) (6) @nsc.eop.gov; Gaynor, Pete (b) (6) @fema.dhs.gov]
Subject: RE: White House Coronavirus Task Force Meeting
Attachments: COVID-19 Test Developer CEO Contact List 2020-03-04.xlsx

Attached is a list of CEOs of test makers, including the ones listed below, and their contact information.

Jeff

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, March 21, 2020 7:32 AM
To: Birx, Deborah L. EOP/NSC <(b) (6) @nsc.eop.gov>; Gaynor, Pete (b) (6) @fema.dhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Re: White House Coronavirus Task Force Meeting

Jeff or Admiral Giroir,
Good morning.
Can you all provide contacts for the vendors below?
Thx
Steve

From: Birx, Deborah L. EOP/NSC <(b) (6) @nsc.eop.gov>
Date: March 21, 2020 at 7:12:34 AM EDT
To: Gaynor, Pete <(b) (6) @fema.dhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: White House Coronavirus Task Force Meeting

Steve
Can you send contacts

From: "Gaynor, Pete" <(b) (6) @fema.dhs.gov>
Date: Saturday, March 21, 2020 at 7:10 AM
To: "Birx, Deborah L. EOP/NSC" <(b) (6) @nsc.eop.gov>
Subject: RE: White House Coronavirus Task Force Meeting

Thanks. Do you have POCs for each?

Pete Gaynor
Administrator
Office: (202) 212-5516 | Mobile (b) (6)
(b) (6) r@fema.dhs.gov

From: Birx, Deborah L. EOP/NSC (b) (6) @nsc.eop.gov>
Sent: Saturday, March 21, 2020 7:09 AM
To: Gaynor, Pete <(b) (6) @fema.dhs.gov>
Cc: Gastfriend, Daniel Z. EOP/OMB <(b) (6) omb.eop.gov>
Subject: Re: White House Coronavirus Task Force Meeting

(b) (4), (b) (5)

Deb

From: "Gaynor, Pete" (b) (6) <(b) (6)@fema.dhs.gov>
Date: Saturday, March 21, 2020 at 6:59 AM
To: "Birx, Deborah L. EOP/NSC" (b) (6) <(b) (6)@nsc.eop.gov>
Subject: RE: White House Coronavirus Task Force Meeting

Ambassador,

Can you send me the information and names of vendor you want me to collect testing data from?

s/f

Pete

Pete Gaynor
 Administrator
 Office: (202) 212-5516 | Mobile: (b) (6)
 (b) (6)@fema.dhs.gov

