
From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/24/2020 9:14:39 AM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Debi Birx [Deborah.L.Birx@nsc.eop.gov]
CC: McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: Follow up on Oracle Platform and therapeutics for COVID-19

Thanks, Bob.

From: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Date: March 24, 2020 at 9:09:57 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Fauci, Anthony S (NIH) (b) (6) @niaid.nih.gov>, Debi Birx <Deborah.L.Birx@nsc.eop.gov>
Cc: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: Follow up on Oracle Platform and therapeutics for COVID-19

Dear Steve

[REDACTED] (b) (5)
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]. peace God bless r3

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From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 8:18:34 AM
To: Fauci, Anthony (NIH/NIAID) [E] (b) (6) @niaid.nih.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Debi Birx <Deborah.L.Birx@nsc.eop.gov>
Cc: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>
Subject: Follow up on Oracle Platform and therapeutics for COVID-19

Dear Colleagues,

I just want to give you an update regarding this platform. [REDACTED] (b) (5)
[REDACTED]

(b) (5)

(b) (5)

Can you let me know your thoughts about this?

Thanks

Steve

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 5/27/2020 6:17:32 AM
To: CMS SV1 [SV1@cms.hhs.gov]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (5) Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]
Subject: Re: Comprehensive use of COVID tests

(b) (5)

Thank you Deb

From: CMS (b) (6) <(b) (6)@cms.hhs.gov>
Date: Tuesday, May 26, 2020 at 9:57 PM
To: "SH1 (fda.hhs.gov)" <SH1@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Butler, Jay C. (CDC/DDID/OD)" <jcb3@cdc.gov>
Cc: Robert Redfield <olx1@cdc.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)@niaid.nih.gov>, "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>, "Short, Marc T. EOP/OVP" <Marc.T.Short@ovp.eop.gov>, "Troye, Nsc" <Olivia.Troye@nsc.eop.gov>
Subject: RE: Comprehensive use of COVID tests

I really liked this document and I think its important we get this out soon. This will be really helpful to Medicare and other health plans to figure out what they will cover. (b) (5)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

(b) (5)

The documents may overlap so just want to make we are all on the same page.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, May 26, 2020 4:18 PM
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov>
Cc: CMS SV1 <(b) (6)@cms.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Troye, Olivia (nsc.eop.gov) <Olivia.Troye@nsc.eop.gov>
Subject: Re: Comprehensive use of COVID tests

Deb,
My comments
Glad to discuss further
Steve

From: Debi Birx <Deborah.L.Birx@nsc.eop.gov>
Date: Tuesday, May 26, 2020 at 9:13 AM
To: "Butler, Jay C (CDC)" <jcb3@cdc.gov>
Cc: Seema Verma <SV1@cms.hhs.gov>, Robert Redfield <olx1@cdc.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Tony Fauci <(b) (6)@niaid.nih.gov>, Brett Giroir <Brett.Giroir@hhs.gov>, Marc Short <Marc.T.Short@ovp.eop.gov>, Olivia Troye <Olivia.Troye@nsc.eop.gov>
Subject: Comprehensive use of COVID tests

(b) (5)

(b) (5) Deb

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/1/2020 8:11:14 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Polowczyk, John P RADM USN JS J4 (USA) [john.p.polowczyk.mil@mail.mil]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-H (b) (6)]
CC: Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]
Subject: Fwd: Ventilator Utilization Matrix for University of Washington Medical Center
Attachments: COVID-19 VENT Matrix.docx; Mount Sinai NIV Repurpose Modification Protocol - v1.01.pdf

Good morning,

I thought your teams would be interested from the front lines re: Utilization matrix for ventilators. This comes from the University of Washington. Dr. Josh Benditt went through this on Saturday's CMS doctors call. Not sure who would own this from a guidelines point of view but thought I would share.

Thanks
Steve

From: Czekai, Alina (CMS/CMMI) <Alina.Czekai@cms.hhs.gov>
Date: March 31, 2020 at 9:55:32 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: Ventilator Utilization Matrix for University of Washington Medical Center

Good evening,

Please see attached ventilator utilization matrix from Dr. Josh Benditt at the University of Washington Medical Center. This is the framework Dr. Benditt shared on Saturday's *Lessons from the Front Lines: COVID-19* call. Please let me know if you'd like me to facilitate any additional follow-up.

Best,
Alina
Alina M. Czekai, MPH
Office of the Administrator | Centers for Medicare and Medicaid Services
Phone: 410-913-6829

From: Joshua O. Benditt (b) (6)@uw.edu
Sent: Tuesday, March 31, 2020 9:30 PM
To: Czekai, Alina (CMS/CMMI) <Alina.Czekai@cms.hhs.gov>
Subject: Ventilator Utilization Matrix for University of Washington Medical Center

Ms. Czekai,

Here is the our ventilator utilization matrix. I have included explanation and how we arrived at this.

I will forward other documents and procedures as we develop them for the surge that is upcoming.

Hope this is helpful.

Josh Benditt

Joshua O. Benditt MD, FCCP, RYT
Medical Director of Respiratory Care Services
and General Pulmonary Clinic
Box 356522
UWMC
1959 NE Pacific St.
Seattle, WA 98195
Ph: 206-543-3166
Fax: 206-685-8673

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/6/2020 10:08:50 AM
To: CMS SV1 (b) (6)cms.hhs.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; 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- (b) (6)]
Subject: Re: testing

(b) (5)

Steve

From: CMS (b) (6)cms.hhs.gov>
Date: May 5, 2020 at 3:24:21 PM EDT
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>
Subject: testing

We are almost ready to announce pricing on serology but would really like to resolve (b) (5)
(b) (5) Joe, can we please devote the next meeting to resolving the issue?

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/20/2020 7:09:22 AM
To: CMS SV1 (b) (6)cms.hhs.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: COVID testing and CLIA

this is terrific, Seema. Well done. I am sharing with my team.

From: CMS (b) (6)cms.hhs.gov>
Date: April 19, 2020 at 10:34:29 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: COVID testing and CLIA

Since there has been a lot of confusion about CLIA and COVID testing, my team put this together. Is it helpful, any questions or suggestions? Its' intended to be a tool for you and labs to address issue that keep coming up

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/17/2020 7:42:47 AM
To: CMS SV1 (b) (6)@cms.hhs.gov; Deborah Birx [deborah.l.birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Re: Updated language for testing section of NH reopening memo based on your earlier email from FDA/CDC and additional input we got today from CDC team
Attachments: QSO-20-XX-NH Reopening 5-16-2020 - Tracked Changes-SMH comments.docx

One change [REDACTED] (b) (5)

Thanks
Steve

From: Seema Verma (b) (6)@cms.hhs.gov>
Date: Saturday, May 16, 2020 at 8:27 PM
To: Debi Birx <deborah.l.birx@nsc.eop.gov>, Robert Redfield <olx1@cdc.gov>, Stephen Hahn <SH1@fda.hhs.gov>
Subject: Fwd: Updated language for testing section of NH reopening memo based on your earlier email from FDA/CDC and additional input we got today from CDC team

This should be final based on today's suggestions. Let me know if anyone has concerns.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/20/2020 9:04:29 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; CMS SV1 (b) (6) cms.hhs.gov]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: Re: COVID testing and CLIA

+ Dr. Shah

Deb,

That is exactly what was raised as an issue. Anand, was going to connect CDRH and CMS.

Thanks

Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 20, 2020 at 8:26:58 AM EDT
To: CMS SV1 <SV1@cms.hhs.gov>
Cc: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: COVID testing and CLIA

There was a question about (b) (5).

Sent from my iPhone

On Apr 19, 2020, at 10:34 PM, CMS (b) (6) cms.hhs.gov> wrote:

Since there has been a lot of confusion about CLIA and COVID testing, my team put this together. Is it helpful, any questions or suggestions? Its' intended to be a tool for you and labs to address issue that keep coming up

<CMS COVID Testing Infographic 2020-04-16 551 pm.pdf>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/30/2020 3:58:43 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS- (b) (6)]
Subject: Fwd: Rural Testing

Thoughts?

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: March 30, 2020 at 3:56:26 PM EDT
To: Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
Cc: Monroe, Stephan S (CDC) <stm2@cdc.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Schuchat, Anne (CDC) <acs1@cdc.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>
Subject: RE: Rural Testing

Let me suggest a strategy as well....

(b) (5)

(b) (5) For discussion

Brett

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

From: Giroir, Brett (HHS/OASH)

Sent: Monday, March 30, 2020 3:42 PM

To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>

Cc: Steve Monroe (CDC/DDPHSS/OLSS/OD) (stm2@cdc.gov) <stm2@cdc.gov>; Robert R. Redfield (CDC/OD) (olx1@cdc.gov) <olx1@cdc.gov>; Tammy Beckham (HHS/OASH) (Tammy.Beckham@hhs.gov) <Tammy.Beckham@hhs.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Carla Haddad (HHS/OASH) (Carla.Haddad@hhs.gov) <Carla.Haddad@hhs.gov>

Subject: Rural Testing

I was tasked with developing a strategy for testing in rural counties. [REDACTED]

(b) (5)

(b) (5)

Thanks for your help

BG

Brett P. Giroir, MD

ADM, US Public Health Service

Assistant Secretary for Health (ASH)

200 Independence Avenue, SW

Washington, DC 20201

Office Phone: 202-690-7694

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/8/2020 8:28:38 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: 4/7 IGA Governor Press Conference Tracker

Ok

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 8, 2020 at 8:28:13 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: Re: 4/7 IGA Governor Press Conference Tracker

In meeting. But Tyler will find time.

Sent from my iPhone

On Apr 8, 2020, at 8:27 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

They want our advice and want to scale up. Are you free for a quick call?
S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 8, 2020 at 8:24:59 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: 4/7 IGA Governor Press Conference Tracker

Yes. (b) (5)

Sent from my iPhone

On Apr 8, 2020, at 8:21 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

I'm sure you are aware of NYS' desire to talk to us about serology testing and their plan to return to work. Deb, (b) (5) Howard Zucker from NYS is supposed to call me today.
Steve

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: April 7, 2020 at 12:10:14 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: FW: 4/7 IGA Governor Press Conference Tracker

From: Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>
Sent: Tuesday, April 7, 2020 12:00 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Stevens, Lee R (OS) <Lee.Stevens@hhs.gov>
Subject: FW: 4/7 IGA Governor Press Conference Tracker

FYSA

Darcie L. Johnston
Director, Intergovernmental Affairs
U.S. Department of Health and Human Services
Office of the Secretary
202-690-1058 (office)
202-853-0582 (cell)

From: DeValliere, Ian C. EOP/WHO <(b) (6)@who.eop.gov>
Sent: Tuesday, April 7, 2020 11:30 AM
To: Pottebaum, Nicholas (who.eop.gov) <(b) (6)@who.eop.gov>; Cytryn, Jen B. EOP/WHO <(b) (6)@who.eop.gov>; Troutman, Joel D. EOP/WHO <(b) (6)@who.eop.gov>; SHORT, CHERIE <cherie.short@hq.dhs.gov>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>; Hill, John <john.h.hill@hq.dhs.gov>; Barbknecht, Nick <nick.barbknecht@hq.dhs.gov>; killionw@state.gov; sean.poole@dot.gov; downing.michael.r@dol.gov; ryan.lambert@sba.gov; Susan.Falconer@ed.gov; Campana, Alexandra D. EOP/WHO <(b) (6)@who.eop.gov>; Harper, Jay (fema.dhs.gov) <jay.harper@fema.dhs.gov>; maria.lujan@fema.dhs.gov; alaina.clark@cisa.dhs.gov; kevin.benacci@cisa.dhs.gov; Barbknecht, Nick EOP/WHO <(b) (6)@who.eop.gov>
Subject: RE: 4/7 IGA Governor Press Conference Tracker

Gov. Andrew Cuomo (D-NY)

- 3 day average hospitalization rate and 3 day intubation rate are both down significantly. There is also a steady increase in the number of discharged patients. There are 5,489 deaths up from 4,758
- The number of deaths are increasing because they entered in the peak and have been on the ventilators the longest. New York has 138,836 cases
- Hospitals rely on the on equipment, staff, and beds- they have 90,000 beds available so that is not an issue- but they are low on staff and equipment
- Want to move the USNS Comfort to make it a COVID only hospital- changed the number of beds from 1,000 to 500
- 3,000 beds given to NYC from the federal government
- Thanked the President for moving as quickly as he did
- Coordinated the shutting down of the Tri-State area. Works closely with CT and NJ
- Have plans to restart life- will take a regional approach with the Tri-State Area

- This will all boil down to how strong their testing programs are
- Need to bring antibody tests to scale and will work with the FDA to get this widely available
- There needs to be a federal stimulus bill to rebuild the state and local governments
- The 1918 pandemic peaked in New York for six months
- Remember that it is about we and not me
- The antibody tests they are looking for will test to see that an individual had the virus and completely resolved the infection

From: DeValliere, Ian C. EOP/WHO

Sent: Tuesday, April 7, 2020 10:34 AM

To: Pottebaum, Nic D. EOP/WHO (b) (6)@who.eop.gov; Cytryn, Jen B. EOP/WHO (b) (6)@who.eop.gov; Troutman, Joel D. EOP/WHO (b) (6)@who.eop.gov; 'SHORT, CHERIE' <cherie.short@hq.dhs.gov>; 'Johnston, Darcie' <Darcie.Johnston@hhs.gov>; 'Laura.Trueman@hhs.gov' <Laura.Trueman@hhs.gov>; 'Hill, John' <john.h.hill@hq.dhs.gov>; 'Barbknecht, Nick' <nick.barbknecht@hq.dhs.gov>; 'killionw@state.gov' <killionw@state.gov>; 'sean.poole@dot.gov' <sean.poole@dot.gov>; 'downing.michael.r@dol.gov' <downing.michael.r@dol.gov>; 'ryan.lambert@sba.gov' <ryan.lambert@sba.gov>; 'Susan.Falconer@ed.gov' <Susan.Falconer@ed.gov>; Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov; 'jay.harper@fema.dhs.gov' <jay.harper@fema.dhs.gov>; 'maria.lujan@fema.dhs.gov' <maria.lujan@fema.dhs.gov>; 'alaina.clark@cisa.dhs.gov' <alaina.clark@cisa.dhs.gov>; 'kevin.benacci@cisa.dhs.gov' <kevin.benacci@cisa.dhs.gov>; Barbknecht, Nicolas EOP/WHO (b) (6)@who.eop.gov

Subject: RE: 4/7 IGA Governor Press Conference Tracker

Mayor Bill de Blasio (New York, NY)

- Spoke at PS1 to discuss the food initiatives they have set up through the public school system to get food to families in need
- Starting to see some change in the data, they have seen more progress. The number of people going to hospitals who need ventilators are dropping, but will not draw conclusions until everyone is 100% sure
- The situation to get people their food is getting worse
- The only comparison right now is the great depression, it is the only parallel we can look at
- They have been planning on fixing the hunger problem from the beginning, and their hunger czar has developed a plan to feed students around the city
- They have provided 2.6 million meals in the last 3 weeks
- There are 434 sites across the city
- There is a donation to the Mayor's Fund to pay for meals for the families of healthcare workers. Debra and Leon Black donated \$10 million to help get food and home goods to the families of healthcare workers
- Moving to him to have Gov. Brown and Gov. Newsom donate ventilators to the states that were hit the hardest

From: DeValliere, Ian C. EOP/WHO

Sent: Tuesday, April 7, 2020 9:58 AM

To: Pottebaum, Nic D. EOP/WHO (b) (6)@who.eop.gov; Cytryn, Jen B. EOP/WHO (b) (6)@who.eop.gov; Troutman, Joel D. EOP/WHO (b) (6)@who.eop.gov; 'SHORT, CHERIE' <cherie.short@hq.dhs.gov>; 'Johnston, Darcie' <Darcie.Johnston@hhs.gov>; 'Laura.Trueman@hhs.gov' <Laura.Trueman@hhs.gov>; 'Hill, John' <john.h.hill@hq.dhs.gov>; 'Barbknecht, Nick' <nick.barbknecht@hq.dhs.gov>; 'killionw@state.gov' <killionw@state.gov>; 'sean.poole@dot.gov' <sean.poole@dot.gov>; 'downing.michael.r@dol.gov' <downing.michael.r@dol.gov>; 'ryan.lambert@sba.gov' <ryan.lambert@sba.gov>; 'Susan.Falconer@ed.gov' <Susan.Falconer@ed.gov>; Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov; 'jay.harper@fema.dhs.gov' <jay.harper@fema.dhs.gov>; 'maria.lujan@fema.dhs.gov' <maria.lujan@fema.dhs.gov>; 'alaina.clark@cisa.dhs.gov' <alaina.clark@cisa.dhs.gov>; 'kevin.benacci@cisa.dhs.gov' <kevin.benacci@cisa.dhs.gov>; Barbknecht, Nicolas EOP/WHO (b) (6)@who.eop.gov

Subject: 4/7 IGA Governor Press Conference Tracker

Known Press Conferences

- Gov. Cuomo (NY) 11:30 a.m. ET
- Gov. Murphy (NJ) 1:00 p.m. ET
- Gov. DeWine (OH) 2:00 p.m. ET
- Gov. Edwards (LA) 3:30 p.m. ET

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/6/2020 12:06:15 PM
To: Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Deborah.L.Birx@nsc.eop.gov; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
CC: marc.t.short@ovp.eop.gov
Subject: Re: Discussion with Montana, Idaho, NH, VT

Thanks, Jerome. This is really helpful.
Steve

From: Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>
Date: April 6, 2020 at 10:57:10 AM EDT
To: Deborah.L.Birx@nsc.eop.gov <Deborah.L.Birx@nsc.eop.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: marc.t.short@ovp.eop.gov <marc.t.short@ovp.eop.gov>
Subject: Discussion with Montana, Idaho, NH, VT

I had a phone call last night with the State Health Directors from Montana, Idaho, NH, and VT regarding their clusters.

ALL shared concerns about testing- they say because they are considered "low risk/ impacted" areas, they are at the back of the line for getting testing processed (many days to weeks to get results), and they also are at the back of the line for reagents for testing. The latter point about lack of access to reagents was universally and vigorously shared.

They would also like more guidance from CDC/ the task force about a testing strategy- Diagnostic vs surveillance, when and where to use the Abbott rapid tests, when and where (and how) to stand up antibody testing, etc.

NH was worried about staffing- much of their staff is out due to exposure. VT and NH were worried about nursing homes as clusters. Montana and Idaho were worried about weak local public health capacity in affected areas that may be isolated. In Idaho they actually had to shut down an entire hospital for a bit due to infections spreading through. █

I can share more, but wanted you to have these major points ASAP.

Jerome

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

(b) (5)

(b) (5)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/1/2020 8:14:19 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Abbott Lateral Flow

I'd like to discuss this with you.

Thanks

Steve

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: April 30, 2020 at 11:35:29 AM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Smith, Brad (CMS) <Brad.Smith@cms.hhs.gov>, Beckham, Tammy (OS) <Tammy.Beacham@hhs.gov>
Subject: Abbott Lateral Flow

Good Morning,

(b) (5)

V/r
Brett

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

(b) (5)

(b) (5)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/13/2020 7:55:39 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Working on testing strategy
Attachments: Testing Strategy.pptx

(b) (5)

S

From: Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>
Date: April 12, 2020 at 1:43:20 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Fauci, Anthony S (NIH) (b) (6)@niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Working on testing strategy

Deb. Believe that you meant to send this?

First comments, written before I saw you plan...

(b) (5)

NLM

Nelson L. Michael, M.D., Ph.D.
Department of the Army Civilian
Director, Center for Infectious Diseases Research
Walter Reed Army Institute of Research
503 Robert Grant Avenue
Silver Spring, MD 20910
Office: (301) 319-7312
Mobile: (301) 792-3430
Email: nelson.l.michael2.civ@mail.mil
Email: nmichael@hivresearch.org

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Sunday, April 12, 2020 1:04 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b) (6)@niaid.nih.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Hahn, Stephen <SH1@fda.hhs.gov>

Cc: Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>

Subject: Working on testing strategy

Just a draft – all comments welcomed

(b) (5)

. Deb

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/9/2020 10:25:40 AM
To: Conley, Sean P. CDR USN WHMO/WHMU [Sean.Conley@whmo.mil]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6)] Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]
CC: Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Jones, James J. EOP/OA (b) (6)@oa.eop.gov]
Subject: Re: HCQ PEP?

I'm not aware but I've pinged our Real World Evidence group and will get back to you.
Steve

From: Conley, Sean P. CDR USN WHMO/WHMU <Sean.Conley@whmo.mil>
Date: May 7, 2020 at 7:16:05 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Fauci, Anthony S (NIH) (b) (6)@niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Lane, Henry C (NIH) <clane@niaid.nih.gov>, Jones, James J. EOP/OA (b) (6)s@oa.eop.gov>
Subject: HCQ PEP?

Doctors,
I just received a report referencing a large "placebo-controlled trial of hydroxychloroquine for prophylaxis of SARS-CoV-2 infection after a discrete exposure".
Does anyone have insight or pre-publication data that they can share? Thanks!

Regards,
Sean

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/3/2020 1:07:05 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: FW: Remdesivir Allocation
Attachments: Allocating Remdesivir v5.pptx; Hospital_Carton_Allocations.xlsx

Anand and Keagan,
I just spoke to Dr. Birx who is copied above. [REDACTED] (b) (5)

Thanks
Steve

From: Polowczyk, John P RADM USN JS J4 (USA) <john.p.polowczyk.mil@mail.mil>
Date: May 2, 2020 at 9:19:33 AM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Kushner, Jared C. EOP/WHO <jck@who.eop.gov>, Pete Gaynor <pete.gaynor@fema.dhs.gov>, Fauci, Anthony S (NIH) [REDACTED] (b) (5) @niaid.nih.gov>
Subject: FW: Remdesivir Allocation

Dr Birx

(b) (5)

V/r John
John Polowczyk
Rear Admiral USN
(C) 571 423 6676
John.p.polowczyk.mil@mail.mil

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/6/2020 7:36:25 AM
To: Uehlecke, Nicholas (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd8adca6507d486fb2017138076f4b49-HHS-Nichola]; mrkim tymak.com [mrkim@tymak.com]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; (b) (3), (b) (6)]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: Time sensitive testing kit information

I'm copying my deputy, Dr. Anand Shah, who can make the connection.
Steve

From: Uehlecke, Nick (HHS/IOS) <Nicholas.Uehlecke@hhs.gov>
Date: May 5, 2020 at 5:06:41 PM EDT
To: mrkim tymak.com <mrkim@tymak.com>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, (b) (3), (b) (6)>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Time sensitive testing kit information

Thank you – will connect you to the right folks

From: mrkim tymak.com <mrkim@tymak.com>
Sent: Tuesday, May 5, 2020 4:49 PM
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; (b) (3), (b) (6) SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>
Cc: Uehlecke, Nick (HHS/IOS) <Nicholas.Uehlecke@hhs.gov>
Subject: Re: Time sensitive testing kit information

Dear Dr. Birx and Nick,

Thank you for the messages. We actually already submitted to FDA our completed establishment registration and device listing, the EUA # is EUA200249.

--Mr. Kim

On May 5, 2020 11:06 AM Birx, Deborah L. EOP/NSC <deborah.l.birx@nsc.eop.gov> wrote:

They should submit to FDA as we have about 90 submissions for Ab tests. Deb

Sent from my iPhone

On May 5, 2020, at 11:05 AM, (b) (3), (b) (6)> wrote:

Good morning Dr. Birx and Nick,

I hope you are well, I am emailing you from my new position over here at DNI where I work for (b) (6) right now.

Mr. Kim (cc'd) reached out to me with a possible highly value-add addition of some rapid testing kits that I thought could be very helpful (details attached.) He is a leader in the tech field, and has brought several other useful ideas to the USG previously, and has a long career in government leadership. I only bring this to you because I think it's got serious potential, and even though it is no longer in my current lane in IC leadership, as a handover of my time working for the VP I wanted to make sure I brought it to your attention.

If one or both of you could direct him to the best POC on the Task Force and/or at HHS to discuss further, I would be very grateful. Thank you again for all that you both are doing.

Very Respectfully,

(b) (3), (b) (6)

<Basic Information MEDsan Rapid Testkit RobertY2k.pdf>

<MEDsan_COVID_19_Rapid_Test_PPTRobertY2k_.pdf>

From: Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]
Sent: 3/23/2020 9:01:29 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Liddell, Christopher P. EOP/WHO [(b) (6)who.eop.gov]
CC: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; CMS SV1 [(b) (6)cms.hhs.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]
Subject: Re: Oracle Platform

Hi Chris - Working

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, March 23, 2020 8:59 AM
To: Liddell, Christopher P. EOP/WHO <(b) (6)who.eop.gov>
Cc: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; CMS SV1 <(b) (6)cms.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <(b) (6)niaid.nih.gov>; Collins, Francis S (NIH) <(b) (6)od.nih.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: Re: Oracle Platform

Chris,
Amy is working on this in real time. We'll get this to you.
Steve

From: Liddell, Christopher P. EOP/WHO <(b) (6)who.eop.gov>
Date: March 22, 2020 at 5:31:29 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; CMS SV1 <SV1@cms.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <clane@niaid.nih.gov>; Collins, Francis S (NIH)

<collinsf@od.nih.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>

Subject: Re: Oracle Platform

Steve

(b) (5)

Thanks

Chris

On Mar 22, 2020, at 4:00 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thanks, Chris. Please let me know if you have any questions.

Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>

Date: March 21, 2020 at 7:29:35 PM EDT

To: CMS SV1 <SV1@cms.hhs.gov>

Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Lane, Henry C (NIH) <clane@niaid.nih.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Liddell, Christopher P. EOP/WHO <(b) (6)@who.eop.gov>

Subject: Re: Oracle Platform

(b) (5)

Sent from my iPhone

On Mar 21, 2020, at 7:02 PM, CMS <(b) (6)@cms.hhs.gov> wrote:

Amy, please work through Brady Brookes for CMS issues.

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Sent: Saturday, March 21, 2020 6:59 PM

To: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; CMS SV1 <(b) (6)@cms.hhs.gov>

Cc: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Joe Grogan <Joseph.J.Grogan@who.eop.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Collins, Francis (NIH/OD) [E] <(b) (6)@od.nih.gov>; Franklin, Joseph (FDA/OC) <Joseph.Franklin@fda.hhs.gov>

Subject: Re: Oracle Platform

Thanks, All.

I am in touch with John Brooks and will connect with Cliff Lane as well.

(b) (5)

Take care,

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b) (6)
Email: amy.abernethy@fda.hhs.gov

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

Sent: Saturday, March 21, 2020 6:53 PM

To: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; (b) (6)cms.hhs.gov <(b) (6)cms.hhs.gov>

Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Joe Grogan <Joseph.J.Grogan@who.eop.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <(b) (6)niaid.nih.gov>; Collins, Francis S (NIH) <(b) (6)od.nih.gov>

Subject: RE: Oracle Platform

+ Seema

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>

Sent: Saturday, March 21, 2020 6:50 PM

To: Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Joe Grogan <Joseph.J.Grogan@who.eop.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <(b) (6)niaid.nih.gov>; Collins, Francis S (NIH) <(b) (6)od.nih.gov>

Subject: RE: Oracle Platform

Steve:

Thanks for the note. Cliff Lane will be my designated person to work with Amy, and if there are other areas of expertise where NIH can contribute such as a person from National Library of Medicine (NLM) and/or the National Center for Advancing Translational Science (NCATS), Cliff will work with me and Dr. Francis Collins (NIH Director) to provide a name and contact information for such a person. I am also copying Dr. Collins on this e-mail.

Best regards,
Tony

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

Sent: Saturday, March 21, 2020 4:31 PM

To: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Abernethy, Amy (FDA/OC) <Amy.Abernethy@fda.hhs.gov>

Cc: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Joe Grogan <Joseph.J.Grogan@who.eop.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>

Subject: Oracle Platform

Tony and Bob,

This email is in follow up to our conversation an hour ago regarding the Oracle Platform. I am adding Dr. Amy Abernathy who is the Principle Deputy Commissioner of FDA. CMS Administrator Verma, Joe Grogan, Stacy Amin, Chief Legal Counsel for FDA, and Keagan Lenihan, my Chief of Staff are copied.

[REDACTED] (b) (5)
[REDACTED]
[REDACTED]
[REDACTED].

The questions are:

(b) (5), (b) (6)

Thanks.
Steve

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 3/31/2020 9:36:02 AM
To: CMS SV1 [SV1@cms.hhs.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: REVISED nursing home action recommendations
Attachments: dbActions to Control COVID-19 Transmission in Nursing Homes FINAL.docx

From: CMS (b) (6)@cms.hhs.gov>
Date: Tuesday, March 31, 2020 at 7:12 AM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "Grogan, Joseph J. EOP/WHO" <Joseph.J.Grogan@who.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Stephen Hahn (FDA)" <sh1@fda.hhs.gov>
Subject: Fwd: REVISED nursing home action recommendations

See attached, these are the recommendations the joint CDC CMS team developed. (b) (5)

Sent from my iPhone

Begin forwarded message:

From: "Hittle, Matthew (CMS/OA)" <Matthew.Hittle@cms.hhs.gov>
Date: March 31, 2020 at 6:57:19 AM EDT
To: CMS (b) (6)@cms.hhs.gov>
Cc: "Brandt, Kimberly (CMS/OA)" <Kimberly.Brandt1@cms.hhs.gov>, "Moody-Williams, Jean D. (CMS/CCSQ)" <jean.moodywilliams@cms.hhs.gov>, "Ling, Shari (CMS/CCSQ)" <Shari.Ling@cms.hhs.gov>, "Good-Cohn, Meredith (CMS/OA)" <Meredith.Good-Cohn@cms.hhs.gov>
Subject: REVISED nursing home action recommendations

Seema – this newest version incorporates an additional bullet from CDC (b) (5).

Matthew Hittle
Senior Advisor
Office of the Administrator
Centers for Medicare & Medicaid Services
Desk: 202-690-6754
Cell: (b) (6)

Deliberative, pre-decisional communication

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 3/31/2020 7:54:16 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Seema Verma [Seema.Verma.OA@cms.hhs.gov]
Subject: Re: Rural Testing

(b) (5)

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Tuesday, March 31, 2020 at 7:29 AM
To: "Grogan, Joseph J. EOP/WHO" <Joseph.J.Grogan@who.eop.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Subject: Fwd: Rural Testing

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: March 30, 2020 at 3:56:26 PM EDT
To: Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
Cc: Monroe, Stephan S (CDC) <stm2@cdc.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Schuchat, Anne (CDC) <acs1@cdc.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>
Subject: RE: Rural Testing

Let me suggest a strategy as well.....

(b) (5)

(b) (5)

(b) (5)..... For discussion

Brett

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

From: Giroir, Brett (HHS/OASH)
Sent: Monday, March 30, 2020 3:42 PM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>
Cc: Steve Monroe (CDC/DDPHSS/OLSS/OD) (stm2@cdc.gov) <stm2@cdc.gov>; Robert R. Redfield (CDC/OD) (olx1@cdc.gov) <olx1@cdc.gov>; Tammy Beckham (HHS/OASH) (Tammy.Beckham@hhs.gov) <Tammy.Beckham@hhs.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Carla Haddad (HHS/OASH) (Carla.Haddad@hhs.gov) <Carla.Haddad@hhs.gov>
Subject: Rural Testing

(b) (5)

Thanks for your help

BG

Brett P. Giroir, MD

ADM, US Public Health Service

Assistant Secretary for Health (ASH)

200 Independence Avenue, SW

Washington, DC 20201

Office Phone: 202-690-7694

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 3/20/2020 4:05:54 PM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffb983419fcd-HHS-olx1-cd]; 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-(b) (6) Uyeki, Timothy M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f106bd981def4bfeb945e86b266662b2-HHS-tmu0-cd]
Subject: Re: [WARNING: UNSCANNABLE EXTRACTION FAILED]Fwd: Information for Clinicians on COVID-19 Therapies

From: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Date: Friday, March 20, 2020 at 4:03 PM
To: "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Stephen Hahn (SH1@fda.hhs.gov)" <SH1@fda.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6) niaid.nih.gov>, "Uyeki, Timothy M. (CDC/DDID/NCIRD/ID)" <tmu0@cdc.gov>
Subject: Re: [WARNING: UNSCANNABLE EXTRACTION FAILED]Fwd: Information for Clinicians on COVID-19 Therapies

From: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Date: Friday, March 20, 2020 at 3:58 PM
To: "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Stephen Hahn (SH1@fda.hhs.gov)" <SH1@fda.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6) niaid.nih.gov>, "Uyeki, Timothy M. (CDC/DDID/NCIRD/ID)" <tmu0@cdc.gov>
Subject: Re: [WARNING: UNSCANNABLE EXTRACTION FAILED]Fwd: Information for Clinicians on COVID-19 Therapies

From: "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>
Date: Wednesday, March 18, 2020 at 10:34 PM
To: "Stephen Hahn (SH1@fda.hhs.gov)" <SH1@fda.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6) niaid.nih.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Uyeki, Timothy M. (CDC/DDID/NCIRD/ID)" <tmu0@cdc.gov>
Subject: [WARNING: UNSCANNABLE EXTRACTION FAILED]Fwd: Information for Clinicians on COVID-19 Therapies

Please forward suggested edits. Thanks peace God bless r3
Get [Outlook for iOS](#)

From: Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>
Sent: Wednesday, March 18, 2020 9:04 PM
To: Redfield, Robert R. (CDC/OD)
Subject: Information for Clinicians on COVID-19 Therapies

Dear Dr. Redfield,

I attached a summary of the document requested "Information for Clinicians on COVID-19 Therapies." I also attached a summary of applicable clinical trials compiled by my team this evening (includes information on trials worldwide) for background in case this information might be useful. Let me know if you have any questions.

Thanks,
Tim

Tim Uyeki MD, MPH, MPP
CDC 2019 Novel Coronavirus Response
Clinical Team Lead
Chief Medical Officer, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Mailstop H24-7
1600 Clifton Road, N.E.
Atlanta, GA 30329
Email: tmu0@cdc.gov
Office phone: 404-639-0277
CDC Cell phone: (b) (6)

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 4/14/2020 9:49:42 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: Quick description of our app

(b) (5)

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Tuesday, April 14, 2020 at 9:12 AM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Cc: "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>
Subject: Re: Quick description of our app

Debi,
Follow up for you re: the Abbott meeting. They completely understood your point about the usage of the PoC serology test.

The CEO wanted me to pass along that the sensitivity/specificity information they gave us was a composite of IgG and IgM. (b) (4), (b) (5)

I also had a conversation with them about manufacturing ramp up and there is some flexibility. (b) (5)

Thanks
Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 14, 2020 at 6:56:23 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Kushner, Jared C. EOP/WHO <jck@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Seema Verma <sv1@cms.hhs.gov>, Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>, Tromberg, Bruce J (NIH) <bruce.tromberg@nih.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>
Subject: Re: Quick description of our app

(b) (5)

?

Sent from my iPhone

On Apr 14, 2020, at 6:51 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thanks, Tony. Debi, (b) (5):?
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>

Date: April 13, 2020 at 10:08:28 PM EDT

To: Hahn, Stephen <SH1@fda.hhs.gov>, Debi Birx MD <Deborah.L.Birx@nsc.eop.gov>, Jared Kushner <Jck@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Joe Grogan <Joseph.J.Grogan@who.eop.gov>, Seema Verma <sv1@cms.hhs.gov>

Cc: Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>, Tromberg, Bruce J (NIH) <bruce.tromberg@nih.gov>, Collins, Francis S (NIH) <(b) (6)od.nih.gov>

Subject: RE: Quick description of our app

Steve:

NIH (Sharpless and Tromberg) have an app that we should have presented to a subset of the Task Force.

Best,

Tony

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

Sent: Monday, April 13, 2020 2:17 PM

To: Debi Birx MD <Deborah.L.Birx@nsc.eop.gov>; Jared Kushner <Jck@who.eop.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Joe Grogan <Joseph.J.Grogan@who.eop.gov>; Seema Verma <sv1@cms.hhs.gov>

Subject: Fwd: Quick description of our app

Is this something we have an interest in?

Steve

Sent from my iPhone

Begin forwarded message:

From: Bob Jackson <bjackson@deerfield.com>

Date: April 13, 2020 at 12:51:47 PM EDT

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

Cc: Bob Jackson <bjackson@deerfield.com>

Subject: Quick description of our app

Thanks Dr. Hahn – below are very quick thoughts and I am working to get your more visual material for your discussion-slides in a couple minutes

(b) (4)

(b) (4)

Robert Jackson, MD
Chief Science Officer
Deerfield Management
347-439-0441

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From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 4/14/2020 5:50:10 AM
To: Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; CMS SV1 [SV1@cms.hhs.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (5) FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
CC: McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: Follow up: Community Mitigation plan

Thank you this is very helpful. (b) (5)

From: "Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)" <dbj0@cdc.gov>
Date: Monday, April 13, 2020 at 7:39 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Grogan, Joseph J. EOP/WHO" <Joseph.J.Grogan@who.eop.gov>, "Troye, Nsc" <Olivia.Troye@nsc.eop.gov>, CMS SV1 <SV1@cms.hhs.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <AFAUCI@niaid.nih.gov>, "Hahn, Stephen (FDA)" <Stephen.Hahn@fda.hhs.gov>
Cc: "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>, "Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)" <dbj0@cdc.gov>
Subject: Follow up: Community Mitigation plan

Dr Birx:
Thanks for the opportunity to discuss surveillance work with you today. Here are the electronic attachments of the CDC's community mitigation plan in slide deck and document format. These are the deliverables requested from (b) (5). Let me know if you have any questions; happy to have a few folks brief you and others on this.
Thanks,
Dan

Daniel B. Jernigan, MD MPH
Director, Influenza Division; HHS-CDC Lead for FEMA-HHS COVID-19 Response
dbj0@cdc.gov
404-375-7508

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@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- (b) (5) Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-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

[REDACTED] (b) (5)
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] 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" <Deborah.L.Birx@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" <Joseph.J.Grogan@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 <Deborah.L.Birx@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 <Joseph.J.Grogan@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

A little more context (perhaps) on point 2- I heard from my conversation with state health officers last night that there are some concerns about the sensitivity and specificity of the serology tests, and implications of letting people back to work and then finding out the test was inaccurate. [REDACTED] (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 <Deborah.L.Birx@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 <Joseph.J.Grogan@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.