From: Birx, Deborah L. EOP/NSC (b) (6) <(b) (6)@nsc.eop.gov>
Sent: Saturday, March 21, 2020 6:56 AM
To: Short, Marc T. EOP/OVP <(b) (6)@ovp.eop.gov>; Troye, Olivia (b) (6) <(b) (6)@nsc.eop.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Pataki, Timothy (who.eop.gov) (b) (6) <(b) (6)@who.eop.gov>; Goyer, James (who.eop.gov) <(b) (6)@who.eop.gov>; Pottebaum, Nicholas (who.eop.gov) <(b) (6)@who.eop.gov>; Haddad, Carla (HHS/OASH) <Carla.Haddad@hhs.gov>; Hodgson, Christopher (ovp.eop.gov) <(b) (6)@ovp.eop.gov>; Hoelscher, Douglas (who.eop.gov) <(b) (6)@who.eop.gov>; Obenshain, Anne (ovp.eop.gov) <(b) (6)@ovp.eop.gov>; Nevins, Kristan K. EOP/WHO <(b) (6)@who.eop.gov>; Stuftt, Julie M. EOP/NSC <(b) (6)@nsc.eop.gov>; Davis, May M. EOP/WHO <(b) (6)@who.eop.gov>; Bonner, Maria K. EOP/WHO <(b) (6)@who.eop.gov>; Hudson, Renee R. EOP/WHO <(b) (6)@who.eop.gov>; O'Malley, Devin (treasury.gov) <Devin.O'Malley@treasury.gov>; Sheehan, Matthew J. EOP/OVP <(b) (6)@ovp.eop.gov>; Moore, Caroline E. EOP/WHO <(b) (6)@who.eop.gov>; Kushner, Jared C. EOP/WHO <(b) (6)@who.eop.gov>; Hicks, Hope C. EOP/WHO <(b) (6)@who.eop.gov>; Fisher, Garrett C. EOP/OVP <(b) (6)@ovp.eop.gov>; Kadlec, Robert <Robert.kadlec@hhs.gov>; Joel.Szabat@dot.gov; (b) (6)@mail.house.gov; Grogan, Joseph J. EOP/WHO <(b) (6)@who.eop.gov>; AMA2@HHS.GOV; stm77@treasury.gov; Kudlow, Larry A. EOP/WHO <(b) (6)@who.eop.gov>; olx1@cdc.gov; (b) (6)@niaid.nih.gov; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; BiegunSE@state.gov; sh1@fda.hhs.gov; AS1CFW <AS1CFW@hq.dhs.gov>; SV1@cms.hhs.gov; rlw@va.gov; Pottinger, Matthew F. EOP/WHO <(b) (6)@who.eop.gov>; Vought, Russell T. EOP/OMB (b) (6)@omb.eop.gov>; Miller, Katie R. (ovp.eop.gov) <(b) (6)@ovp.eop.gov>; Liddell, Christopher P. EOP/WHO <(b) (6)@who.eop.gov>; Grisham, Stephanie A. EOP/WHO <(b) (6)@who.eop.gov>; Philbin, Patrick F. EOP/WHO <(b) (6)@who.eop.gov>; Miller, Stephen EOP/WHO <(b) (6)@who.eop.gov>; Gaynor, Pete <(b) (6)@fema.dhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Kate@mail.house.gov; DeValliere, Ian C. EOP/WHO <(b) (6)@who.eop.gov>; Campana, Alexandra D. EOP/WHO <(b) (6)@who.eop.gov>; Zachary.McEntee@treasury.gov; shirley.gathers@treasury.gov; Andrew.Hughes@hud.gov; Jennifer.L.Naaden@hud.gov; Lin, Merry S. EOP/WHO

HHS-FDA-20-0498-F-000046

(b)(6)

2020-2523 CDRH

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Subject: Re: White House Coronavirus Task Force Meeting

Electronic version of today's data summary – not for forwarding or public

From: "Hurst, Natalie R. EOP/OVP" <(b)(6)@ovp.eop.gov> on behalf of "Short, Marc T. EOP/OVP" <(b)(6)@ovp.eop.gov>

Date: Friday, March 20, 2020 at 9:58 PM

To: "Troye, Nsc" <(b)(6)@nsc.eop.gov>; "Brian.Harrison@hhs.gov" <Brian.Harrison@hhs.gov>; "Pataki, Tim A. EOP/WHO" <(b)(6)@who.eop.gov>; "Goyer, Jim L. IV EOP/WHO" <(b)(6)@who.eop.gov>; "Pottebaum, Nic D. EOP/WHO" <(b)(6)@who.eop.gov>; "Haddad, Carla (HHS/OASH)" <Carla.Haddad@hhs.gov>; "Hodgson, Christopher M. EOP/OVP" <(b)(6)@ovp.eop.gov>; "Hoelscher, Douglas L. EOP/WHO" <(b)(6)@who.eop.gov>; "Obenshain, Tucker T. EOP/OVP" <(b)(6)@ovp.eop.gov>; "Nevins, Kristan K. EOP/WHO" <(b)(6)@who.eop.gov>; "Stufft, Julie M. EOP/NSC" <(b)(6)@nsc.eop.gov>; "Davis, May M. EOP/WHO" <(b)(6)@who.eop.gov>; "Bonner, Maria K. EOP/WHO" <(b)(6)@who.eop.gov>; "Hudson, Renee R. EOP/WHO" <(b)(6)@who.eop.gov>; "Devin.O'Malley@treasury.gov" <Devin.O'Malley@treasury.gov>; "Sheehan, Matthew J. EOP/OVP" <(b)(6)@ovp.eop.gov>; "Moore, Caroline E. EOP/WHO" <(b)(6)@who.eop.gov>; "Kushner, Jared C. EOP/WHO" <(b)(6)@who.eop.gov>; "Hicks, Hope C. EOP/WHO" <(b)(6)@who.eop.gov>; "Fisher, Garrett C. EOP/OVP" <(b)(6)@ovp.eop.gov>; "Robert.Kadlec@hhs.gov" <Robert.Kadlec@hhs.gov>; "Joel.Szabat@dot.gov" <Joel.Szabat@dot.gov>; <(b)(6)@mail.house.gov>; <(b)(6)@mail.house.gov>; "Grogan, Joseph J. EOP/WHO" <(b)(6)@who.eop.gov>; "AMA2@HHS.GOV" <AMA2@HHS.GOV>; "stm77@treasury.gov" <stm77@treasury.gov>; "Kudlow, Larry A. EOP/WHO" <(b)(6)@who.eop.gov>; "olx1@cdc.gov" <olx1@cdc.gov>; <(b)(6)@niaid.nih.gov>; <(b)(6)@niaid.nih.gov>; "Jerome.Adams@hhs.gov" <Jerome.Adams@hhs.gov>; "Bieganofsky@state.gov" <Bieganofsky@state.gov>

HHS-FDA-20-0498-F-000047

AMERICAN
OVERSIGHT

FDA-CVD-SHURENJ-00033183

FDA-CDRH-2020-2523-000047

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Cc: Hoosier Calendar <(b)(6)OVP.eop.gov>, "Bauer, Zachary C. EOP/OVP" <(b)(6)OVP.eop.gov>, 20-0498-F-000048

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Subject: White House Coronavirus Task Force Meeting

All –

There will be a **White House Coronavirus Task Force Meeting** on **Saturday, March 21, 2020 at 10:00am**.
Seating chart and agenda attached.

Thank you,

Natalie Hurst

Operations Coordinator, White House Coronavirus Task Force

Executive Assistant to the Chief of Staff

The Office of the Vice President

(202) (b)(6)

Major Kit Manufacturers (all are developing IVD tests):