(b) (5)

Best
Steve

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 4/5/2020 8:54:59 PM
To: Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: Testing Partnership Expansion Soft/Pre Launch

Haven't seen anything -

From: "Troye, Nsc" <Olivia.Troye@nsc.eop.gov>
Date: Sunday, April 5, 2020 at 8:54 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, Steve Hahn <SH1@fda.hhs.gov>
Subject: Fwd: Testing Partnership Expansion Soft/Pre Launch

(b) (5)

Olivia Troye
Special Advisor for Homeland Security and Counterterrorism
Office of the Vice President
White House Coronavirus Task Force
Office: (202) 456-2641
Mobile: (202) 881-9378 (Does not receive texts)

Begin forwarded message:

From: "Heck, Mia (HHS/OASH)" <Mia.Heck@hhs.gov>
Date: April 5, 2020 at 7:39:45 PM EDT
To: "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>
Cc: "Arbes, Sarah (HHS/ASL)" <Sarah.Arbes@hhs.gov>, "Overton, Heidi N. EOP/WHO" (b) (6)@who.eop.gov, "Heighberger, Eric (fema.dhs.gov)" (b) (6)@fema.dhs.gov, "Greenberg, Jeremy (fema.dhs.gov)" (b) (6)@fema.dhs.gov, "Ramsay, Cindy" (b) (6)@fema.dhs.gov, "Harper, Jay (fema.dhs.gov)" (b) (6)@fema.dhs.gov, (b) (6)@fema.dhs.gov, (b) (6)@fema.dhs.gov, (b) (6)@fema.dhs.gov, "Tagliento, Marc" (b) (6)@fema.dhs.gov, "McMillin, Virginia D. EOP/WHO" (b) (6)@who.eop.gov, "Pratt, Michael (OS/ASPA)" <Michael.Pratt@hhs.gov>, "Fulmer, Brendan (HHS/IOS)" <Brendan.Fulmer@hhs.gov>, "Schwartz, Erica (HHS/OASH)" <Erica.Schwartz@hhs.gov>, "Nalepa, Jessica (fema.dhs.gov)" (b) (6)@fema.dhs.gov, "Ditto, Jessica E. EOP/WHO" (b) (6)@who.eop.gov, "Miller, Katie R. EOP/OVP" <Katie.R.Miller@ovp.eop.gov>, "O'Malley, Devin M. EOP/OVP" <Devin.M.O'Malley@ovp.eop.gov>, "Troye, Olivia EOP/NSC" <Olivia.Troye@nsc.eop.gov>, "Smith, Brad (CMS/OA)" <Brad.Smith@cms.hhs.gov>, "Sartin, Shannon (CMS/OA)" <Shannon.Sartin@cms.hhs.gov>, "Broido, Tara (HHS/OASH)" <Tara.Broido@hhs.gov>, "Aikin, Ann (OS/OASH)" <Ann.Aikin@hhs.gov>, "Haigwood, Patricia (HHS/OASH)" <Patricia.Haigwood@hhs.gov>, "Richardson, Yasamie (fema.dhs.gov)" (b) (6)@fema.dhs.gov, "Migliaccio-Grabill, Kate (HHS/OASH)" <Kate.Migliaccio-Grabill@hhs.gov>, "Cox, Jordan (HHS/ASL)" <Jordan.Cox@hhs.gov>, "Crawford, Sean (DHS.GOV)" (b) (6)@fema.dhs.gov, "Alpern, Ethan" (b) (6)@fema.dhs.gov, "Hurley, Carolina L. EOP/WHO" (b) (6)y@who.eop.gov, "Stainsby, Leiloni" (b) (6)y@fema.dhs.gov, "Hoffman, Peter D. EOP/WHO" (b) (6)@who.eop.gov, "Horstman, John H. EOP/WHO" (b) (6)@who.eop.gov, "Murphy, Ryan (OS/ASPA)" <Ryan.Murphy1@hhs.gov>, "Oakley, Caitlin B. (OS/ASPA)" <Caitlin.Oakley@HHS.GOV>, "McKeogh, Katherine (OS/ASPA)" <Katherine.McKeogh@hhs.gov>, "Shuy, Caitrin (HHS/ASFR)" <Caitrin.Shuy@hhs.gov>, "Pinson, Alexander (HHS/ASFR)" <Alexander.Pinson@hhs.gov>, "Montesi, Janet" (b) (6)@fema.dhs.gov, "Johnston, Darcie (HHS/IEA)" <Darcie.Johnston@hhs.gov>, "Stevens, Lee (OS/IEA)" <Lee.Stevens@hhs.gov>, "Baker, Michael (OS/IEA)" <Michael.Baker@hhs.gov>, "Haddad, Carla (HHS/OASH)" <Carla.Haddad@hhs.gov>, "Planning, David M. EOP/WHO" (b) (6)@who.eop.gov, "Hodgson, Christopher M. EOP/OVP" (b) (6)@ovp.eop.gov, "Morse, Sara (HHS/ASL)" <Sara.Morse@hhs.gov>, "Mango, Paul (HHS/IOS)"

<Paul.Mango@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Tignor, Beth (HHS/IOS)" <Beth.Tignor@hhs.gov>, "Puesan, Cesar (HHS/OS/IOS)" <Cesar.Puesan@hhs.gov>

Subject: Re: Testing Partnership Expansion Soft/Pre Launch

Let me confirm and will circle back with you on separate thread.

Sent from my iPhone

On Apr 5, 2020, at 7:38 PM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov> wrote:

Mia,

[REDACTED] (b) (5)

Judy

Sent from my iPhone

On Apr 5, 2020, at 7:30 PM, Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov> wrote:

+ a few other leg affairs

From: Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>

Sent: Sunday, April 5, 2020 7:18 PM

To: Overton, Heidi N. EOP/WHO <Heidi.N.Overton@who.eop.gov>; Heighberger, Eric (fema.dhs.gov) <(b) (6)@fema.dhs.gov>; Greenberg, Jeremy (fema.dhs.gov) <(b) (6)@fema.dhs.gov>; Ramsay, Cindy <(b) (6)@fema.dhs.gov>; Harper, Jay (fema.dhs.gov) <(b) (6)@fema.dhs.gov>; <(b) (6)@fema.dhs.gov>; Tagliento, Marc <(b) (6)@fema.dhs.gov>; Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; Fulmer, Brendan (HHS/IOS) <Brendan.Fulmer@hhs.gov>; Schwartz, Erica (HHS/OASH) <Erica.Schwartz@hhs.gov>; Nalepa, Jessica (fema.dhs.gov) <(b) (6)@fema.dhs.gov>; Ditto, Jessica (who.eop.gov) <Jessica.E.Ditto@who.eop.gov>; Miller, Katie R. (ovp.eop.gov) <Katie.R.Miller@ovp.eop.gov>; Devin.M.O'Malley@ovp.eop.gov; Troye, Olivia (nsc.eop.gov) <Olivia.Troye@nsc.eop.gov>; Smith, Brad (CMS/OA) <Brad.Smith@cms.hhs.gov>; Sartin, Shannon (CMS/OA) <Shannon.Sartin@cms.hhs.gov>; Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>; Aikin, Ann (OS/OASH) <Ann.Aikin@hhs.gov>; Haigwood, Patricia (HHS/OASH) <Patricia.Haigwood@hhs.gov>; Richardson, Yasamie (fema.dhs.gov) <(b) (6)@fema.dhs.gov>; Migliaccio-Grabill, Kate (HHS/OASH) <Kate.Migliaccio-Grabill@hhs.gov>; Cox, Jordan (HHS/ASL) <Jordan.Cox@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Crawford, Sean (DHS.GOV) <(b) (6)@fema.dhs.gov>; Alpern, Ethan <(b) (6)@fema.dhs.gov>; Hurley, Carolina L. EOP/WHO <Carolina.L.Hurley@who.eop.gov>; Stainsby, Leiloni <(b) (6)@fema.dhs.gov>; Hoffman, Peter D. EOP/WHO <Peter.D.Hoffman@who.eop.gov>; Horstman, John H. EOP/WHO <John.H.Horstman@who.eop.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>; Montesi, Janet <janet.montesi@fema.dhs.gov>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Stevens, Lee (OS/IEA) <Lee.Stevens@hhs.gov>; Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Haddad, Carla (HHS/OASH) <Carla.Haddad@hhs.gov>

Subject: Testing Partnership Expansion Soft/Pre Launch

Hi everyone,

(b) (5)

Please let us know if you have suggestions/changes to this plan or have edits to the reactive statement.

Mia

Mia Palmieri Heck
Director of External Affairs
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
(202) 578-6071

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/20/2020 6:56:00 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: Treatment Document

Deb and Bob,

[REDACTED] (b) (5)
[REDACTED]. Sound ok?
Steve

From: Fauci, Anthony (NIH/NIAID) [E] (b) (6)@niaid.nih.gov>
Date: March 20, 2020 at 6:45:32 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Lane, Henry C (NIH) (b) (6)@niaid.nih.gov>
Subject: Treatment Document

Team:

As per my discussion with Steve a few minutes ago, I have made some changes in the document. (b) (6)

[REDACTED]
[REDACTED]
[REDACTED] I am attaching a tracked version of the document that was your FINAL as well as a clean copy with all of the changes accepted. Please take a look and Steve said that he would like to set up a quick call to discuss after you have had a look. I am very sorry to come in with these changes at this late point, but I really did not get a chance to have a good look at the document as I was in a car.

Thanks,
Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

(b) (6)

National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/15/2020 5:14:19 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: FW: Devices received by NCI

FYSA

From: Sharpless, Norman (NIH/NCI) [E] <norman.sharpless@nih.gov>
Date: April 15, 2020 at 2:52:16 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Lowy, Douglas R (NIH) <lowyd@mail.nih.gov>
Subject: FW: Devices received by NCI

Brett, Steve and Anand

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

Let me know if you have other questions

Ned

Norman E. Sharpless, MD
Director, The National Cancer Institute



Pre-decisional / FOUO / Deliberative

From: Cherry, Jim (NIH/NCI) [E] <jim.cherry@nih.gov>
Sent: Wednesday, April 15, 2020 11:13 AM

To: Sharpless, Norman (NIH/NCI) [E] <norman.sharpless@nih.gov>; Lowy, Douglas (NIH/NCI) [E] <lowyd@mail.nih.gov>

Cc: Lubenow, Anne (NIH/NCI) [E] <lubenowa@occ.nci.nih.gov>; Pinto, Ligia (NIH/NCI) [C] <pintol@mail.nih.gov>

Subject: Devices received by NCI

Ned and Doug, I wanted to share with you the most updated list of kits that has been received as of 11am today. I am sure you both have meetings throughout the day and could be asked. The list will be updated and shared with you all at the end of the week. If there are any questions or concerns please to let me know.

Ligia your guys have been absolutely amazing to work with!

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

Jim

James M. Cherry Ph.D
Scientific Program Director
Contracting Officer Representative (COR III), OSO, OD, NCI
NCI Campus at Frederick
Bldg. 427, Rm. 11
Frederick, MD 21702
Phone: 301-846-6811
Mobile: (b) (6)
Fax: 301-846-1494
E-mail: jim.cherry@nih.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/28/2020 7:45:21 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Redd, Stephen C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb0e6496f1af42ce9f8e0d4f92fae009-HHS-scr1-cd]
Subject: Re: Flagging NIH Media Product for Release Tomorrow

this is great news. Bruce Tromberg is terrific.
Steve

From: Fauci, Anthony (NIH/NIAID) [E] (b) (6) niaid.nih.gov>
Date: April 27, 2020 at 5:48:56 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Redd, Stephen C (CDC) <scr1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Flagging NIH Media Product for Release Tomorrow

Deb:

As an FYI. This is an initiative from NBIB/NIH on development of POC diagnostics for SARS-CoV-2.

Best,
Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

(b) (6)
National Institutes of Health
Bethesda, MD 20892-2520
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E-mail: (b) (6)

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/24/2020 8:29:24 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [nelson.l.michael2.civ@mail.mil]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: RE: if possible review in mins not hours

Sounds good.

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>
Date: April 23, 2020 at 10:00:19 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: RE: if possible review in mins not hours

Agree. (b) (5)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Thursday, April 23, 2020 4:41 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>; Fauci, Anthony (NIH/NIAID) [E] (b) (6)@niaid.nih.gov; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Subject: Re: if possible review in mins not hours

(b) (5)

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Thursday, April 23, 2020 at 4:36 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA)" <nelson.l.michael2.civ@mail.mil>, "Fauci, Anthony S (NIH)" (b) (6)@niaid.nih.gov, "Redfield, Robert R (CDC)" <olx1@cdc.gov>
Subject: Re: if possible review in mins not hours

(b) (5)

?

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 23, 2020 at 4:32:54 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>, Fauci, Anthony S (NIH) (b) (6)@niaid.nih.gov, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: if possible review in mins not hours

(b) (5)

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

Date: Thursday, April 23, 2020 at 4:30 PM

To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA)" <nelson.l.michael2.civ@mail.mil>, "Fauci, Anthony S (NIH)" <afauci@niaid.nih.gov>, "Redfield, Robert R (CDC)" <olx1@cdc.gov>

Subject: Re: if possible review in mins not hours

Looks good

(b) (5)

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

Date: April 23, 2020 at 2:14:58 PM EDT

To: Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>, Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>

Subject: if possible review in mins not hours

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/21/2020 8:25:43 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Billet, Courtney R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04ddfe30e6154dd5ab720f23eb6070df-HHS-billetec]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Myles, Renate H (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04a3e5f0ac384bd6b70bd9cdee9082f2-HHS-mylesr-]
Subject: Re: FYI - "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines"

Thanks, Tony.
Steve

From: Fauci, Anthony (NIH/NIAID) [E] (b) (6) niaid.nih.gov>
Date: April 20, 2020 at 11:54:01 AM EDT
To: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>, Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Billet, Courtney R (NIH) <billetec@niaid.nih.gov>, Hall, Bill (OS) <bill.hall@hhs.gov>, O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lane, Henry C (NIH) <(b) (6) niaid.nih.gov>, Myles, Renate H (NIH) <mylesr@mail.nih.gov>
Subject: FYI - "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines"

Katie/Marc:

Just as an FYI - "The Coronavirus Disease 2019 (COVID-19) Treatment Guidelines" that were developed here at NIH, and a copy of which I provided to Deb Birx and ultimately to Mark Meadows is moving forward. Mark Meadows (b) (5)

[REDACTED]

Press release will come from NIH with clearance through the appropriate channels (see attachment as an FYI). I anticipate that this will happen in the next day or two. Thanks.

Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

(b) (6)

National Institutes of Health
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Phone: (b) (6)

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/10/2020 6:16:41 PM
To: Tyler McGuffee [Tyler.A.McGuffee2@ovp.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS (b) (6)]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: FW: testing, testing, testing

Tyler Ann,

(b) (5)

Thanks
Steve

From: Tony Fauci (b) (6)@niaid.nih.gov>
Date: Sunday, May 10, 2020 at 4:27 PM
To: Debi Birx <deborah.L.Birx@nsc.eop.gov>, Robert Redfield <olx1@cdc.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Jerome Adams <Jerome.Adams@hhs.gov>, Brett Giroir <Brett.Giroir@hhs.gov>, Robert Kadlec <Robert.Kadlec@hhs.gov>
Subject: testing, testing, testing

Folks:

The link below is an article by Harold Varmus representing the deliberations of 10 world-class scientists. (b) (5)

[Redacted text block]

This article is worth a read. Maybe we can discuss it the next time we meet, which might be virtual.

<https://www.theatlantic.com/ideas/archive/2020/05/lack-testing-holding-science-back/611422/>

Thanks,
Tony

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 3/20/2020 7:19:38 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: Treatment Document
Attachments: db1Information for Clinicians on COVID-19 Therapies31hcl - with Fauci and Lane tracked changes showing.docx

(b) (5)

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Friday, March 20, 2020 at 7:06 PM
To: "Fauci, Anthony S (NIH)" (b) (6)@niaid.nih.gov>
Cc: "Redfield, Robert R (CDC)" <olx1@cdc.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Lane, Henry C (NIH)" <(b) (6)niaid.nih.gov>, "McGuffee, Tyler A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>
Subject: Re: Treatment Document

I have a couple of comments

1. There are some typos which appear to be related to having multiple versions.

(b) (5)

(b) (5)

I'll await for other comments.

Thanks
Steve

Sent from my iPad

On Mar 20, 2020, at 6:45 PM, Fauci, Anthony (NIH/NIAID) [E] (b) (6)@niaid.nih.gov> wrote:

Team:

As per my discussion with Steve a few minutes ago, I have made some changes in the document. (b) (5)

I am attaching a tracked version of the document that was your FINAL as well as a clean copy with all of the changes accepted. Please take a look and Steve said that he would like to set up a quick call to discuss after you have had a look. I am very sorry to come in with these changes at this late point, but I really did not get a chance to have a good look at the document as I was in a car.

Thanks,
Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

(b) (6)

(b) (6)

National Institutes of Health

Bethesda, MD 20892-2520

Phone: (b) (6)

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E-mail: (b) (6)

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<dbInformation for Clinicians on COVID-19 Therapies31hcl - with Fauci and Lane tracked changes showing.docx>

<dbInformation for Clinicians on COVID-19 Therapies31hcl - with Fauci and Lane tracked Clean copy.docx>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/23/2020 2:20:51 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-H (b) (6)]
CC: Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Quick Review: Press Conference Open - March 23

(b) (5)

S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 23, 2020 at 10:31:46 AM EDT
To: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lane, Henry C (NIH) <clane@niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: Quick Review: Press Conference Open - March 23

(b) (5)

From: "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>
Date: Monday, March 23, 2020 at 10:17 AM
To: "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>
Subject: RE: Quick Review: Press Conference Open - March 23

Steve:

Please see my edits in red below.

Thanks,

Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

(b) (6)

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Phone: (b) (6)

FAX: (301) 496-4409

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

Sent: Monday, March 23, 2020 10:04 AM

To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Debi Birx <Deborah.L.Birx@nsc.eop.gov>

Subject: Re: Quick Review: Press Conference Open - March 23

(b) (5)

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>

Date: March 23, 2020 at 9:03:21 AM EDT

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

Subject: FW: Quick Review: Press Conference Open - March 23

Here it is

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

(b) (6)
National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
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From: Fauci, Anthony (NIH/NIAID) [E]

Sent: Monday, March 23, 2020 8:54 AM

To: Staff Secretary (b) (6)who.eop.gov>; Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>; Kushner, Jared C. EOP/WHO <jck@who.eop.gov>; Philbin, Patrick F. EOP/WHO (b) (6)@who.eop.gov>; Eisenberg, John A. EOP/WHO (b) (6)g@who.eop.gov>; Ueland, Eric M. EOP/WHO (b) (6)@who.eop.gov>; (b) (6)who.eop.gov; 'Mizelle, Chad' <chad.mizelle@hq.dhs.gov>; Liddell, Christopher P. EOP/WHO (b) (6)@who.eop.gov>; Moore, Caroline E. EOP/WHO (b) (6)@who.eop.gov>; Hutchinson, Cassidy J. EOP/WHO (b) (6)@who.eop.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Kudlow, Larry A. EOP/WHO <(b) (6)who.eop.gov>; Conway, Kellyanne E. EOP/WHO <KAC@who.eop.gov>; Miller, Stephen EOP/WHO <Stephen.Miller@who.eop.gov>; Vought, Russell T. EOP/OMB (b) (6)@omb.eop.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Pottinger, Matthew F. EOP/WHO (b) (6)@who.eop.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Lewis, Oliver CAPT SD <Oliver.Lewis@sd.mil>; Levi, William (OAG) <William.Levi@usdoj.gov>

Subject: RE: Quick Review: Press Conference Open - March 23

Please see attached document with tracked suggested edits and comments.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

Building 31, Room 7A-03
(b) (6)
Bethesda, MD 20892-2520
Phone: (b) (6)
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From: Staff Secretary (b) (6)@who.eop.gov>

Sent: Monday, March 23, 2020 8:02 AM

To: Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>; Kushner, Jared C. EOP/WHO <jck@who.eop.gov>; Philbin, Patrick

F. EOP/WHO (b) (6)@who.eop.gov>; Eisenberg, John A. EOP/WHO (b) (6)@who.eop.gov>; Ueland, Eric M. EOP/WHO (b) (6)@who.eop.gov>; (b) (6)@who.eop.gov>; 'Mizelle, Chad' <chad.mizelle@hq.dhs.gov>; Liddell, Christopher P. EOP/WHO <(b) (6)@who.eop.gov>; Moore, Caroline E. EOP/WHO (b) (6)@who.eop.gov>; Hutchinson, Cassidy J. EOP/WHO (b) (6)@who.eop.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Kudlow, Larry A. EOP/WHO <Lawrence.A.Kudlow@who.eop.gov>; Conway, Kellyanne E. EOP/WHO <KAC@who.eop.gov>; Miller, Stephen EOP/WHO <Stephen.Miller@who.eop.gov>; Vought, Russell T. EOP/OMB (b) (6)@omb.eop.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>; Pottinger, Matthew F. EOP/WHO (b) (6)@who.eop.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Lewis, Oliver CAPT SD <Oliver.Lewis@sd.mil>; Levi, William (OAG) <William.Levi@usdoj.gov>
Cc: Staff Secretary <(b) (6)@who.eop.gov>
Subject: Quick Review: Press Conference Open - March 23

All,

Please see attached for draft remarks for today's press conference. Affirmative clearance is requested from **WHCO, HHS, DHS, and DOJ**. All others welcome to comment as well. Please send all comments and clearances to Staff Secretary **by 1pm today**.