Manufacturer	CEO/Senior Contact	Email	Phone	Other Senior Executives	Comments
ThermoFisher	Marc Casper	Marc.Casper@thermofisher.com	(b) (6)	Peter Shearstone, VP Global Mobile (b) (6)	
IDT President	Trey Martin	tmartin@idtdna.com	(b) (6)		
Biosearch	Tim Robinson	(b) (6)	44920534118		add + for London
Roche	Severin Schwan	severin.schwan@roche.com		Danelle Miller, VP Global Mobile # (b) (6)	
Quidel	Doug Bryant	(b) (6)	(b) (6)		
Hologic	Stephen P MacMillan	(b) (6)		Jeff Zinza, Sr Director of RA Mobile (b) (4)	
BD	Tom Polen	(b) (6)			
InBios	Estela Raychaudhuri	(b) (6)	206-344-5821		
Diasorin	Carlo Rosa	(b) (6)			
Danaher/Cepheid	Thomas Joyce, Jr	(b) (6)		Shamiram Feinglass, VP of Govt & RA Mobile# (b) (6)	
Vela Diagnostic	Sam Dajani		(b) (6)		
Biomerieux/Biofire	Alexandre Merieux	(b) (6)		Benjamin Smith, VP of Global Quality/Compliance Phone# (b) (6)	
Abbott/Abbott Molecular	Robert Ford	Robert.Ford@abbott.com	(510) 452-7181		
Major Reference Labs					
LabCorp	Adam Schechter	(b) (6)		Sandra Van der vaart Senior Vice President vaarts@labcorp.com	
Mayo	Gianrico Farrugia	(b) (6)	904-953-2100		
Quest	Stephen Rusckowski		800-222-0446 (b) (6)		
ARUP	Sherrie L Perkins		801-581-5854; 800-242-2787		
BioReference	Geoff Monk				Personal email ID: (b) (6)
WH Requests					
Alere, Inc	Owned by Abbott- See Abbott	(b) (6)			
Bio-Reference Laboratories	Jon Cohen		(b) (6)		
DaVita Healthcare Partners, Inc	Javier J Rodriguez			Kate Stabrawa, Sr Director Communications (b) (6)	Personal email (b) (6)
Genomic Health, Inc	Kevin Conroy	(b) (6)	(b) (6)		
Myriad Genetics, Inc	Bryan Riggsbee				(b) (6)
NeoGenomics, Inc	Douglas M VanOort				
Siemens Healthineers	Bernd Montag			Renee Howell (Senior Director of Clinical Affairs, Lab Diagnostics), (b) (6)	Corporate Info and LinkedIn shows location in Germany Corporate contact numbers: +49 69 66826602; +49-80020102022
Sonic Healthcare Limited	Dr Colin Goldschmidt	(b) (6)	(b) (6)		Company Secretary phone #: (b) (6)
Spectra Laboratories	Rice Powell				Spectra Laboratories is a wholly-owned subsidiary of Fresenius Medical Care
SYNLAB International GMBH	Mathieu Floreani			Alexander Hagen, Head of Marketing & Communication (b) (6) email ID: (b) (6)	Corporate Info and LinkedIn shows his location to be in Germany Corporate number: +49 89 307602-0

From: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
Sent: 3/20/2020 11:43:25 AM
To: Grogan, Joseph J. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>
CC: Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Campana, Alexandra D. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>; Bonner, Maria K. EOP/WHO [(b)(6)]<[redacted]@who.eop.gov>; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: "Serology test"?? COVID-19

Got it. For the list of tests below, we don't have either any or any great data to draw a conclusion as to whether or not they are promising. That said, as a general matter, the antigen tests are likely to be promising. Those are all the tests in the list below that are identified as a Ag versus Ab or otherwise described.

Jeff

From: Grogan, Joseph J. EOP/WHO <[(b)(6)]<[redacted]@who.eop.gov>
Date: March 20, 2020 at 10:51:01 AM EDT
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Campana, Alexandra D. EOP/WHO <[(b)(6)]<[redacted]@who.eop.gov>, Bonner, Maria K. EOP/WHO <[(b)(6)]<[redacted]@who.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: "Serology test"?? COVID-19

From: Jeff.Shuren@fda.hhs.gov [Jeff.Shuren@fda.hhs.gov]
Sent: 3/20/2020 7:59:13 AM
To: Grogan, Joseph J. EOP/WHO [(b)(6)] who.eop.gov]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Allen.Flann]
CC: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Campana, Alexandra D. EOP/WHO [(b)(6)] who.eop.gov]; Bonner, Maria K. EOP/WHO [(b)(6)] who.eop.gov]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: "Serology test"? COVID-19

Joe,

I wanted to give you an update on where we are at present. We received notifications and pre-EUAs for four of the tests, all CE marked according to the email you sent. We received notifications, but no pre-EUA, for two of the tests. We received pre-EUAs only for five of the tests. Two of the companies have provided neither a notification nor a pre-EUA but from which we have received a submission since 2011 for other in vitro diagnostics. Finally, one of the companies has not been in touch with us regarding the test identified in your email but we do have another test for which they have a pre-EUA.

The team is reviewing the list to see if we have any data for any of these tests to give you some idea as to whether or not we can determine if they look promising. I anticipate we won't have much information.

If you let me know what in particular you are looking for or how you would like to use the information, we can better tailor our search and review to best meet your needs.

Jeff

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 19, 2020 at 4:16:00 PM EDT
To: Grogan, Joseph J. EOP/WHO <(b)(6)] who.eop.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Campana, Alexandra D. EOP/WHO <(b)(6)] who.eop.gov>, Bonner, Maria K. EOP/WHO <(b)(6)] who.eop.gov>
Subject: RE: "Serology test"? COVID-19

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/14/2020 9:54:05 AM
To: 'Birx, Deborah L. EOP/NSC' (b) (6) @nsc.eop.gov]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; McGuffee, Tyler A. (ovp.eop.gov) (b) (6) ovp.eop.gov]
Subject: EXTERNAL: Telecon: Mark Stevenson (Thermo Fisher) - Birx, Hahn, Shah, Shuren, Lenihan
Location: dial-in tbp
Start: 5/14/2020 4:00:00 PM
End: 5/14/2020 4:30:00 PM
Show Time As: Tentative

Required Attendees: 'Birx, Deborah L. EOP/NSC'; Shah, Anand; Jeffrey Shuren; Keagan Lenihan; McGuffee, Tyler A. (ovp.eop.gov)

Government Participants:

Dr. Birx
Dr. Hahn
Dr. Shah
Dr. Shuren
Ms. Lenihan

Thermo Fisher Participant:

Mr. Mark Stevenson, CEO

Purpose:

Discussion regarding the automation and ramp up of Thermo Fisher's platforms for COVID-19 diagnostics.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/14/2020 11:45:38 AM
To: 'Birx, Deborah L. EOP/NSC' (b) (6) @nsc.eop.gov]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; McGuffee, Tyler A. (ovp.eop.gov) [(b) (6) ovp.eop.gov]
Subject: EXTERNAL: Telecon: Mark Stevenson (Thermo Fisher) - Birx, Hahn, Shah, Shuren, Lenihan
Location: 1-888-913-9943,, (b) (6)
Start: 5/14/2020 4:00:00 PM
End: 5/14/2020 4:30:00 PM
Show Time As: Tentative

Required Attendees: 'Birx, Deborah L. EOP/NSC'; Shah, Anand; Shuren, Jeff; Lenihan, Keagan; McGuffee, Tyler A. (ovp.eop.gov)

Government Participants:

Dr. Birx
Dr. Hahn
Dr. Shah
Dr. Shuren
Ms. Lenihan

Thermo Fisher Participants:

Mr. Mark Stevenson, CEO
Tim Fenton, Vice President, Global Government Relations & Public Affairs
Mark Smedley, President, Genetic Sciences Division

Purpose:

Discussion regarding the automation and ramp up of Thermo Fisher's platforms for COVID-19 diagnostics.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/14/2020 9:56:16 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; 'Birx, Deborah L. EOP/NSC' (b) (6) @nsc.eop.gov; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; McGuffee, Tyler A. (ovp.eop.gov) [(b)(6) ovp.eop.gov]
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Start: 5/14/2020 4:00:00 PM
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Mr. Mark Stevenson, CEO

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Sent: 5/14/2020 12:22:39 PM
To: Debi Birx [(b) (6)]@nsc.eop.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Fwd: COVID diagnostics

Background for our call.
 Steve

From: Stevenson, Mark [(b)(6)]@thermofisher.com>
Date: May 14, 2020 at 9:49:10 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COVID diagnostics

Dear Steve,

Yes, fine to share email. The attachment was more related to vaccine proposal note diagnostic testing.

For clarity here are the 5 items I regard as follow up.

1. As states prepare scaling their COVID testing plan, they want HHS advice on what is FDA approved, what is supply capacity etc who are contacts etc. Our team had a separate request from the White House around providing technical assistance prior to a webinar for states that Dr. Birx wanted to host, but my understand is at this point, the webinar is not set up.