Thank you,
Staff Secretary

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/22/2020 3:56:25 PM
To: CMS SV1 [(b) (6)cms.hhs.gov]; 'Grogan, Joseph J. EOP/WHO' [Joseph.J.Grogan@who.eop.gov]
CC: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbddd983419fcd-HHS-olx1-cd]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Liddell, Christopher P. EOP/WHO [(b) (6)who.eop.gov]
Subject: RE: Oracle Platform

Thanks, Seema.

From: CMS [(b) (6)cms.hhs.gov]
Date: March 21, 2020 at 8:54:23 PM EDT
To: 'Grogan, Joseph J. EOP/WHO' <Joseph.J.Grogan@who.eop.gov>
Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Lane, Henry C (NIH) <(b) (6)niaid.nih.gov>, Collins, Francis S (NIH) <(b) (6)od.nih.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Liddell, Christopher P. EOP/WHO <(b) (6)who.eop.gov>
Subject: RE: Oracle Platform

We can help with issue number 2. [(b) (5)].

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Sent: Saturday, March 21, 2020 7:29 PM
To: CMS SV1 <SV1@cms.hhs.gov>
Cc: Abernethy, Amy (FDA/OC) <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>; Lane, Cliff (NIH/NIAID) [E] <clane@niaid.nih.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; Franklin, Joseph (FDA/OC) <Joseph.Franklin@fda.hhs.gov>; Liddell, Christopher P. EOP/WHO

<[REDACTED] (b) (6)@who.eop.gov>

Subject: Re: Oracle Platform

[REDACTED] (b) (5)

Sent from my iPhone

On Mar 21, 2020, at 7:02 PM, CMS [REDACTED] (b) (6)@cms.hhs.gov> wrote:

Amy, please work through Brady Brookes for CMS issues.

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Sent: Saturday, March 21, 2020 6:59 PM

To: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <[REDACTED] (b) (6)@niaid.nih.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; CMS SV1 <[REDACTED] (b) (6)@cms.hhs.gov>

Cc: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Joe Grogan <Joseph.J.Grogan@who.eop.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>; Lane, Cliff (NIH/NIAID) [E] <[REDACTED] (b) (6)@niaid.nih.gov>; Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)@od.nih.gov>; Franklin, Joseph (FDA/OC) <Joseph.Franklin@fda.hhs.gov>

Subject: Re: Oracle Platform

Thanks, All.

I am in touch with John Brooks and will connect with Cliff Lane as well.

[REDACTED] (b) (5)

Take care,

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: [REDACTED] (b) (6)

Email: amy.abernethy@fda.hhs.gov

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

Sent: Saturday, March 21, 2020 6:53 PM

To: Fauci, Anthony S (NIH) <[REDACTED] (b) (6)@niaid.nih.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; [REDACTED] (b) (6)@cms.hhs.gov <[REDACTED] (b) (6)@cms.hhs.gov>

Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Joe Grogan <Joseph.J.Grogan@who.eop.gov>; Verma, Seema (CMS)

<Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <(b) (6)niaid.nih.gov>; Collins, Francis S (NIH) <(b) (6)od.nih.gov>

Subject: RE: Oracle Platform

+ Seema

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>

Sent: Saturday, March 21, 2020 6:50 PM

To: Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Joe Grogan <Joseph.J.Grogan@who.eop.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <clane@niaid.nih.gov>; Collins, Francis S (NIH) <(b) (6)od.nih.gov>

Subject: RE: Oracle Platform

Steve:

Thanks for the note. Cliff Lane will be my designated person to work with Amy, and if there are other areas of expertise where NIH can contribute such as a person from National Library of Medicine (NLM) and/or the National Center for Advancing Translational Science (NCATS), Cliff will work with me and Dr. Francis Collins (NIH Director) to provide a name and contact information for such a person. I am also copying Dr. Collins on this e-mail.

Best regards,

Tony

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

Sent: Saturday, March 21, 2020 4:31 PM

To: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Abernethy, Amy (FDA/OC) <Amy.Abernethy@fda.hhs.gov>

Cc: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Joe Grogan <Joseph.J.Grogan@who.eop.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>

Subject: Oracle Platform

Tony and Bob,

This email is in follow up to our conversation an hour ago regarding the Oracle Platform. I am adding Dr. Amy Abernathy who is the Principle Deputy Commissioner of FDA. CMS Administrator Verma, Joe Grogan, Stacy Amin, Chief Legal Counsel for FDA, and Keagan Lenihan, my Chief of Staff are copied.

(b) (5)

The questions are:

(b) (5)

(b) (6), (b) (5)

Thanks.
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/19/2020 8:31:54 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: Information for Clinicians on COVID-19 Therapies

This is where we are with guidance on therapeutics.

Sent from my iPad

Begin forwarded message:

From: "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>
Date: March 19, 2020 at 7:42:19 AM EDT
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Redfield, Robert R (CDC)" <olx1@cdc.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Uyeki, Timothy M (CDC)" <tmu0@cdc.gov>
Cc: "Lane, Henry C (NIH)" <(b) (6)niaid.nih.gov>
Subject: RE: Information for Clinicians on COVID-19 Therapies

Folks:

Of note, there is an interagency working group that has just developed recommendations as well. (b) (5)

(b) (5)

Happy to discuss.
Best regards,
Tony

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Thursday, March 19, 2020 7:39 AM
To: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Stephen Hahn (SH1@fda.hhs.gov) <SH1@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@CDC.GOV>
Subject: Re: Information for Clinicians on COVID-19 Therapies

(b) (5)

From: "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>
Date: Thursday, March 19, 2020 at 6:24 AM
To: "Stephen Hahn (SH1@fda.hhs.gov)" <SH1@fda.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <[\(b\) \(6\)niaid.nih.gov](mailto:(b) (6)niaid.nih.gov)>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Uyeki, Timothy M. (CDC/DDID/NCIRD/ID)" <tmu0@cdc.gov>
Subject: Re: Information for Clinicians on COVID-19 Therapies

Any edits ??

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From: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Sent: Wednesday, March 18, 2020 10:34:01 PM
To: Stephen Hahn (SH1@fda.hhs.gov) <sh1@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <AFAUCI@niaid.nih.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>
Subject: Fwd: Information for Clinicians on COVID-19 Therapies

Please forward suggested edits. Thanks peace God bless r3
Get [Outlook for iOS](#)

From: Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>
Sent: Wednesday, March 18, 2020 9:04 PM
To: Redfield, Robert R. (CDC/OD)
Subject: Information for Clinicians on COVID-19 Therapies

Dear Dr. Redfield,

I attached a summary of the document requested "Information for Clinicians on COVID-19 Therapies." I also attached a summary of applicable clinical trials compiled by my team this evening (includes information on trials worldwide) for background in case this information might be useful. Let me know if you have any questions.

Thanks,
Tim

Tim Uyeki MD, MPH, MPP
CDC 2019 Novel Coronavirus Response
Clinical Team Lead
Chief Medical Officer, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Mailstop H24-7
1600 Clifton Road, N.E.
Atlanta, GA 30329
Email: tmu0@cdc.gov
Office phone: 404-639-0277
CDC Cell phone [\(b\) \(6\)](tel:(b) (6))

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/21/2020 1:55:47 PM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-H (b) (6)]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

(b) (5)

From: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Date: March 21, 2020 at 1:54:45 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Lane, Henry C (NIH) <clane@niaid.nih.gov>, McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>, Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, McGowan, Robert K (CDC) <omc2@cdc.gov>
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

(b) (5)

Get Outlook for iOS

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, March 21, 2020 12:48:12 PM
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>; Fauci, Anthony (NIH/NIAID) [E] <AFAUCI@niaid.nih.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Cc: Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

(b) (5)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 21, 2020 at 12:40:16 PM EDT
To: Lane, Henry C (NIH) <clane@niaid.nih.gov>, McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>, Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, McGowan, Robert K (CDC) <omc2@cdc.gov>
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

(b) (5)

deb

From: "Lane, Cliff (NIH/NIAID) [E]" ((b) (6))niaid.nih.gov>
Date: Saturday, March 21, 2020 at 12:31 PM
To: "McGuffee, Tyler A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>
Cc: "Rom, Colin (FDA/OC)" <Colin.Rom@fda.hhs.gov>, "McGowan, Robert (Kyle) (CDC/OD/OCS)" <omc2@cdc.gov>
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

I realize I am on the cc line, however I have three comments and have tracked suggestions:

(b) (5)

Cliff Lane

From: "McGuffee, Tyler A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>
Date: Saturday, March 21, 2020 at 11:33 AM
To: Anthony Fauci <(b) (6)niaid.nih.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>
Cc: "Lane, Cliff (NIH/NIAID) [E]" <clane@niaid.nih.gov>, "Rom, Colin (FDA/OC)" <Colin.Rom@fda.hhs.gov>, "McGowan, Robert (Kyle) (CDC/OD/OCS)" <omc2@cdc.gov>
Subject: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

Per Dr. Hahn, V6 attached for FINAL approval. Please REPLY ALL with affirmative clearance.

Sincerely,
TAM

Tyler Ann McGuffee
 Assistant to Ambassador Birx, M.D.
 Office of the White House Coronavirus Response Coordinator
 Associate Advisor to the Office of the Vice President
 C: ((b) (6)) [no text]

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Sent: Friday, March 20, 2020 7:47 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Lane, Cliff (NIH/NIAID) [E] ((b) (6))niaid.nih.gov>; McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>
Subject: RE: Treatment Document

Sounds good to me.
Thanks,

Tony

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

Sent: Friday, March 20, 2020 7:36 PM

To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>

Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; tyler.a.mcguffee2@ovp.eop.gov; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>

Subject: Re: Treatment Document

Tony,

(b) (5)

Steve

Sent from my iPad

On Mar 20, 2020, at 7:06 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

I have a couple of comments

(b) (5)

I'll await for other comments.

Thanks

Steve

Sent from my iPad

On Mar 20, 2020, at 6:45 PM, Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov> wrote:

Team:

As per my discussion with Steve a few minutes ago, I have made some changes in the document. (b) (5)

I am attaching a tracked version of the document that was your FINAL as well as a clean copy with all of the changes accepted. Please take a look and Steve said that he would like to set up a quick call to discuss after you have had a look. I am very sorry to come in with these changes at this late point, but I really did not get a chance to have a good look at the document as I was in a car.

Thanks,

Tony

Anthony S. Fauci, MD

Director

National Institute of Allergy and Infectious Diseases

(b) (6)

National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6) [niaid.nih.gov](mailto:(b) (6)niaid.nih.gov)

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<dbInformation for Clinicians on COVID-19 Therapies31hcl - with Fauci and Lane tracked changes showing.docx>
<dbInformation for Clinicians on COVID-19 Therapies31hcl - with Fauci and Lane tracked Clean copy.docx>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/15/2020 1:56:34 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Quick description of our app
Attachments: COVID Tech-enabled solutions.pdf

(b) (5)

From: Kratsios, Michael J. EOP/OSTP (b) (6)@ostp.eop.gov>
Date: April 15, 2020 at 8:52:58 AM EDT
To: Liddell, Christopher P. EOP/WHO <(b) (6)who.eop.gov>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Kushner, Jared C. EOP/WHO <jck@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Seema Verma <sv1@cms.hhs.gov>, Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>, Tromberg, Bruce J (NIH) <bruce.tromberg@nih.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>, Butterfield, Nicholas W. EOP/WHO (b) (6)@who.eop.gov>, Droegemeier, Kelvin K. EOP/OSTP (b) (6)ostp.eop.gov>
Subject: RE: Quick description of our app

Hi All – attached is a summary slide of six categories of COVID-related tech-solutions/apps we've identified. Each solution presents unique and important privacy considerations. (b) (5).

Thanks,
Michael

From: Liddell, Christopher P. EOP/WHO <(b) (6)who.eop.gov>
Sent: Tuesday, April 14, 2020 5:05 PM
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Kratsios, Michael J. EOP/OSTP <Michael.J.Kratsios@ostp.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Kushner, Jared C. EOP/WHO <jck@who.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Seema Verma <sv1@cms.hhs.gov>; Sharpless, Norman (NIH/NCI) [E] <norman.sharpless@nih.gov>; Tromberg, Bruce (NIH/NIBIB) [E] <bruce.tromberg@nih.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; Butterfield, Nicholas W. EOP/WHO (b) (6)@who.eop.gov>; Droegemeier, Kelvin K. EOP/OSTP (b) (6)@ostp.eop.gov>
Subject: RE: Quick description of our app

+ Michael Kratsios (CTO)

(b) (5)

If anyone on this string could help him with the inventory, please just email him directly

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Sent: Monday, April 13, 2020 10:12 PM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Kushner, Jared C.

EOP/WHO <jck@who.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Seema Verma <sv1@cms.hhs.gov>; Sharpless, Norman (NIH/NCI) [E] <norman.sharpless@nih.gov>; Tromberg, Bruce (NIH/NIBIB) [E] <bruce.tromberg@nih.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; Liddell, Christopher P. EOP/WHO <(b) (6) l@who.eop.gov>

Subject: Re: Quick description of our app

Let's do it. Chris Liddell is working with a number tech companies on response

Sent from my iPhone

On Apr 13, 2020, at 10:08 PM, Fauci, Anthony (NIH/NIAID) [E] <(b) (6) niaid.nih.gov> wrote:

Steve:

NIH (Sharpless and Tromberg) have an app that we should have presented to a subset of the Task Force.

Best,

Tony

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

Sent: Monday, April 13, 2020 2:17 PM

To: Debi Birx MD <Deborah.L.Birx@nsc.eop.gov>; Jared Kushner <Jck@who.eop.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6) niaid.nih.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Joe Grogan <Joseph.J.Grogan@who.eop.gov>; Seema Verma <sv1@cms.hhs.gov>

Subject: Fwd: Quick description of our app

Is this something we have an interest in?

Steve

Sent from my iPhone

Begin forwarded message:

From: Bob Jackson <bjackson@deerfield.com>

Date: April 13, 2020 at 12:51:47 PM EDT

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

Cc: Bob Jackson <bjackson@deerfield.com>

Subject: Quick description of our app

Thanks Dr. Hahn – below are very quick thoughts and I am working to get your more visual material for your discussion-slides in a couple minutes

(b) (4)

(b) (4)

Robert Jackson, MD
Chief Science Officer
Deerfield Management
347-439-0441

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/7/2020 9:47:20 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Serology Surveillance

Do we have a list of these groups who have developed LDT serology tests already?

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 1, 2020 at 11:57:57 AM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Watson, Ian D. EOP/OSTP (b) (6)@ostp.eop.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Serology Surveillance

Brett

(b) (5)

From: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>
Date: Wednesday, April 1, 2020 at 11:24 AM
To: "Watson, Ian D. EOP/OSTP" <Ian.D.Watson@ostp.eop.gov>
Cc: "Beckham, Tammy (HHS/OASH)" <Tammy.Beckham@hhs.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Subject: RE: Serology Surveillance

Ian,

(b) (5)

BG

From: Watson, Ian D. EOP/OSTP (b) (6)@ostp.eop.gov>
Sent: Wednesday, April 1, 2020 11:03 AM
To: Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>
Subject: Serology Surveillance

Tammy/Chris, I hope you two are doing well. I wanted to reach out because Dr. Birx has asked Dr. Droegemeier and OSTP to work with our academic partners regarding serological surveillance networks. I know that your new WG is focusing on getting folks back to work (b) (5)

(b) (5). Let me know if we can find some time for a quick call.

(b) (5)

Stay healthy.

Ian D. Watson
Assistant Director for Biotechnology & Biosecurity
Office of Science & Technology Policy
Office: EEOB 490

(b) (6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/6/2020 2:36:16 PM
To: Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: [REDACTED] (b) (5)

[REDACTED] (b) (5)

Thanks
S

From: Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>
Date: April 5, 2020 at 8:54:18 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: [REDACTED] (b) (5)

[REDACTED] (b) (5)

Olivia Troye
Special Advisor for Homeland Security and Counterterrorism
Office of the Vice President
White House Coronavirus Task Force
Office: (202) 456-2641
Mobile: [REDACTED] (b) (6) (Does not receive texts)

Begin forwarded message:

From: "Heck, Mia (HHS/OASH)" <Mia.Heck@hhs.gov>
Date: April 5, 2020 at 7:39:45 PM EDT
To: "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>
Cc: "Arbes, Sarah (HHS/ASL)" <Sarah.Arbes@hhs.gov>, "Overton, Heidi N. EOP/WHO" [REDACTED] (b) (6)@who.eop.gov>, "Heighberger, Eric (fema.dhs.gov)" [REDACTED] (b) (6)@fema.dhs.gov>, "Greenberg, Jeremy (fema.dhs.gov)" [REDACTED] (b) (6)@fema.dhs.gov>, "Ramsay, Cindy" [REDACTED] (b) (6)y@fema.dhs.gov>, "Harper, Jay (fema.dhs.gov)" [REDACTED] (b) (6)@fema.dhs.gov>, [REDACTED] (b) (6)@fema.dhs.gov" [REDACTED] (b) (6)@fema.dhs.gov>, "Tagliento, Marc" [REDACTED] (b) (6)@fema.dhs.gov>, "McMillin, Virginia D. EOP/WHO" [REDACTED] (b) (6)@who.eop.gov>, "Pratt, Michael (OS/ASPA)" <Michael.Pratt@hhs.gov>, "Fulmer, Brendan (HHS/IOS)" <Brendan.Fulmer@hhs.gov>, "Schwartz, Erica (HHS/OASH)" <Erica.Schwartz@hhs.gov>, "Nalepa, Jessica (fema.dhs.gov)" <jessica.nalepa@fema.dhs.gov>, "Ditto, Jessica E. EOP/WHO" [REDACTED] (b) (6)@who.eop.gov>, "Miller, Katie R. EOP/OVP" <Katie.R.Miller@ovp.eop.gov>, "O'Malley, Devin M. EOP/OVP" <Devin.M.O'Malley@ovp.eop.gov>, "Troye, Olivia EOP/NSC" <Olivia.Troye@nsc.eop.gov>, "Smith, Brad (CMS/OA)" <Brad.Smith@cms.hhs.gov>, "Sartin, Shannon (CMS/OA)" <Shannon.Sartin@cms.hhs.gov>, "Broido, Tara (HHS/OASH)" <Tara.Broido@hhs.gov>, "Aikin, Ann (OS/OASH)" <Ann.Aikin@hhs.gov>, "Haigwood, Patricia (HHS/OASH)" <Patricia.Haigwood@hhs.gov>, "Richardson, Yasamie (fema.dhs.gov)" [REDACTED] (b) (6)@fema.dhs.gov>, "Migliaccio-Grabill, Kate (HHS/OASH)" <Kate.Migliaccio-Grabill@hhs.gov>, "Cox, Jordan (HHS/ASL)" <Jordan.Cox@hhs.gov>, "Crawford, Sean (DHS.GOV)" [REDACTED] (b) (6)@fema.dhs.gov>, "Alpern, Ethan" [REDACTED] (b) (6)@fema.dhs.gov>, "Hurley, Carolina L. EOP/WHO" [REDACTED] (b) (6)@who.eop.gov>,"

"Stainsby, Leiloni" <Leiloni.Stainsby@fema.dhs.gov>, "Hoffman, Peter D. EOP/WHO" (b) (6)@who.eop.gov>, "Horstman, John H. EOP/WHO" (b) (6)@who.eop.gov>, "Murphy, Ryan (OS/ASPA)" <Ryan.Murphy1@hhs.gov>, "Oakley, Caitlin B. (OS/ASPA)" <Caitlin.Oakley@HHS.GOV>, "McKeogh, Katherine (OS/ASPA)" <Katherine.McKeogh@hhs.gov>, "Shuy, Caitrin (HHS/ASFR)" <Caitrin.Shuy@hhs.gov>, "Pinson, Alexander (HHS/ASFR)" <Alexander.Pinson@hhs.gov>, "Montesi, Janet" <janet.montesi@fema.dhs.gov>, "Johnston, Darcie (HHS/IEA)" <Darcie.Johnston@hhs.gov>, "Stevens, Lee (OS/IEA)" <Lee.Stevens@hhs.gov>, "Baker, Michael (OS/IEA)" <Michael.Baker@hhs.gov>, "Haddad, Carla (HHS/OASH)" <Carla.Haddad@hhs.gov>, "Planning, David M. EOP/WHO" (b) (6)@who.eop.gov>, "Hodgson, Christopher M. EOP/OVP" (b) (6)@ovp.eop.gov>, "Morse, Sara (HHS/ASL)" <Sara.Morse@hhs.gov>, "Mango, Paul (HHS/IOS)" <Paul.Mango@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Tignor, Beth (HHS/IOS)" <Beth.Tignor@hhs.gov>, "Puesan, Cesar (HHS/OS/IOS)" <Cesar.Puesan@hhs.gov>
Subject: Re: (b) (5)

Let me confirm and will circle back with you on separate thread.