(b)(4)

3. Serology pre submission from our WuXi/Mayo collaboration (<https://thermofisher.mediaroom.com/2020-05-13-Thermo-Fisher-Scientific-Response-to-COVID-19-Expands-to-Include-New-Serology-Test>)
4. After action report (when quieter)
5. Vaccine capacity for surge: I learnt our team had a call with Peter Marks and his team Monday afternoon along with our quality leaders to discuss vaccine manufacturing proposals in (b)(4). Follow up meetings are planned.

Regards

Mark

From: Steve Hahn <SH1@fda.hhs.gov>
Date: Thursday, May 14, 2020 at 8:31 AM
To: Mark Stevenson [(b)(6)]@thermofisher.com>
Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah,

Anand" <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

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Mark,

We are setting up a call with Dr. Birx and Jeff Shuren. Is it ok if I share this email and the attachments with Dr. Birx prior to the call?

Thanks

Steve

From: Stevenson, Mark (b)(6) @thermofisher.com>

Date: May 10, 2020 at 8:17:11 AM EDT

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

Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

Steve

Janice and my assistant are connected and to arrange a call. Plenty of topics to cover around public health.

Our submissions to amendment to our FDA EUA to expand our qPCR platforms and protocols was approved which will greatly expand platforms already installed able to run the COVID19 assay, including in a 384 well throughput. We have

(b)(4)

(b)(4)

Best Mark

From: Steve Hahn <SH1@fda.hhs.gov>

Date: Saturday, May 9, 2020 at 10:14 AM

To: Mark Stevenson(b)(6) @thermofisher.com>

Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

HHS-FDA-20-0498-F-000057

Mark,
thank you very much for your message. Great work on all counts. We very much appreciate the work with Thermo Fisher. It would be great to arrange a call in the upcoming week. I'll ask Janice to arrange.

I am in self-quarantine but doing well.

Best

Steve

From: Stevenson, Mark (b)(6) n@thermofisher.com>

Date: May 9, 2020 at 9:53:38 AM EDT

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

Subject: COVID diagnostics

Dear Steve,

I had read you will self-quarantine for 14 days after exposure to White House spokesperson Katie Miller, who tested positive for Covid-19 on Friday, so it prompted me to send a note. I hope you remain negative but I know you will have plenty of access to FDA EUA tests!

Quick update from Thermo Fisher. Your team has continued to be incredibly responsive providing feedback as we continue to expand use of our qPCR based testing to increase the platforms and workflows available for us which will expand testing capacity to reopen the economy. We signed a distribution agreement for the saliva based test from (b)(4) that was approved with Rutgers on our TaqPath Assay so we will now submit additional work to expand home use testing. We also worked with Gates Foundation on alternative swabs.

We have also followed up on the work done with Mayo Clinic on ELISA lab based serology testing and signed an agreement with Mayo/WuXi for that test for total antibodies (IgM/IgG). We will make a submission for that serology test will be coming to the FDA in the next few weeks.

We have also engaged with the NIH on their RADx to continue to innovate around diagnostic testing for COVID.

Let me know if we can be helpful during this unprecedented times. I'm sure at some point we can also spend time to share observations and lessons learnt in a post COVID world for how industry and FDA work together.

Best Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451

(b)(6)

(b)(6) @thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill

T (b)(6)

(b)(6) @thermofisher.com

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/23/2020 9:34:42 AM
To: Sheila Peel (b)(6)@hivresearch.org]; Birx, Deborah L. EOP/NSC (b)(6)@nsc.eop.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: [EXTERNAL] RUO and EUA

Copying Jeff Shuren the Director of CDRH

From: Sheila Peel <(b)(6)@hivresearch.org>
Date: April 22, 2020 at 10:48:22 AM EDT
To: Birx, Deborah L. EOP/NSC (b)(6)@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: [EXTERNAL] RUO and EUA

Ma'am, Sir,

Thank you.

V/r
 Sheila

Sheila A Peel, MSPH, PhD, DAC
 Director, Diagnostics and Countermeasures Branch
 Laboratory Director, HDRL, LDL
 Center Infectious Disease Research
 Walter Reed Institute of Research
 503 Robert Grant Ave; Rm 1A32
 Silver Spring, MD 30910
 Office: (b)(6)
 iPhone: (b)(6)@hivresearch.org
 (b)(6)@mail.mil

From: "Birx, Deborah L. EOP/NSC" <(b)(6)@nsc.eop.gov>
Date: Tuesday, April 21, 2020 at 4:59 PM
To: Sheila Peel (b)(6)@hivresearch.org>
Cc: "Hahn, Stephen" <SH1@fda.hhs.gov>
Subject: [EXTERNAL] RUO and EUA

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Dr Hahn said they can be one thing. Deb

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/20/2020 7:52:31 AM
To: Ford, Robert B [Robert.Ford@abbott.com]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Deborah Birx (b) (6) :@nsc.eop.gov) (b) (6) :@nsc.eop.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]
Subject: Re: Abbott's Covid Data

Thanks, Robert

From: Ford, Robert B <Robert.Ford@abbott.com>
Date: April 19, 2020 at 6:03:59 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Deborah Birx (b) (6) :@nsc.eop.gov) (b) (6) :@nsc.eop.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>
Subject: Re: Abbott's Covid Data

Dear All,

I wanted to make sure I made this comment regarding utilization of the automated antibody test.

As you can see we made a commitment to ship (b) (4) between Thur, Fri and Saturday. (b) (4) that (we were able to (b) (4)). We will recover that beginning of the week. There are some challenges on (b) (4) the weekend that we need to work though.

You will see that the column on tests performed (b) (4) I will expect that column to start to get populated by Monday/Tuesday. The reason for this is:

- A) These are shipments; so many of these accounts have not even received them yet, although we are expediting them.
- B) The lab will need to run calibrations and controls so they can validate the test per their internal protocols. Some labs are faster than others. But this system is much easier to use vs the m2000 RNA test, so I believe it will be done faster.
- B) The pre-test process requires the doctor prescription and obviously the sample collection process.

Best,

Robert B. Ford

On Apr 19, 2020, at 4:37 PM, Wainer, Andrea F <andrea.wainer@abbott.com> wrote:

Good evening,

Please find attached Abbott's data as of April 18 for (1) m2000; (2) ID NOW; and (3) ARCHITECT testing platforms.

For m2000 test data, there are two types of data we have:

1. Information in our control such as the names and addresses of our customers and the number of tests we shipped to them cumulatively and this week (Sunday to Saturday shipments).
2. Raw data we receive from a remote data link that is sent from the instruments at the customers to Abbott.
 - a. We only receive the remote data link from certain customers (on the spreadsheet, the customers we don't receive data from are in gray).
 - b. For those customers with the remote data link, we are providing raw data that has the number of tests run and the number of positives. Customers run their own required protocols to validate the accuracy of a test when a new test first becomes available. Those validation processes include negative and positive samples. The raw data we get from data link of the instrument cannot distinguish between validation samples and patient samples.
3. We do not have data regarding inventory at the labs.

For ID NOW test data:

1. We are reporting names, addresses, total cumulative tests shipped, and total tests shipped this week (Monday to Sunday shipments).
2. Unlike the m2000 instrument, we do not have any data on tests performed from the ID NOW instruments.

For ARCHITECT test data, there are two types of data we have:

1. Information in our control such as the names and addresses of our customers and the number of tests we shipped to them cumulatively and this week (Sunday to Saturday shipments).
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 - a. We only receive the remote data link from certain customers (on the spreadsheet, the customers we don't receive data from are in gray).

- b. For those customers with the remote data link, we will be providing raw data that has the number of tests run and the number of positives.
3. We do not have data regarding inventory at the labs.