Sent from my iPhone

On Apr 5, 2020, at 7:38 PM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov> wrote:

Mia,

Has Adm Giroir briefed S1 on this yet? If not we need to schedule ASAP and Beth can connect with Adm Giroir team and Cesar will get materials.

Judy

Sent from my iPhone

On Apr 5, 2020, at 7:30 PM, Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov> wrote:

+ a few other leg affairs

From: Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>

Sent: Sunday, April 5, 2020 7:18 PM

To: Overton, Heidi N. EOP/WHO (b) (6)@who.eop.gov>; Heighberger, Eric (fema.dhs.gov) (b) (6)@fema.dhs.gov>; Greenberg, Jeremy (fema.dhs.gov) <(b) (6)@fema.dhs.gov>; Ramsay, Cindy (b) (6)@fema.dhs.gov>; Harper, Jay (fema.dhs.gov) (b) (6)@fema.dhs.gov>; (b) (6)@fema.dhs.gov; Tagliento, Marc (b) (6)@fema.dhs.gov>; Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; Fulmer, Brendan (HHS/IOS) <Brendan.Fulmer@hhs.gov>; Schwartz, Erica (HHS/OASH) <Erica.Schwartz@hhs.gov>; Nalepa, Jessica (fema.dhs.gov) (b) (6)@fema.dhs.gov>; Ditto, Jessica (who.eop.gov) (b) (6)@who.eop.gov>; Miller, Katie R. (ovp.eop.gov) <Katie.R.Miller@ovp.eop.gov>; Devin.M.O'Malley@ovp.eop.gov; Troye, Olivia (nsc.eop.gov) <Olivia.Troye@nsc.eop.gov>; Smith, Brad (CMS/OA) <Brad.Smith@cms.hhs.gov>; Sartin, Shannon (CMS/OA) <Shannon.Sartin@cms.hhs.gov>; Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>; Aikin, Ann (OS/OASH) <Ann.Aikin@hhs.gov>; Haigwood, Patricia (HHS/OASH) <Patricia.Haigwood@hhs.gov>; Richardson, Yasamie (fema.dhs.gov) (b) (6)@fema.dhs.gov>; Migliaccio-Grabill, Kate (HHS/OASH) <Kate.Migliaccio-Grabill@hhs.gov>; Cox, Jordan (HHS/ASL) <Jordan.Cox@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Crawford, Sean (DHS.GOV) (b) (6)@fema.dhs.gov>; Alpern, Ethan <ethan.alpern@fema.dhs.gov>; Hurley, Carolina L. EOP/WHO (b) (6)@who.eop.gov>; Stainsby, Leiloni

<Leiloni.Stainsby@fema.dhs.gov>; Hoffman, Peter D. EOP/WHO (b) (6)@who.eop.gov>; Horstman, John H. EOP/WHO (b) (6)@who.eop.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>; Montesi, Janet (b) (6)@fema.dhs.gov>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Stevens, Lee (OS/IEA) <Lee.Stevens@hhs.gov>; Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Haddad, Carla (HHS/OASH) <Carla.Haddad@hhs.gov>

Subject: Testing Partnership Expansion Soft/Pre Launch

Hi everyone,

Hope you are well. (b) (5)

(b) (5)

Please let us know if you have suggestions/changes to this plan or have edits to the reactive statement.

Mia

Mia Palmieri Heck
Director of External Affairs
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
(202) 578-6071

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 (b) (6) cms.hhs.gov]; Good-Cohn, Meredith (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e06154b83bb4cb8a7b01816905e1300-HHS-Meredit]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Debi Birx [Deborah.L.Birx@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-(b) (6) Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-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 (b) (6) 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 <Deborah.L.Birx@nsc.eop.gov>, Giroir, Brett (OS) <Brett.Giroir@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

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 <Deborah.L.Birx@nsc.eop.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6) niaid.nih.gov>; Joe Grogan <Joseph.J.Grogan@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 (b) (6) 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 <Deborah.L.Birx@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 <Joseph.J.Grogan@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

good point, Jerome. NIH/CDC are validating some tests and the commercial manufacturers intend to go through the EUA process so we'll definitely have insight into the operating characteristics of those commercial tests. (b) (5)

Steve

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 <Deborah.L.Birx@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

A little more context (perhaps) on point 2- I heard from my conversation with state health officers last night that there are some concerns about the sensitivity and specificity of the serology tests, and implications of letting people back to work and then finding out the test was inaccurate. (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 <Deborah.L.Birx@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 <Joseph.J.Grogan@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.

(b) (5)

Best
Steve

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 3/21/2020 6:25:36 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: slight revisions for re-clearance

There is still a yellow text area. [REDACTED] (b) (5):.

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Saturday, March 21, 2020 at 6:23 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "McGuffee, Tyler A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: Fwd: slight revisions for re-clearance

[REDACTED] (b) (5)

From: Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>
Date: March 21, 2020 at 6:19:54 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: slight revisions for re-clearance

Commissioner Hahn,

I attached slight revisions to the previous document, highlighted in yellow. Feel free to suggest additional edits. The attached document can be re-cleared if you are okay with it. Feel free to call me if you have any questions (CDC cell phone: [REDACTED] (b) (6))

Thanks,
Tim

Tim Uyeki MD, MPH, MPP
CDC 2019 Novel Coronavirus Response
Clinical Team Lead
Chief Medical Officer, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Mailstop H24-7
1600 Clifton Road, N.E.
Atlanta, GA 30329
Email: tmu0@cdc.gov
Office phone: 404-639-0277
CDC Cell phone [REDACTED] (b) (6)

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 3/23/2020 9:27:03 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]
Subject: Re: Genentech and COVID-19

(b) (6)

Sent from my iPhone

On Mar 23, 2020, at 7:11 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Tony and Deb, (b) (5)

Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: March 22, 2020 at 6:44:52 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McGowan, Robert K (CDC) <omc2@cdc.gov>
Subject: RE: Genentech and COVID-19

In my opinion, (b) (5)

. I agree with Dr. Birx

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Sunday, March 22, 2020 6:38 PM
To: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>
Subject: Re: Genentech and COVID-19

(b) (5).

Sent from my iPhone

On Mar 22, 2020, at 6:37 PM, McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov> wrote:

Flagging – Genentech just followed with an advanced copy of a Genentech Press Release for 9:00am tomorrow morning acknowledging “FDA’s rapid approval of a clinical study for Actemra as well as recognizes our strong partnership with BARDA. It also announces our intention to provide 10,000 units of Actemra to the Strategic National Stockpile.

From: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>

Sent: Sunday, March 22, 2020 5:16 PM

To: Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>

Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>

Subject: Genentech and COVID-19

Dr. Hahn, Dr. Redfield, Dr. Fauci,

Per Dr. Birx – please see the highlighted note below from Dr. Birx.

Two attachments from Genentech are provided for additional context.

I am on standby, as always, and stand ready to help coordinate [REDACTED] (b) (5)
[REDACTED] Let me know how I can be helpful.

Sincerely,
TAM

Tyler Ann McGuffee
Assistant to Ambassador Birx, M.D.
Office of the White House Coronavirus Response Coordinator
Associate Advisor to the Office of the Vice President
C: (202) 881-8195 [no text]

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

Sent: Sunday, March 22, 2020 11:30 AM

To: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>

Subject: Fwd: [EXTERNAL] Fwd: Fwd: Genentech and COVID-19

[REDACTED] (b) (5)

Sent from my iPhone

Ambassador Birx, I look forward to connecting with you as soon as possible. As you know, Roche Diagnostics was in close contact with you as it relates to the EUA for fully automated SARS-CoV-2 molecular diagnostic. Additionally, I'd like to detail our extensive efforts to contribute to COVID-19 response, specifically relating to our medicine Actemra (tocilizimab).

Specifically, I would like to update you on:

- Our submission of an IND for a randomized controlled trial of Actemra (tocilizimab) in severely ill COVID-19 patients
- Our intent to donate 10,000 vials of Actemra to the Strategic National Stockpile for future use at the discretion of the USG
- Our experience globally in China, Italy, and other countries relating to the use and demand
- Our thinking around distribution of product to best ensure patient access

- Our initial thinking on key supply issues including increased global demand and our thinking around our domestic infrastructure

----- Forwarded message -----

From: Frederick Bittenbender <bittenbf@gene.com>
Date: Tuesday, March 17 2020 at 8:27 AM EDT
Subject: Fwd: Genentech and COVID-19
To: natsturner@gmail.com
Cc: Alexander Hardy <ahardy@gene.com>

Nat:

After much internal discussion, we finalized the attached memo. I sent this to Joe Grogan as he asked for something as well. This is ripe for the White House Coronavirus Task Force as there must be coordination across multiple agencies. Roche/Genentech stands ready to do everything we can to support the US Government's efforts during this pandemic. Both FDA and BARDA have been incredible partners to date. The 4,000 units is an initial donation to treat approximately 1,000-1250 patients. More supply will be donated if needed.

Let's discuss when you have a free moment.

Best

Fritz

Sent from my iPad

Begin forwarded message:

From: Fritz Bittenbender <bittenbf@gene.com>
Date: March 16, 2020 at 10:01:15 PM EDT
To: joseph.j.grogan@who.eop.gov
Cc: David Burt <burt.david@gene.com>
Subject: Genentech and COVID-19

Dear Joe:

Attached is the memo that we discussed. Genentech has had very productive on-going conversations with both FDA and BARDA regarding possible usage of Actemra to treat a sub-set of very ill COVID-19 patients.

- Genentech/Roche's priority is to conduct a randomized, controlled clinical trial to test the safety and efficacy of Actemra (tocilizumab) for the treatment of severely ill COVID-19 patients
- Toward this end, we are committed to working with the FDA, in collaboration with BARDA, to develop, enroll, and complete this clinical study as our first priority
- Separately, we seek to enter into an agreement with BARDA under our existing Other Transactions Authority (OTA) agreement that would allow for a donation of an initial 4000 vials of Actemra to the U.S.

government reserved for patient treatment outside of the clinical trial, only in the event of an escalating emergency, should physicians decide to prescribe this product off label.

- Under this agreement, Genentech would seek assistance from BARDA (and appropriate federal agencies) to develop and disseminate guidelines for appropriate clinical use and to coordinate with Genentech's distribution capabilities.

We stand ready to discuss this further at anytime.

Best regards,

Fritz Bittenbender

Senior Vice President
Genentech

<mime-attachment>

<2020-03-16_Genentech_WH Memo-Actemra-COVID-19_FINAL.docx>

<mime-attachment>

From: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Sent: 4/7/2020 1:27:33 PM
To: 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]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: [EXTERNAL] URgent RequestDiatherix Eurofins Inventory Needs- Laboratory Testing COVID-19

Thank you

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Tuesday, April 7, 2020 1:26 PM
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: [EXTERNAL] URgent RequestDiatherix Eurofins Inventory Needs- Laboratory Testing COVID-19

(b) (5)

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

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Sent: Tuesday, April 7, 2020 1:20 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: [EXTERNAL] URgent RequestDiatherix Eurofins Inventory Needs- Laboratory Testing COVID-19

Guys, see below.

From: Craig Deligdish <deligdishc@omnihealthcare.com>
Sent: Tuesday, April 7, 2020 1:11 PM
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Campana, Alexandra D. EOP/WHO <Alexandra.D.Campana2@who.eop.gov>
Subject: [EXTERNAL] URgent RequestDiatherix Eurofins Inventory Needs- Laboratory Testing COVID-19

Joe,

OMNI Healthcare, located in Melbourne, FL is testing upwards of 1,000 Floridians daily for Coronavirus, using five laboratories that have obtained EUA from the FDA. Our goal is to report these results within 24 hours. One of these labs is Diatherix located in Huntsville, AL and New York. OMNI has been sending specimens to this lab for two weeks. We have validated Diatherix's accuracy and turnaround time (**same day**)

and this has been further documented in the attached WSJ article published 4/2/20. I have been asked to reach out to you to assist in maintaining Diatherix' supply chain.

From March 16th through today, Diatherix, has result reported over (b) (4) COVID-19 results the same day as specimen receipt. This is due to that fact that Diatherix is a high throughput lab, servicing the US, with capabilities to receive and report on the same day up to 5000 specimens. Diatherix has over 10,000 unique physicians and 2000 individual hospitals or physician offices that have ordered this year. So far, they been able to provide the necessary testing supplies (swabs and tubes) as well as run the specimens in the lab without issues. They want to avoid an interruption of service through securing our most significant supply chain issues.

Like many healthcare companies and laboratories, Diatherix has entered a period of concern that could halt its COVID testing directly as a result of the inability to obtain key products. They have worked hard to find alternate solutions, each of which have to be evaluated and validated within the process to ensure accurate results. There are several that continue to provide concern, and they need help to protect their supply chains from those that seek to over-order and hoard these products. These needs include primers, reagents, plates, transport media, swabs and the other supplies necessary to support testing.

(b) (4)

Please let me know what information we can provide to help secure these products so that may continue to service the Floridians.

Supplier	Catalog #	Description	Quantity on Reorder	UOM
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(b) (4)

If you need additional information, I would recommend contacting me directly anytime of the day or night or contacting Jennifer Care, the president of Diatherix directly. Her contact information is below.

Craig Deligdish, MD
Associate Professor of Medicine
University of Central Florida College of Medicine
Medical Director
Parrish Cancer Center-A Member of the Mayo Clinic Network
President
OMNI Healthcare
1344 South Apollo Blvd.
Melbourne, FL 32901

>><https://protect2.fireeye.com/url?k=3b114985-67444096-3b1178ba-0cc47adb5650-4d07524037ac49b4&u=http://www.omnihealthcare.com/><<

Tel: 321-727-3495

Cell: 321-223-3196

Jennifer Cart
President
Diatherix Eurofins
601 Genome Way, Suite 2100
Huntsville, AL 35806
United States
Cell: (b) (6)
Lab: 866.979.4242

Email: JenniferCart@eurofinsus.com

Website: >><https://protect2.fireeye.com/url?k=d2cab705-8e9fbe16-d2ca863a-0cc47adb5650-99c716310e4e5a3f&u=http://www.eurofins-diatherix.com/><<

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From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 4/1/2020 9:02:50 PM
To: CMS SV1 [SV1@cms.hhs.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffb983419fcd-HHS-olx1-cd]
CC: Campana, Alexandra D. EOP/WHO [Alexandra.D.Campana2@who.eop.gov]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Bonner, Maria K. EOP/WHO (b) (5)@who.eop.gov
Subject: Re: [EXTERNAL] Timely Request ID Now

(b) (5)

tracing. Deb

From: CMS SV1 <SV1@cms.hhs.gov>
Date: Wednesday, April 1, 2020 at 7:26 PM
To: "Grogan, Joseph J. EOP/WHO" <Joseph.J.Grogan@who.eop.gov>, Stephen Hahn <SH1@fda.hhs.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>
Cc: "Campana, Alexandra D. EOP/WHO" <Alexandra.D.Campana2@who.eop.gov>, "Brookes, Brady (CMS/OA)" <Brady.Brookes@cms.hhs.gov>, "Bonner, Maria K. EOP/WHO" <Maria.K.Bonner@who.eop.gov>
Subject: RE: [EXTERNAL] Timely Request ID Now

(b) (5)

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Sent: Wednesday, April 1, 2020 7:19 PM
To: CMS SV1 <SV1@cms.hhs.gov>; Stephen Hahn <SH1@fda.hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Cc: Campana, Alexandra D. EOP/WHO <Alexandra.D.Campana2@who.eop.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>; Bonner, Maria K. EOP/WHO <Maria.K.Bonner@who.eop.gov>
Subject: Fwd: [EXTERNAL] Timely Request ID Now

(b) (5)

Sent from my iPhone

Begin forwarded message:

From: "Foltz, Nicole" <nicole.foltz@abbott.com>
Date: April 1, 2020 at 6:17:18 PM EDT
To: "Grogan, Joseph J. EOP/WHO" <Joseph.J.Grogan@who.eop.gov>
Subject: [EXTERNAL] Timely Request ID Now

Hi Joe,

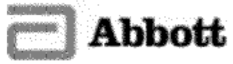
Thank your offering to help. Abbott has started shipping the 5-minute COVID tests around the country. But we are hearing from states and health care providers that CMS guidance on COVID testing is ambiguous as to whether the test can be used outside the hospital or core laboratory (i.e. drive-through testing, outpatient clinics, etc.). They've said they

cannot test in these settings under current guidance. States and providers need clarification that the ID NOW test is waived and can be used in these settings. Can you help us get that clarification so they can start testing?

Thank you for all of your work.

Nicole

202.717.7370



Nicole Foltz
Senior Director
Federal Government Affairs

Abbott
1399 New York Ave. NW
Suite 200
Washington, DC 20005

O: 202-378-2020
F: 202-783-6631
M: 202.717.7370
nicole.foltz@abbott.com

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From: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Sent: 4/4/2020 8:52:13 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: Hydroxychloroquine

Yes 5 minutes

Sent from my iPhone

On Apr 4, 2020, at 8:42 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Joe,
FYI. Do you have time for a call this morning?
Steve

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHPSE) <zud4@cdc.gov>
Date: April 3, 2020 at 5:15:31 PM EDT
To: Schuchat, Anne (CDC) <acs1@cdc.gov>, Messonnier, Nancy E (CDC) <nar5@cdc.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Brooks, John T (CDC) <zud4@cdc.gov>
Subject: RE: Hydroxychloroquine

Afternoon all,

Studies described in the attached

Dosing in each as follows:

(b) (5)

Cheers,

-john

John T. Brooks, MD
Chief Medical Officer, CDC COVID-19 Response
Email: zud4@cdc.gov

Apologies for errors in my messages that may be due to my need to dictate.

<image002.jpg>

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Sent: Friday, April 3, 2020 5:04 PM
To: Brooks, John T. (CDC/DDID/NCHHSTP/DHPSE) <zud4@cdc.gov>
Subject: RE: Hydroxychloroquine

(b) (5)

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHPSE) <zud4@cdc.gov>
Sent: Friday, April 3, 2020 5:02 PM
To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Subject: RE: Hydroxychloroquine

(b) (5)

John T. Brooks, MD
Chief Medical Officer, CDC COVID-19 Response
Email: zud4@cdc.gov

Apologies for errors in my messages that may be due to my need to dictate.