Best regards,

Andrea

(b)(6)

<image001.jpg>

Andrea Wainer
Executive Vice President
Rapid & Molecular Diagnostics

Abbott
100 Abbott Park Road
Building AP6C-2
Abbott Park, IL 60064

O: +1 224-668-9155
andrea.wainer@abbott.com

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<Abbott m2000 COVID19 Testing Sites as of 4-18-20 (4-19-20 Report).xlsx>

<Abbott ID NOW COVID19 Testing Sites as of 4-18-20 (4-19-20 Report).xlsx>

<Abbott ARCHITECT COVID19 Testing Sites as of 4-18-20 (4-19-20 Report).xlsx>

From: Birx, Deborah L. EOP/NSC [(b) (6)]@nsc.eop.gov]
Sent: 4/19/2020 6:58:09 PM
To: Ford, Robert B [Robert.Ford@abbott.com]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]
Subject: Re: [EXTERNAL] Re: Abbott's Covid Data

Thank you

From: "Ford, Robert B" <Robert.Ford@abbott.com>
Date: Sunday, April 19, 2020 at 6:03 PM
To: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" <[(b) (6)]@nsc.eop.gov>, "Shuren, Jeff (FDA/CDRH)" <Jeff.Shuren@fda.hhs.gov>, "Stenzel, Timothy (FDA/CDRH)" <Timothy.Stenzel@fda.hhs.gov>, "Haddad, Carla (HHS/OASH)" <Carla.Haddad@hhs.gov>
Subject: [EXTERNAL] Re: Abbott's Covid Data

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Robert B. Ford

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1. Information in our control such as the names and addresses of our customers and the number of tests we shipped to them cumulatively and this week (Sunday to Saturday shipments).
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 - b. For those customers with the remote data link, we will be providing raw data that has the number of tests run and the number of positives.
3. We do not have data regarding inventory at the labs.

Best regards,
Andrea

(b)(6)

<image001.jpg>

Andrea Wainer
Executive Vice President
Rapid & Molecular Diagnostics

Abbott
100 Abbott Park Road
Building AP6C-2
Abbott Park, IL 60064

O: +1 224-668-9155
andrea.wainer@abbott.com

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<Abbott ID NOW COVID19 Testing Sites as of 4-18-20 (4-19-20 Report).xlsx>

<Abbott ARCHITECT COVID19 Testing Sites as of 4-18-20 (4-19-20 Report).xlsx>

From: Birx, Deborah L. EOP/NSC [(b) (6)] @nsc.eop.gov]
Sent: 4/19/2020 6:57:23 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Re: Spun polyester swabs US Cotton

Grateful. Deb

From: "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>
Date: Sunday, April 19, 2020 at 6:12 PM
To: "Giroir, Brett (OS)" <Brett.Giroir@hhs.gov>
Cc: "Hahn, Stephen" <SH1@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" <(b) (6) @nsc.eop.gov>, "Fauci, Anthony S (NIH)" <(b) (6) @niaid.nih.gov>, "Redfield, Robert R (CDC)" <olx1@cdc.gov>
Subject: Re: Spun polyester swabs US Cotton

Yes, that is a yes.

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: April 19, 2020 at 6:02:17 PM EDT
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Debi Birx <(b) (6) @nsc.eop.gov>, Fauci, Anthony S (NIH) <(b) (6) @niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: Spun polyester swabs US Cotton

Ok. I am going to take that as a yes for 175 with appropriate care once opened.

Sent from my iPhone

On Apr 19, 2020, at 5:58 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

(b) (5)



From: Hahn, Stephen <SH1@fda.hhs.gov>

Date: April 19, 2020 at 5:24:46 PM EDT

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

Cc: Debi Birx <(b) (6)@nsc.eop.gov>, Fauci, Anthony S (NIH) (b) (6)@niaid.nih.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>

Subject: Spun polyester swabs US Cotton

Jeff

(b) (5)

Steve