<image006.jpg>

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Sent: Friday, April 3, 2020 5:00 PM
To: Brooks, John T. (CDC/DDID/NCHHSTP/DHPSE) <zud4@cdc.gov>
Subject: FW: Hydroxychloroquine

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, April 3, 2020 4:59 PM
To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Hydroxychloroquine

(b) (5)

Can I get help from CDC?

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, April 3, 2020 4:54 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Hydroxychloroquine

Think CDC would have to give you that, since this would be considered off label use.

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, April 3, 2020 4:37 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Hydroxychloroquine

(b) (5)

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

<COVID-19 Science Update - Special Topic CQ-HCQ - 2020-04-03 - FINAL.pdf>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/27/2020 9:53:25 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; 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=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]
Subject: Re: Testing Strategy

My edits are within the document that was attached . If you need me to send again, please let me know

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 27, 2020 at 9:50:35 AM EDT
To: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: Testing Strategy

Steve and Bob – can you quickly review – I need to send to Governors. Deb

From: "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>
Date: Monday, April 27, 2020 at 9:07 AM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>
Subject: RE: Testing Strategy

See my tracked edits in the attached document. Thanks.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

(b) (6)
National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)niaid.nih.gov

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From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Monday, April 27, 2020 7:53 AM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Subject: FW: Testing Strategy

Please review redline word document. I did not participate in the PPT. Deb

From: "Lyons, Derek S. EOP/WHO" (b) (6)@who.eop.gov>
Date: Sunday, April 26, 2020 at 8:06 PM
To: "Meadows, Mark R. EOP/WHO" (b) (6)@who.eop.gov>, "Kushner, Jared C. EOP/WHO" <jck@who.eop.gov>, "Hicks, Hope C. EOP/WHO" <Hope@who.eop.gov>, "Gilmartin, Kayleigh M. EOP/WHO" <Kayleigh.McEnany@who.eop.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Boehler, Adam" <Adam.Boehler@dfc.gov>, "Short, Marc T. EOP/OVP" <Marc.T.Short@ovp.eop.gov>, "Farah, Alyssa A. EOP/WHO" (b) (6)@who.eop.gov>, "Liddell, Christopher P. EOP/WHO" <(b) (6)who.eop.gov>, "Philbin, Patrick F. EOP/WHO" (b) (6)@who.eop.gov>, "Vought, Russell T. EOP/OMB" (b) (6)@omb.eop.gov>
Cc: "Kan, Derek T. EOP/OMB" (b) (6)@omb.eop.gov>, "brad.smith@cms.hhs.gov" <brad.smith@cms.hhs.gov>, "Rader, John N. EOP/NSC" (b) (6)@nsc.eop.gov>, "Storch, Thomas H. EOP/NSC" (b) (6)@nsc.eop.gov>, "Rinat, Ory S. EOP/WHO" (b) (6)who.eop.gov>, "Butterfield, Nicholas W. EOP/WHO" (b) (6)@who.eop.gov>, "Dumbauld, Cassidy M. EOP/WHO" (b) (6)@who.eop.gov>, "Miller, Ovp" <Katie.R.Miller@ovp.eop.gov>, "Keller, Catherine B. EOP/WHO" (b) (6)@who.eop.gov>, "Porter, Madison F. EOP/WHO" (b) (6)@who.eop.gov>
Subject: RE: Testing Strategy

All – Once again, thanks for your input. I've attached the latest documents. We had to implement quite a few comments from the last versions, particularly on the Word Document. My hope is that the changes did not affect the substance, but I've attached a redline for those who might need it. Please review and send any RED FLAGS no later than 700 am tomorrow.

Thanks,
Derek

From: Lyons, Derek S. EOP/WHO
Sent: Saturday, April 25, 2020 7:16 PM
To: Meadows, Mark R. EOP/WHO (b) (6)@who.eop.gov>; Kushner, Jared C. EOP/WHO <jck@who.eop.gov>; Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>; Gilmartin, Kayleigh M. EOP/WHO <Kayleigh.McEnany@who.eop.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; 'Boehler, Adam' <Adam.Boehler@dfc.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Farah, Alyssa A. EOP/WHO (b) (6)@who.eop.gov>; Liddell, Christopher P. EOP/WHO <(b) (6)who.eop.gov>; Philbin, Patrick F. EOP/WHO (b) (6)@who.eop.gov>
Cc: Kan, Derek T. EOP/OMB (b) (6)@omb.eop.gov>; 'brad.smith@cms.hhs.gov' <brad.smith@cms.hhs.gov>; Rader, John N. EOP/NSC (b) (6)@nsc.eop.gov>; Storch, Thomas H. EOP/NSC (b) (6)h@nsc.eop.gov>; Rinat, Ory S. EOP/WHO (b) (6)@who.eop.gov>; Butterfield, Nicholas W. EOP/WHO (b) (6)@who.eop.gov>; Dumbauld, Cassidy M. EOP/WHO (b) (6)@who.eop.gov>
Subject: RE: Testing Strategy

All – Thank you for your input over the past few days. Please find revised documents attached. We are still working on formatting, but the language should be firming up. Please let me know if you have additional comments or edits.

I've added Pat Philbin to this chain for legal review.

Derek

From: Lyons, Derek S. EOP/WHO
Sent: Friday, April 24, 2020 7:59 PM
To: Meadows, Mark R. EOP/WHO (b) (6)who.eop.gov>; Kushner, Jared C. EOP/WHO <jck@who.eop.gov>; Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>; Gilmartin, Kayleigh M. EOP/WHO <Kayleigh.McEnany@who.eop.gov>; Birx,

Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Boehler, Adam <Adam.Boehler@dfc.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Farah, Alyssa A. EOP/WHO (b) (6)h@who.eop.gov>; Liddell, Christopher P. EOP/WHO <(b) (6)who.eop.gov>
Cc: Kan, Derek T. EOP/OMB (b) (6)@omb.eop.gov>; 'brad.smith@cms.hhs.gov' <brad.smith@cms.hhs.gov>; Rader, John N. EOP/NSC (b) (6)@nsc.eop.gov>; Storch, Thomas H. EOP/NSC (b) (6)@nsc.eop.gov>; Rinat, Ory S. EOP/WHO (b) (6)@who.eop.gov>; Butterfield, Nicholas W. EOP/WHO (b) (6)@who.eop.gov>; Dumbauld, Cassidy M. EOP/WHO (b) (6)@who.eop.gov>

Subject: Testing Strategy

All –

Please see the latest iteration of the testing documents for Monday. If possible, I would appreciate any comments/concerns about noon tomorrow so we can continue to progress. In addition to content, I believe we still need to do the following:

(b) (5)

Derek

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/27/2020 9:52:24 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS (b) (6)]
Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Tyler Ann McGuffee [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: Testing Strategy

I sent my comments at 8:30 am and then also sent to Tyler. Received?

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 27, 2020 at 9:50:35 AM EDT
To: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: Testing Strategy

Steve and Bob – (b) (6) Deb

From: "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>
Date: Monday, April 27, 2020 at 9:07 AM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>
Subject: RE: Testing Strategy

See my tracked edits in the attached document. Thanks.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

(b) (6)
National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)niaid.nih.gov

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From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Monday, April 27, 2020 7:53 AM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Subject: FW: Testing Strategy

Please review redline word document. I did not participate in the PPT. Deb

From: "Lyons, Derek S. EOP/WHO" <(b) (6)@who.eop.gov>
Date: Sunday, April 26, 2020 at 8:06 PM
To: "Meadows, Mark R. EOP/WHO" <(b) (6)@who.eop.gov>, "Kushner, Jared C. EOP/WHO" <jck@who.eop.gov>, "Hicks, Hope C. EOP/WHO" <Hope@who.eop.gov>, "Gilmartin, Kayleigh M. EOP/WHO" <Kayleigh.McEnany@who.eop.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Boehler, Adam" <Adam.Boehler@dfc.gov>, "Short, Marc T. EOP/OVP" <Marc.T.Short@ovp.eop.gov>, "Farah, Alyssa A. EOP/WHO" <Alyssa.A.Farah@who.eop.gov>, "Liddell, Christopher P. EOP/WHO" <(b) (6)@who.eop.gov>, "Philbin, Patrick F. EOP/WHO" <(b) (6)@who.eop.gov>, "Vought, Russell T. EOP/OMB" <(b) (6)@omb.eop.gov>
Cc: "Kan, Derek T. EOP/OMB" <(b) (6)@omb.eop.gov>, "brad.smith@cms.hhs.gov" <brad.smith@cms.hhs.gov>, "Rader, John N. EOP/NSC" <(b) (6)nsc.eop.gov>, "Storch, Thomas H. EOP/NSC" <(b) (6)@nsc.eop.gov>, "Rinat, Ory S. EOP/WHO" <(b) (6)who.eop.gov>, "Butterfield, Nicholas W. EOP/WHO" <(b) (6)@who.eop.gov>, "Dumbauld, Cassidy M. EOP/WHO" <(b) (6)@who.eop.gov>, "Miller, Ovp" <Katie.R.Miller@ovp.eop.gov>, "Keller, Catherine B. EOP/WHO" <(b) (6)@who.eop.gov>, "Porter, Madison F. EOP/WHO" <(b) (6)@who.eop.gov>
Subject: RE: Testing Strategy

All – Once again, thanks for your input. I've attached the latest documents. We had to implement quite a few comments from the last versions, particularly on the Word Document. My hope is that the changes did not affect the substance, but I've attached a redline for those who might need it. Please review and send any RED FLAGS no later than 700 am tomorrow.

Thanks,
Derek

From: Lyons, Derek S. EOP/WHO
Sent: Saturday, April 25, 2020 7:16 PM
To: Meadows, Mark R. EOP/WHO <(b) (6)@who.eop.gov>; Kushner, Jared C. EOP/WHO <jck@who.eop.gov>; Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>; Gilmartin, Kayleigh M. EOP/WHO <Kayleigh.McEnany@who.eop.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; 'Boehler, Adam' <Adam.Boehler@dfc.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Farah, Alyssa A. EOP/WHO <(b) (6)who.eop.gov>; Liddell, Christopher P. EOP/WHO <(b) (6)who.eop.gov>; Philbin, Patrick F. EOP/WHO <(b) (6)who.eop.gov>
Cc: Kan, Derek T. EOP/OMB <(b) (6)@omb.eop.gov>; 'brad.smith@cms.hhs.gov' <brad.smith@cms.hhs.gov>; Rader, John N. EOP/NSC <(b) (6)@nsc.eop.gov>; Storch, Thomas H. EOP/NSC <(b) (6)@nsc.eop.gov>; Rinat, Ory S. EOP/WHO <(b) (6)@who.eop.gov>; Butterfield, Nicholas W. EOP/WHO <(b) (6)@who.eop.gov>; Dumbauld, Cassidy M. EOP/WHO <(b) (6)@who.eop.gov>
Subject: RE: Testing Strategy

All – Thank you for your input over the past few days. Please find revised documents attached. We are still working on formatting, but the language should be firming up. Please let me know if you have additional comments or edits.

I've added Pat Philbin to this chain for legal review.

Derek

From: Lyons, Derek S. EOP/WHO
Sent: Friday, April 24, 2020 7:59 PM
To: Meadows, Mark R. EOP/WHO <(b) (6)@who.eop.gov>; Kushner, Jared C. EOP/WHO <jck@who.eop.gov>; Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>; Gilmartin, Kayleigh M. EOP/WHO <Kayleigh.McEnany@who.eop.gov>; Birx,

Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Boehler, Adam <Adam.Boehler@dfc.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Farah, Alyssa A. EOP/WHO (b) (6)@who.eop.gov>; Liddell, Christopher P. EOP/WHO <(b) (6)@who.eop.gov>
Cc: Kan, Derek T. EOP/OMB (b) (6)@omb.eop.gov>; 'brad.smith@cms.hhs.gov' <brad.smith@cms.hhs.gov>; Rader, John N. EOP/NSC (b) (6)@nsc.eop.gov>; Storch, Thomas H. EOP/NSC (b) (6)@nsc.eop.gov>; Rinat, Ory S. EOP/WHO (b) (6)@who.eop.gov>; Butterfield, Nicholas W. EOP/WHO (b) (6)@who.eop.gov>; Dumbauld, Cassidy M. EOP/WHO (b) (6)@who.eop.gov>

Subject: Testing Strategy

All –

Please see the latest iteration of the testing documents for Monday. If possible, I would appreciate any comments/concerns about noon tomorrow so we can continue to progress. In addition to content, I believe we still need to do the following:

(b) (5)

Derek

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/3/2020 9:00:58 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]
Subject: RE: New Understanding of Covid Infection

Totally agree. Look forward to it.
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: May 2, 2020 at 9:56:49 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: RE: New Understanding of Covid Infection

Amen.

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

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Saturday, May 2, 2020 8:02 PM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Subject: Re: New Understanding of Covid Infection

Absolutely. (b) (5)

Sent from my iPhone

> On May 2, 2020, at 8:00 PM, Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov> wrote:

>
> We should discuss all of this on Monday

> -----Original Message-----

> **From:** Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
> **Sent:** Saturday, May 2, 2020 7:05 PM
> **To:** Hahn, Stephen <SH1@fda.hhs.gov>
> **Cc:** Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
> **Subject:** Re: New Understanding of Covid Infection

> Thank you. (b) (5).

> Sent from my iPhone

>> On May 2, 2020, at 6:59 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

>>
>>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/27/2020 11:37:30 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]
Subject: Re: Testing

(b) (5)

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 27, 2020 at 8:58:37 AM EDT
To: Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: Testing

(b) (5)

Sent from my iPhone

Begin forwarded message:

From: "Hicks, Hope C. EOP/WHO" <Hope@who.eop.gov>
Date: April 27, 2020 at 8:52:27 AM EDT
To: CMS SV1 <SV1@cms.hhs.gov>, "adam@dfc.gov" <adam@dfc.gov>, "Kushner, Jared C. EOP/WHO" <jck@who.eop.gov>, "Grogan, Joseph J. EOP/WHO" <Joseph.J.Grogan@who.eop.gov>, "Short, Marc T. EOP/OVP" <Marc.T.Short@ovp.eop.gov>, "Troye, Olivia EOP/NSC" <Olivia.Troye@nsc.eop.gov>, "Miller, Katie R. EOP/OVP" <Katie.R.Miller@ovp.eop.gov>
Cc: "Gilmartin, Kayleigh M. EOP/WHO" <Kayleigh.McEnany@who.eop.gov>, "Farah, Alyssa A. EOP/WHO" <(b) (6)@who.eop.gov>
Subject: RE: Testing

Thank you! Looping in K and A

From: CMS SV1 <(b) (6)@cms.hhs.gov>
Sent: Monday, April 27, 2020 8:51 AM
To: adam@dfc.gov; Kushner, Jared C. EOP/WHO <jck@who.eop.gov>; Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>; Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>; Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Subject: Testing

(b) (5)

(b) (5)

From: CMS (b) (6)@cms.hhs.gov
Sent: Sunday, April 26, 2020 10:40 PM
To: Bhat, Nisha (CMS/OA) <Nisha.Bhat@cms.hhs.gov>; Bell, Damian (CMS/OC) <Damian.Bell@cms.hhs.gov>
Cc: Good-Cohn, Meredith (CMS/OA) <Meredith.Good-Cohn@cms.hhs.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>
Subject: RE: IFC 2 Press call topper

Here are talkers. (b) (5)

From: Bhat, Nisha (CMS/OA) <Nisha.Bhat@cms.hhs.gov>
Sent: Sunday, April 26, 2020 10:31 PM
To: CMS (b) (6)@cms.hhs.gov>; Bell, Damian (CMS/OC) <Damian.Bell@cms.hhs.gov>
Cc: Good-Cohn, Meredith (CMS/OA) <Meredith.Good-Cohn@cms.hhs.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>
Subject: RE: IFC 2 Press call topper

Yes I'll confirm the FDA language, language in powerpoint and work with Damian on talkers.

From: CMS (b) (6)
Sent: Sunday, April 26, 2020 10:19 PM
To: Bhat, Nisha (CMS/OA) <Nisha.Bhat@cms.hhs.gov>; Bell, Damian (CMS/OC) <Damian.Bell@cms.hhs.gov>
Cc: Good-Cohn, Meredith (CMS/OA) <Meredith.Good-Cohn@cms.hhs.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>
Subject: RE: IFC 2 Press call topper

(b) (5), did you see Tom's email? Please review that document, its due at 8am. We just need a few lines here. The topper you did for me, (b) (5), the FDA issue is outstanding.

From: Bhat, Nisha (CMS/OA) <Nisha.Bhat@cms.hhs.gov>
Sent: Sunday, April 26, 2020 9:28 PM
To: CMS (b) (6)@cms.hhs.gov>; Bell, Damian (CMS/OC) <Damian.Bell@cms.hhs.gov>
Cc: Good-Cohn, Meredith (CMS/OA) <Meredith.Good-Cohn@cms.hhs.gov>; Brookes, Brady (CMS/OA)

<Brady.Brookes@cms.hhs.gov>

Subject: RE: IFC 2 Press call topper

Attached are additional information based on the discussion this afternoon. I've added another slide to describe the scenarios for (b) (5) and it's in a word format. I've updated the talkers (b) (5). CM has reviewed the language.

From: Bhat, Nisha (CMS/OA)

Sent: Sunday, April 26, 2020 1:10 PM

To: CMS (b) (6)@cms.hhs.gov; Bell, Damian (CMS/OC) <damian.bell@cms.hhs.gov>

Cc: Good-Cohn, Meredith (CMS/OA) <Meredith.Good-Cohn@cms.hhs.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>

Subject: RE: IFC 2 Press call topper

Attached talkers that have been reviewed by Damian and Chris. Also included the latest version of the (b) (6)

From: Bhat, Nisha (CMS/OA)

Sent: Sunday, April 26, 2020 11:26 AM

To: CMS (b) (6)@cms.hhs.gov; Bell, Damian (CMS/OC) <damian.bell@cms.hhs.gov>

Cc: Good-Cohn, Meredith (CMS/OA) <Meredith.Good-Cohn@cms.hhs.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>

Subject: RE: IFC 2 Press call topper

Yes, working on this and will send materials.

From: CMS SV1

Sent: Sunday, April 26, 2020 10:45 AM

To: Bell, Damian (CMS/OC) <Damian.Bell@cms.hhs.gov>

Cc: Bhat, Nisha (CMS/OA) <Nisha.Bhat@cms.hhs.gov>; Good-Cohn, Meredith (CMS/OA) <Meredith.Good-Cohn@cms.hhs.gov>

Subject: Re: IFC 2 Press call topper

Nisha, can I get pharmacy talkers ASAP. Also please resend the testing chart.

Sent from my iPhone

On Apr 25, 2020, at 10:25 PM, Bell, Damian (CMS/OC) <Damian.Bell@cms.hhs.gov> wrote:

Administrator –

Attached is a press call topper on IFC 2 for your review and feedback if you get a chance. Nisha and I worked with CM SMEs on this (b) (5)

. Thanks.

Damian

<IFC 2 Topper 04.25.20.docx>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/25/2020 12:43:34 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: If possible review with written responses by 1030 am

(b) (5)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 25, 2020 at 9:12:39 AM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Schuchat, Anne (CDC) <acs1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, CMS SV1 <SV1@cms.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Adams, Jerome (OS) <Jerome.Adams@hhs.gov>
Cc: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: Re: If possible review with written responses by 1030 am

(b) (5)

From: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>
Date: Saturday, April 25, 2020 at 9:09 AM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Schuchat, Anne MD (CDC/OD)" <acs1@cdc.gov>, "SH1 (fda.hhs.gov)" <SH1@fda.hhs.gov>, CMS SV1 <SV1@cms.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "Adams, Jerome (HHS/OASH)" <Jerome.Adams@hhs.gov>
Cc: "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: RE: If possible review with written responses by 1030 am

I really think this is excellent. Clearly outlines what has been done and the strategy going forward.

Although technical, I do think the appendix on predictive values is helpful and will assist the intelligent non-expert (and most clinicians) how this fits.

My only suggestion is about this part, which I suggest we keep general :

(b) (5)

Super great job and this is exciting.

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: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>

Sent: Saturday, April 25, 2020 8:20 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; CMS SV1 <SV1@cms.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>

Cc: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>

Subject: If possible review with written responses by 1030 am

Thank you

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/25/2020 12:26:09 PM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acsc1-cd]; CMS (b) (6) [(b) (6) cms.hhs.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]
CC: McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: If possible review with written responses by 1030 am

Debi,

Looks good to me too. (b) (5)?

Steve

(b) (5)

From: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Date: April 25, 2020 at 9:59:40 AM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Schuchat, Anne (CDC) <acs1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, CMS SV1 <SV1@cms.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>, Adams, Jerome (OS) <Jerome.Adams@hhs.gov>
Cc: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: Re: If possible review with written responses by 1030 am

Deb looks good

(b) (5)

Get [Outlook for iOS](#)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Saturday, April 25, 2020 9:12:25 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; CMS SV1 <SV1@cms.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>
Cc: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: Re: If possible review with written responses by 1030 am

(b) (5)

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

Date: Saturday, April 25, 2020 at 9:09 AM

To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Schuchat, Anne MD (CDC/OD)" <acs1@cdc.gov>, "SH1 (fda.hhs.gov)" <SH1@fda.hhs.gov>, CMS SV1 <SV1@cms.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "Adams, Jerome (HHS/OASH)" <Jerome.Adams@hhs.gov>

Cc: "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>

Subject: RE: If possible review with written responses by 1030 am

I really think this is excellent. Clearly outlines what has been done and the strategy going forward. Although technical, I do think the appendix on predictive values is helpful and will assist the intelligent non-expert (and most clinicians) how this fits.

My only suggestion is about this part, which I suggest we keep general :



(b) (5)

Super great job and this is exciting.

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: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>

Sent: Saturday, April 25, 2020 8:20 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; CMS SV1 <SV1@cms.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>

Cc: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>

Subject: If possible review with written responses by 1030 am

Thank you

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/21/2020 3:42:42 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: RE: Viral Clades Brufsky 42020 Accepted Final.pdf

Thanks, Tony. I'll be sending another article that is (b) (4) from the same US authors.
(b) (5)?
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: April 21, 2020 at 3:41:13 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: RE: Viral Clades Brufsky 42020 Accepted Final.pdf

A Chinese study is apparently finding the same thing. I will send now by another e-mail a commentary on the Chinese study that is not peer-reviewed yet.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

(b) (6)
National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)niaid.nih.gov

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From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Tuesday, April 21, 2020 3:34 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Subject: Re: Viral Clades Brufsky 42020 Accepted Final.pdf

Very – (b) (5)
Deb

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Tuesday, April 21, 2020 at 3:29 PM
To: "Fauci, Anthony S (NIH)" <(b) (6)niaid.nih.gov>, "Redfield, Robert R (CDC)" <olx1@cdc.gov>, "Birx,

Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>

Subject: Viral Clades Brufsky 42020 Accepted Final.pdf

Sorry for all of the emails [REDACTED] (b) (5).
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/27/2020 2:24:16 PM
To: Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; CMS (b) (6) [mailto:(b) (6)@cms.hhs.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Birx, Deborah L. EOP/NSC [mailto:Deborah.L.Birx@nsc.eop.gov]
CC: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Troye, Olivia (nsc.eop.gov) [mailto:Olivia.Troye@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Beckham, Tammy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]
Subject: RE: Comprehensive use of COVID tests

Thanks, Jay

From: Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov>
Date: May 27, 2020 at 1:57:58 PM EDT
To: CMS SV1 <SV1@cms.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>, Troye, Olivia (nsc.eop.gov) <Olivia.Troye@nsc.eop.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: Comprehensive use of COVID tests

FYSA to all—the attached draft was developed with CMS for (b) (6)

From: CMS SV1 <SV1@cms.hhs.gov>
Sent: Wednesday, May 27, 2020 10:50 AM
To: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov>
Cc: SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Troye, Olivia (nsc.eop.gov) <Olivia.Troye@nsc.eop.gov>
Subject: RE: Comprehensive use of COVID tests

Per question on CMS payment guidance, we are basing everything off on CDC documents to ensure alignment.

From: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Sent: Wednesday, May 27, 2020 9:09 AM
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov>
Cc: CMS SV1 <SV1@cms.hhs.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Troye, Olivia (nsc.eop.gov) <Olivia.Troye@nsc.eop.gov>
Subject: Re: Comprehensive use of COVID tests

Deb I apologize. I thought we were aligned . I take responsibility for timing of posting . Will double check through your Office in future. Cdc and FDA worked together I thought all were set to go .

Get Outlook for iOS

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Wednesday, May 27, 2020 8:21:31 AM
To: Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov>
Cc: CMS SV1 <SV1@cms.hhs.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <[\(b\)\(6\)@niaid.nih.gov](mailto:(b)(6)@niaid.nih.gov)>; Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>
Subject: Re: Comprehensive use of COVID tests

Just a quick aside Jay. [REDACTED] (b) (5)
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Deb

Sent from my iPhone

On May 26, 2020, at 10:11 PM, Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov> wrote:

Updates on the various documents/workstreams you have outlined below:

(b) (5)

I hope that is helpful for clarification.

From: CMS SV1 <SV1@cms.hhs.gov>
Sent: Tuesday, May 26, 2020 9:42 PM
To: SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov>
Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <[\(b\)\(6\)@niaid.nih.gov](mailto:(b)(6)@niaid.nih.gov)>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Troye, Olivia (nsc.eop.gov) <Olivia.Troye@nsc.eop.gov>
Subject: RE: Comprehensive use of COVID tests

I really liked this document and I think its important we get this out soon. This will be really helpful to Medicare and other health plans to figure out what they will cover (b) (5)

(b) (5)

The documents may overlap so just want to make we are all on the same page.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, May 26, 2020 4:18 PM
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov>
Cc: CMS (b) (6) <cms.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Troye, Olivia (nsc.eop.gov) <Olivia.Troye@nsc.eop.gov>
Subject: Re: Comprehensive use of COVID tests

Deb,
My comments
Glad to discuss further
Steve

From: Debi Birx <Deborah.L.Birx@nsc.eop.gov>
Date: Tuesday, May 26, 2020 at 9:13 AM
To: "Butler, Jay C (CDC)" <jcb3@cdc.gov>
Cc: Seema Verma <SV1@cms.hhs.gov>, Robert Redfield <olx1@cdc.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Tony Fauci <(b) (6)niaid.nih.gov>, Brett Giroir <Brett.Giroir@hhs.gov>, Marc Short <Marc.T.Short@ovp.eop.gov>, Olivia Troye <Olivia.Troye@nsc.eop.gov>
Subject: Comprehensive use of COVID tests

(b) (5)

Deb

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/18/2020 1:43:42 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Re: First attempt
Attachments: Comprehensive use of COVID - with Fauci suggested edits-SMH edits.docx

Great start. Thanks, Debi.

My comments attached. Happy to work more on this. Perhaps we need a working call?
Steve

From: Tony Fauci <(b) (6)niaid.nih.gov>
Date: Sunday, May 17, 2020 at 12:29 PM
To: Debi Birx <Deborah.L.Birx@nsc.eop.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Robert Redfield <olx1@cdc.gov>
Subject: RE: First attempt

A small start (see attached)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Sunday, May 17, 2020 8:41 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Subject: Re: First attempt

Sorry – its been a long morning

From: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Date: Sunday, May 17, 2020 at 8:40 AM
To: "Hahn, Stephen" <SH1@fda.hhs.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, Anthony S Fauci <(b) (6)niaid.nih.gov>
Subject: First attempt

(b) (5)

. Deb

From: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Sent: 5/27/2020 8:22:57 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; CMS (b) (6)@cms.hhs.gov; Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]
Subject: Re: Comprehensive use of COVID tests

That's a great idea Deb

From: Debi Birx <Deborah.L.Birx@nsc.eop.gov>
Date: Wednesday, May 27, 2020 at 8:01 AM
To: Stephen Hahn <(b) (6)@fda.hhs.gov>, Seema Verma <SV1@cms.hhs.gov>, "Butler, Jay C (CDC)" <jcb3@cdc.gov>
Cc: Robert Redfield <olx1@cdc.gov>, Tony Fauci <(b) (6)@niaid.nih.gov>, Brett Giroir <Brett.Giroir@hhs.gov>, Marc Short <Marc.T.Short@ovp.eop.gov>, Olivia Troye <Olivia.Troye@nsc.eop.gov>
Subject: Re: Comprehensive use of COVID tests

(b) (5)

Attached

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Wednesday, May 27, 2020 at 7:37 AM
To: CMS (b) (6) <(b) (6)@cms.hhs.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Butler, Jay C (CDC)" <jcb3@cdc.gov>
Cc: Robert Redfield <olx1@cdc.gov>, "Fauci, Anthony S (NIH)" <(b) (6)@niaid.nih.gov>, "Giroir, Brett (OS)" <Brett.Giroir@hhs.gov>, "Short, Marc T. EOP/OVP" <Marc.T.Short@ovp.eop.gov>, "Troye, Nsc" <Olivia.Troye@nsc.eop.gov>
Subject: Re: Comprehensive use of COVID tests

Seema,

The CDC guidance around serology went live.

Here it is featured on our landing page: ><https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html><.

Here are the guidelines: ><https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html><

Steve

From: Seema Verma (b) (6)@cms.hhs.gov
Date: Tuesday, May 26, 2020 at 9:57 PM
To: Stephen Hahn <SH1@fda.hhs.gov>, Debi Birx <Deborah.L.Birx@nsc.eop.gov>, "Butler, Jay C (CDC)" <jcb3@cdc.gov>

Cc: Robert Redfield <olx1@cdc.gov>, Tony Fauci <(b) (6)niaid.nih.gov>, Brett Giroir <Brett.Giroir@hhs.gov>, Marc Short <Marc.T.Short@ovp.eop.gov>, Olivia Troye <Olivia.Troye@nsc.eop.gov>

Subject: RE: Comprehensive use of COVID tests

I really liked this document and I think its important we get this out soon. This will be really helpful to Medicare and other health plans to figure out what they will cover. (b) (5)

[Redacted]

(b) (5)

The documents may overlap so just want to make we are all on the same page.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, May 26, 2020 4:18 PM
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov>
Cc: CMS (b) (6)cms.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Troye, Olivia (nsc.eop.gov) <Olivia.Troye@nsc.eop.gov>
Subject: Re: Comprehensive use of COVID tests

Deb,
My comments
Glad to discuss further
Steve

From: Debi Birx <Deborah.L.Birx@nsc.eop.gov>
Date: Tuesday, May 26, 2020 at 9:13 AM
To: "Butler, Jay C (CDC)" <jcb3@cdc.gov>
Cc: Seema Verma <SV1@cms.hhs.gov>, Robert Redfield <olx1@cdc.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Tony Fauci <(b) (6)niaid.nih.gov>, Brett Giroir <Brett.Giroir@hhs.gov>, Marc Short <Marc.T.Short@ovp.eop.gov>, Olivia Troye <Olivia.Troye@nsc.eop.gov>
Subject: Comprehensive use of COVID tests

[Redacted] (b) (5)
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted] . Deb

(b) (5)

(b) (5)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/8/2020 12:29:13 PM
To: Tyler Ann McGuffee [Tyler.A.McGuffee2@ovp.eop.gov]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Fwd: Follow up discussion (5/8) 3:00pm Ward Room

Tyler Ann,

(b) (5)

thanks
Steve

From: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Date: May 8, 2020 at 12:26:20 PM EDT
To: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Conrad, Patricia L (NIH) <conradpa@niaid.nih.gov>, Knotts, Ashley (CDC) <vqf0@cdc.gov>, Good-Cohn, Meredith (CMS) <Meredith.Good-Cohn@cms.hhs.gov>, Sherman, Jennifer (OS) <Jennifer.Sherman@hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, 'SV1@cms.hhs.gov' <SV1@cms.hhs.gov>, Adams, Jerome (OS) <Jerome.Adams@hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: RE: Follow up discussion (5/8) 3:00pm Ward Room

Roosevelt Room is unavailable. I asked the person to switch rooms and they declined.

Sincerely,
TAM

Tyler Ann McGuffee
Assistant to Ambassador Birx, M.D. | Office of the White House Coronavirus Response Coordinator
Associate Advisor | Office of the Vice President
Office: (202) 456-5984 | Mobile: (b) (6) no text]
Email: Tyler.A.McGuffee2@ovp.eop.gov

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Sent: Friday, May 8, 2020 11:10 AM
To: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>; Sheehy, Janice (FDA/ORA) <Janice.Sheehy@fda.hhs.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; Conrad, Patricia (NIH/NIAID) [E] <conradpa@niaid.nih.gov>; Knotts, Ashley (CDC/OD/OCS) <vqf0@cdc.gov>; Good-Cohn, Meredith (CMS/OA) <Meredith.Good-Cohn@cms.hhs.gov>; Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; 'SV1@cms.hhs.gov' <SV1@cms.hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: RE: Follow up discussion (5/8) 3:00pm Ward Room

I will be there in person. [REDACTED]

(b) (5)

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases

[REDACTED] (b) (6)

National Institutes of Health
Bethesda, MD 20892-2520
Phone: [REDACTED] (b) (6)
FAX: (301) 496-4409
E-mail: [REDACTED] (b) (6) niaid.nih.gov

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From: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>

Sent: Friday, May 8, 2020 9:57 AM

To: Sheehy, Janice (FDA/ORR) <Janice.Sheehy@fda.hhs.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; Conrad, Patricia (NIH/NIAID) [E] <conradpa@niaid.nih.gov>; Knotts, Ashley (CDC/OD/OCS) <vqf0@cdc.gov>; Good-Cohn, Meredith (CMS/OA) <Meredith.Good-Cohn@cms.hhs.gov>; Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>

Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <[REDACTED] (b) (6) niaid.nih.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; 'SV1@cms.hhs.gov' <SV1@cms.hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>

Subject: Follow up discussion (5/8) 3:00pm Ward Room

Dr. Birx is requesting to convene a follow up discussion with principals in the Ward Room today at 3:00pm. Please let me know if your principal is able to attend. Thank you.

Attendees:

Dr. Birx
Dr. Hahn
Dr. Fauci
Dr. Redfield
Dr. Adams
Administrator Verma

Sincerely,
TAM

Tyler Ann McGuffee
Assistant to Ambassador Birx, M.D. | Office of the White House Coronavirus Response Coordinator
Associate Advisor | Office of the Vice President
Office: (202) 456-5984 | Mobile: [REDACTED] (b) (6) [no text]
Email: Tyler.A.McGuffee2@ovp.eop.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/14/2020 8:02:36 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) CMS (b) (6) [(b) (6)@cms.hhs.gov]; Deborah Birx [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: RE: Nursing home reopening and testing guidance- draft. Confidential. Deliberative

Seema,
I am also on that teleconference. If it's ok with you, I'll ask Anand to attend.
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>
Date: May 14, 2020 at 6:35:52 AM EDT
To: CMS (b) (6)@cms.hhs.gov>, Deborah Birx <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: RE: Nursing home reopening and testing guidance- draft. Confidential. Deliberative

Seema:
Unfortunately, I will miss part or all of the discussion today since I have a teleconference with Sec. Azar that overlaps with your meeting. I will catch up about this with you later.
Thanks,
Tony

From: CMS (b) (6)@cms.hhs.gov>
Sent: Wednesday, May 13, 2020 10:16 PM
To: Deborah Birx <Deborah.L.Birx@nsc.eop.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>
Subject: Nursing home reopening and testing guidance- draft. Confidential. Deliberative

For discussion tomorrow.

(b) (5)

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 4/25/2020 10:30:34 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-ac1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; CMS SV1 [SV1@cms.hhs.gov]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]
CC: McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: If possible review with written responses by 1030 am

Thank you everything. Deb

From: "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>
Date: Saturday, April 25, 2020 at 10:25 AM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Schuchat, Anne MD (CDC/OD)" <acs1@CDC.GOV>, "Hahn, Stephen" <sh1@fda.hhs.gov>, CMS SV1 <SV1@cms.hhs.gov>, "Adams, Jerome (HHS/OASH)" <Jerome.Adams@hhs.gov>
Cc: "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: RE: If possible review with written responses by 1030 am

Deb:

Nice job! I am attaching the document with some suggested edits that are tracked.

Thanks,

Tony

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Saturday, April 25, 2020 8:20 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@CDC.GOV>; Hahn, Stephen <sh1@fda.hhs.gov>; CMS SV1 <SV1@cms.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>
Cc: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: If possible review with written responses by 1030 am

Thank you

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 4/19/2020 12:10:08 PM
To: Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [nelson.l.michael2.civ@mail.mil]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: Testing update

Sorry – today.

From: "[REDACTED] (b) (6)"
Date: Sunday, April 19, 2020 at 12:09 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>
Subject: RE: Testing update

[REDACTED] (b) (6), (b) (5)

[REDACTED] (b) (6)

Walter Reed Army Institute of Research

[REDACTED] (b) (6)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Sunday, April 19, 2020 12:07 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>
Subject: FW: Testing update

[REDACTED] (b) (5)

From: "Farah, Alyssa A. EOP/WHO" <Alyssa.A.Farah@who.eop.gov>
Date: Sunday, April 19, 2020 at 11:42 AM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: Fwd: Testing update

Dr. Birx -great job on the shows this morning! [REDACTED] (b) (5)

Alyssa Farah
Director of Strategic Communications
The White House

Sent from my iPhone

Begin forwarded message:

From: "Gilmartin, Kayleigh M. EOP/WHO" <Kayleigh.McEnany@who.eop.gov>

Date: April 19, 2020 at 11:29:23 AM EDT

To: "Henning, Alexa A. EOP/WHO" <[\(b\) \(6\)g@who.eop.gov](mailto:(b) (6)g@who.eop.gov)>

Cc: "Farah, Alyssa A. EOP/WHO" <[\(b\) \(6\)@who.eop.gov](mailto:(b) (6)@who.eop.gov)>, "Gilmartin, Kayleigh M. EOP/WHO" <Kayleigh.McEnany@who.eop.gov>

Subject: Re: Testing update

(b) (5)

Sent from my iPhone

On Apr 19, 2020, at 11:17 AM, Henning, Alexa A. EOP/WHO <[\(b\) \(6\)@who.eop.gov](mailto:(b) (6)@who.eop.gov)> wrote:

(b) (5)

•

[Redacted]

[Redacted]

(b) (5)

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 4/25/2020 9:20:15 AM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c243d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; CMS SV1 [SV1@cms.hhs.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]
CC: McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: If possible review with written responses by 1030 am
Attachments: 20200422 Testing Strategy UPDATE4db.docx

Modified wording. Full appendixes attached

From: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>
Date: Saturday, April 25, 2020 at 9:09 AM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Schuchat, Anne MD (CDC/OD)" <acs1@cdc.gov>, "SH1 (fda.hhs.gov)" <SH1@fda.hhs.gov>, CMS SV1 <SV1@cms.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "Adams, Jerome (HHS/OASH)" <Jerome.Adams@hhs.gov>
Cc: "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: RE: If possible review with written responses by 1030 am

I really think this is excellent. Clearly outlines what has been done and the strategy going forward. Although technical, I do think the appendix on predictive values is helpful and will assist the intelligent non-expert (and most clinicians) how this fits.

My only suggestion is about this part, which I suggest we keep general :

(b) (5)

Super great job and this is exciting.

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: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>

Sent: Saturday, April 25, 2020 8:20 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; CMS SV1 <SV1@cms.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>

Cc: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>

Subject: If possible review with written responses by 1030 am

Thank you

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 4/25/2020 9:12:25 AM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-ac1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; CMS SV1 [SV1@cms.hhs.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]
CC: McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: If possible review with written responses by 1030 am

(b) (5)

From: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>
Date: Saturday, April 25, 2020 at 9:09 AM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Schuchat, Anne MD (CDC/OD)" <acs1@cdc.gov>, "SH1 (fda.hhs.gov)" <SH1@fda.hhs.gov>, CMS (b) (6)@cms.hhs.gov, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "Adams, Jerome (HHS/OASH)" <Jerome.Adams@hhs.gov>
Cc: "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: RE: If possible review with written responses by 1030 am

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My only suggestion is about this part, which I suggest we keep general :

(b) (5)

Super great job and this is exciting.

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: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>

Sent: Saturday, April 25, 2020 8:20 AM

To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; CMS SV1 <SV1@cms.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>

Cc: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>

Subject: If possible review with written responses by 1030 am

Thank you

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 5/27/2020 9:04:01 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]
CC: CMS SV1 [SV1@cms.hhs.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS- (b) (5) Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]
Subject: Re: Comprehensive use of COVID tests

All good but I should have gotten to WH comms yesterday ahead of the story rather than after. Looks like it was posted a few days ago (b) (5)

Deb

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Wednesday, May 27, 2020 at 8:57 AM
To: "Butler, Jay C (CDC)" <jcb3@cdc.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Cc: CMS (b) (6) <(b) (6)@cms.hhs.gov>, Robert Redfield <olx1@cdc.gov>, "Fauci, Anthony S (NIH)" <(b) (6)@niaid.nih.gov>, "Troye, Nsc" <Olivia.Troye@nsc.eop.gov>
Subject: Re: Comprehensive use of COVID tests

Thank you, Jay.

Deb, this was the guidance (b) (5). Our teams have been working on it, as Jay discussed. (b) (5).
Steve

From: "Butler, Jay C. (CDC/DDID/OD)" <jcb3@cdc.gov>
Date: Wednesday, May 27, 2020 at 8:48 AM
To: Debi Birx <Deborah.L.Birx@nsc.eop.gov>
Cc: Seema Verma <SV1@cms.hhs.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Robert Redfield <olx1@cdc.gov>, Tony Fauci <(b) (6)@niaid.nih.gov>, Olivia Troye <Olivia.Troye@nsc.eop.gov>
Subject: RE: Comprehensive use of COVID tests

(b) (5)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Wednesday, May 27, 2020 8:22 AM
To: Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov>
Cc: CMS SV1 <SV1@cms.hhs.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <AFAUCI@niaid.nih.gov>; Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>
Subject: Re: Comprehensive use of COVID tests

Just a quick aside Jay. (b) (5)

(b) (5)

? Deb

Sent from my iPhone

On May 26, 2020, at 10:11 PM, Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov> wrote:

Updates on the various documents/workstreams you have outlined below:

(b) (5)

I hope that is helpful for clarification.

From: CMS (b) (6) <cms.hhs.gov>

Sent: Tuesday, May 26, 2020 9:42 PM

To: SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov>

Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] (b) (6) <@niaid.nih.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>; Troye, Olivia (nsc.eop.gov) <Olivia.Troye@nsc.eop.gov>

Subject: RE: Comprehensive use of COVID tests

I really liked this document and I think its important we get this out soon. This will be really helpful to Medicare and other health plans to figure out what they will cover. (b) (5)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 5/12/2020 9:34:03 AM
To: CMS SV1 [SV1@cms.hhs.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; 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]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-H (b) (6)]
Subject: Re: Testing-
Attachments: CDC ELC-Healthcare-Enhancement Guidance BGTB_response from ELC_v6 May11pm.docx

(b) (5)

From: CMS (b) (6)@cms.hhs.gov>
Date: Tuesday, May 12, 2020 at 9:00 AM
To: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "SH1 (fda.hhs.gov)" <SH1@fda.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Subject: RE: Testing-

Have we put out any guidance that makes this clear?

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Tuesday, May 12, 2020 8:58 AM
To: CMS SV1 <SV1@cms.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; 'Birx, Deborah L. EOP/NSC' <Deborah.L.Birx@nsc.eop.gov>
Subject: RE: Testing-

(b) (5)

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

From: CMS (b) (6)@cms.hhs.gov>
Sent: Tuesday, May 12, 2020 8:57 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>; 'Birx, Deborah L. EOP/NSC' <Deborah.L.Birx@nsc.eop.gov>
Subject: Testing-

Team,

(b) (5)

I was hoping to have more discussion at our meetings and would like to get your input. Will also work with OMB on this.

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 5/12/2020 9:30:24 AM
To: CMS SV1 [SV1@cms.hhs.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; 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]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-H (b) (6)]
Subject: Re: Testing-

(b) (5)

. Deb

From: CMS (b) (6)@cms.hhs.gov
Date: Tuesday, May 12, 2020 at 9:12 AM
To: "Giroir, Brett (HHS/OASH)" <Brett.Giroir@hhs.gov>, "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "SH1 (fda.hhs.gov)" <SH1@fda.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Subject: Testing-

Team,

(b) (5)

I was hoping to have more discussion at our meetings and would like to get your input. Will also work with OMB on this.

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 5/7/2020 9:25:16 AM
To: Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; AMA2 (OS/IOS) [AMA2@HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Lukens IV, Mel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaa0ae6a04b943ec9d926f56f4c50b50-HHS-Mel.Luk]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6)]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Polowczyk, John P (MIL) [john.p.polowczyk.mil@mail.mil]; Falcon, Jessica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3824ed33f07143e791acff770662ee48-HHS-Jessica]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: AMA Follow up Discussion

This time won't work for me. Deb

From: "Secretary Scheduler (OS/IOS)" <Secretary.Scheduler@hhs.gov>
Date: Thursday, May 7, 2020 at 9:24 AM
To: "AMA2 (OS/IOS)" <AMA2@HHS.GOV>, "Apple, Matthew (HHS/IOS)" <Matthew.Apple@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Lukens IV, Mel (HHS/IOS)" <Mel.Lukens@hhs.gov>, "Mango, Paul (HHS/IOS)" <Paul.Mango@hhs.gov>, "Puesan, Cesar (HHS/OS/IOS)" <Cesar.Puesan@hhs.gov>, "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>, "Tignor, Beth (HHS/IOS)" <Beth.Tignor@hhs.gov>, "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>, "Ford-Barnes, Arwenthia (OS/ASPR/IO)" <Arwenthia.FordBarnes@hhs.gov>, "Redd, John (OS/ASPR/SPPR)" <John.Redd@hhs.gov>, "Shah, Anand (FDA/OC)" <Anand.Shah@fda.hhs.gov>, "SH1 (fda.hhs.gov)" <SH1@fda.hhs.gov>, "Sheehy, Janice (FDA/OR)" <Janice.Sheehy@fda.hhs.gov>, "Troye, Nsc" <Olivia.Troye@nsc.eop.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" <conradpa@niaid.nih.gov>, "Deborah.L.Birx@nsc.eop.gov" <Deborah.L.Birx@nsc.eop.gov>, "McGuffee, Tyler Ann A. EOP/OVP"

<Tyler.A.McGuffee2@ovp.eop.gov>, "Polowczyk, John P (MIL)" (b) (6)@mail.mil>, "Falcon, Jessica (OS/ASPR/SIIM)" <Jessica.Falcon@hhs.gov>, "Lenihan, Keagan (FDA/OC)" <Keagan.Lenihan@fda.hhs.gov>

Subject: AMA Follow up Discussion

866-731-6162, (b) (6)

Leader: (b) (6)

Attendees

Secretary Azar

Dr. Birx

Adm Polowczyk

Dr. Hahn

Dr. Fauci- confirmed

Dr. Kadlec – confirmed

Anand Shah - confirmed

Olivia Troye

Jessica Falcon

From: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Sent: 4/28/2020 7:51:50 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; CMS SV1 [SV1@cms.hhs.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@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-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]
Subject: RE: Antibody test

Ok. Ill try to set up a call for today.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, April 28, 2020 7:51 AM
To: CMS (b) (6)cms.hhs.gov>; Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>; Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: Antibody test

It would be great to have additional discussion about these issues. I'm sure we are all getting a lot of questions.
Steve

From: CMS (b) (6)cms.hhs.gov>
Date: April 27, 2020 at 1:05:45 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Antibody test

(b) (5)

We will need to nail down for Medicare coverage issues and other insurers will want to know as well.

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 5/7/2020 1:01:15 PM
To: Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS- (b) (6) Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
CC: Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Ford-Barnes, Arwenhia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenh]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]
Subject: Re: (b) (5)

(b) (5) ?

From: "Redd, John (OS/ASPR/SPPR)" <John.Redd@hhs.gov>
Date: Thursday, May 7, 2020 at 12:42 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "SH1 (fda.hhs.gov)" <SH1@fda.hhs.gov>, "Troye, Nsc" <Olivia.Troye@nsc.eop.gov>, "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>
Cc: "Callahan, Victoria (OS/ASPR/IO) (CTR)" <Victoria.Callahan@hhs.gov>, "Lenihan, Keagan (FDA/OC)" <Keagan.Lenihan@fda.hhs.gov>, "Ford-Barnes, Arwenhia (OS/ASPR/IO)" <Arwenhia.FordBarnes@hhs.gov>, "Mango, Paul (HHS/IOS)" <Paul.Mango@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>
Subject: RE: Setting up Conference Call with Amb Birx as soon as her schedule will permit on Remdesivir Allocation and Distribution

Day 1 was transmitted to Gilead on Monday evening for action Tuesday (b) (5)

From: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Date: May 7, 2020 at 12:05:50 PM EDT
To: "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)niaid.nih.gov>, "SH1 (fda.hhs.gov)" <SH1@fda.hhs.gov>, "Redd, John (OS/ASPR/SPPR)" <John.Redd@hhs.gov>, "Troye, Olivia (nsc.eop.gov)" <Olivia.Troye@nsc.eop.gov>, "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>
Cc: "Callahan, Victoria (OS/ASPR/IO) (CTR)" <Victoria.Callahan@hhs.gov>, "Lenihan, Keagan (FDA/OC)" <Keagan.Lenihan@fda.hhs.gov>, "Ford-Barnes, Arwenhia (OS/ASPR/IO)" <Arwenhia.FordBarnes@hhs.gov>, "Mango, Paul (HHS/IOS)" <Paul.Mango@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>
Subject: Re: (b) (5)

(b) (5)

From: "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>

Date: Thursday, May 7, 2020 at 11:27 AM

To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <[\(b\) \(6\)niaid.nih.gov](mailto:(b) (6)niaid.nih.gov)>, "SH1 (fda.hhs.gov)" <SH1@fda.hhs.gov>, "Redd, John (OS/ASPR/SPPR)" <John.Redd@hhs.gov>, "Troye, Nsc" <Olivia.Troye@nsc.eop.gov>, "McGuffee, Tyler Ann A. EOP/OVP" <Tyler.A.McGuffee2@ovp.eop.gov>

Cc: "Callahan, Victoria (OS/ASPR/IO) (CTR)" <Victoria.Callahan@hhs.gov>, "Lenihan, Keagan (FDA/OC)" <Keagan.Lenihan@fda.hhs.gov>, "Ford-Barnes, Arwenhithia (OS/ASPR/IO)" <Arwenhithia.FordBarnes@hhs.gov>, "Mango, Paul (HHS/IOS)" <Paul.Mango@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>

Subject: (b) (5)

Tyler Ann can you please indicate when we can schedule a

(b) (5)

. Thank you.

Arwenhithia and Victoria can you please set us conference line and invitation to those on this distribution Thank you

Bob

(b) (5)

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 [Deborah.L.Birx@nsc.eop.gov]; Gaynor, Pete [pete.gaynor@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 <Deborah.L.Birx@nsc.eop.gov>, Gaynor, Pete <pete.gaynor@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 <Deborah.L.Birx@nsc.eop.gov>; Gaynor, Pete <pete.gaynor@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 <Deborah.L.Birx@nsc.eop.gov>
Date: March 21, 2020 at 7:12:34 AM EDT
To: Gaynor, Pete <pete.gaynor@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" <pete.gaynor@fema.dhs.gov>
Date: Saturday, March 21, 2020 at 7:10 AM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@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)

Pete.Gaynor@fema.dhs.gov

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

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

To: Gaynor, Pete <pete.gaynor@fema.dhs.gov>

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

Subject: Re: White House Coronavirus Task Force Meeting

(b) (5)

(b) (5) Deb

From: "Gaynor, Pete" <pete.gaynor@fema.dhs.gov>

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

To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@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)

Pete.Gaynor@fema.dhs.gov

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

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

To: Short, Marc T. EOP/OVP (b) (6) @ovp.eop.gov>; Troye, Olivia <Olivia.Troye@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) (b) (6) @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/WHC (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 <jck@who.eop.gov>; Hicks, Hope C. EOP/WHO

<Hope@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

<Joseph.J.Grogan@who.eop.gov>; AMA2@HHS.GOV; stm77@treasury.gov; Kudlow, Larry A. EOP/WHO

<Lawrence.A.Kudlow@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) <Katie.R.Miller@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 <Stephen.Miller@who.eop.gov>; Gaynor, Pete <pete.gaynor@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; conradpa@niaid.nih.gov; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@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>; Jennifer.Stewart@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>; Hannah.Gonzalez@sd.mil; michael.harrison@sd.mil; anne.powers@sd.mil; Cytryn, (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 <DL.COMMS.Speechwriters@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) @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" <Olivia.Troye@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"

<Matthew.J.Sheehan@ovp.eop.gov>, "Moore, Caroline E. EOP/WHO" <Caroline.E.Moore@who.eop.gov>, "Kushner, Jared C. EOP/WHO" <jck@who.eop.gov>, "Hicks, Hope C. EOP/WHO" <Hope@who.eop.gov>, "Fisher, Garrett C. EOP/OVP" <Garrett.C.Fisher@ovp.eop.gov>, "Robert.Kadlec@hhs.gov" <Robert.Kadlec@hhs.gov>, "Joel.Szabat@dot.gov" <Joel.Szabat@dot.gov>, "randal@mail.house.gov" <randal@mail.house.gov>, "Grogan, Joseph J. EOP/WHO" <Joseph.J.Grogan@who.eop.gov>, "AMA2@HHS.GOV" <AMA2@HHS.GOV>, "stm77@treasury.gov" <stm77@treasury.gov>, "Kudlow, Larry A. EOP/WHO" <Lawrence.A.Kudlow@who.eop.gov>, "olx1@cdc.gov" <olx1@cdc.gov>, (b) (6)@niaid.nih.gov" <AFAUCI@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>, "Birn, Deborah L. EOP/NSC" <Deborah.L.Birn@nsc.eop.gov>, (b) (6)@cms.hhs.gov" (b) (6)@cms.hhs.gov>, "rlw@va.gov" <rlw@va.gov>, "Pottinger, Matthew F. EOP/WHO" (b) (6)@who.eop.gov>, "Vought, Russell T. EOP/OMB" <Russell.T.Vought@omb.eop.gov>, "Miller, Ovp" <Katie.R.Miller@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" <Stephen.Miller@who.eop.gov>, "Pete.Gaynor@fema.dhs.gov" <Pete.Gaynor@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>, "conradpa@niaid.nih.gov" <conradpa@niaid.nih.gov>, "hilary.marston@nih.gov" <hilary.marston@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>, "Jennifer.Stewart@sd.mil" <Jennifer.Stewart@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>, "Hannah.Gonzalez@sd.mil" <Hannah.Gonzalez@sd.mil>, "michael.harrison@sd.mil" <michael.harrison@sd.mil>, "anne.powers@sd.mil" <anne.powers@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. EOP/WHO" (b) (6)@who.eop.gov>, DL WHO COMMS Speechwriters

<DL.COMMS.Speechwriters@whmo.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>,
"lauren.fischer@fema.dhs.gov" <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" <Victoria.Callahan@hhs.gov>, "Croghan, Mary E. EOP/WHO"
(b) (6) @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: 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) 881-9981

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/15/2020 6:02:04 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffb983419fcd-HHS-olx1-cd]
Subject: Re: Issue for VP TF

Thanks

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 15, 2020 at 6:01:04 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: Issue for VP TF

I'll give him a (b) (5).

Sent from my iPhone

On Apr 15, 2020, at 5:55 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

(b) (5)
Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 14, 2020 at 1:58:13 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Issue for VP TF

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

Jeff

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/24/2020 8:27:59 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: CVS Action on Potentially Short Supply Drugs

FYI

From: Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>
Date: March 24, 2020 at 8:25:04 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: CVS Action on Potentially Short Supply Drugs

Thanks I agree with Patrizia

Douglas C. Throckmorton MD
Deputy Director for Regulatory Programs
CDER FDA
240-402-5400

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 8:23 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>
Subject: RE: CVS Action on Potentially Short Supply Drugs

+ Doug

These restrictions are not surprising and they will limit hoarding . CDER DSS are already on this and doing outreach .
Patrizia

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 24, 2020 at 8:18:59 PM EDT
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: CVS Action on Potentially Short Supply Drugs

(b) (5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Tuesday, March 24, 2020 8:04 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: FW: CVS Action on Potentially Short Supply Drugs

FYI

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

Date: March 24, 2020 at 5:42:03 PM EDT

To: Williams, James H. EOP/WHO <(b) (6)@>, Jonas, Seth H. EOP/NSC

(b) (6)>, Cavanaugh, Brian (nsc.eop.gov) (b) (6)@>, Baehr, James S. EOP/WHO <James.S.Baehr@who.eop.gov>, Sun, Eric C. EOP/

(b) (6) Chang, William (OS) <William.Chang@hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Mango, Paul (OS) <Paul.Mango@hhs.gov>

Subject: FW: CVS Action on Potentially Short Supply Drugs

Importance: High

Following up on the conversations yesterday around drug supply, this is CVS's request for national guidance on recommended prescription limits for certain drugs.

Albuterol Meter Dose Inhalers:

- Two per 30 days (200 inhalations per device) at retail or six per 90 days at mail. Applies only to inhalers and not nebulizer solutions or oral tablets.

Chloroquine, hydroxychloroquine, Kaletra and azithromycin:

- Chloroquine, hydroxychloroquine: 10-day supply, limit of one fill per 60 days
- Kaletra: 14-day supply, limit of one fill per 60 days
- Azithromycin 250 mg tablets, limit of 6 tablets or one blister pack of 6 tablets per five days; limit of one fill per 60 days.
- Limit of one fill of each product

Limits apply to claims from all pharmacies.

From: (b) (6)@CVSHealth.com>

Sent: Tuesday, March 24, 2020 3:49 PM

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

Subject: CVS Action on Potentially Short Supply Drugs

Importance: High

Hi John,

In order to stave off potential longer term supply shortages, CVSH through both its Pharmacy Benefit Manager (PBM), Caremark, and its retail pharmacies has begun implementing policies designed to limit overprescribing and overdispensing of these medications in order to preserve the supply nationally. We have also begun working with states to establish guidelines for appropriate prescribing and dispensing. But a national standard would likely provide stronger protection against runs on these products and ensure that the right patients get the appropriate prescription to treat their conditions.

Caremark has begun implementing a number of Utilization Management (UM) tools to limit overutilization of these critical drugs, while also maintaining continuity of care for existing patients. For inhalers, we have limited permissible dispensing limits for new prescriptions to two per 30 days. For oral solid products, we have established dispensing limits

in line with regular treatment of the disease. These limits allow for an initial treatment and a single refill in a 60-day period, adjusted appropriately for each drug. In order to maintain continuity for existing patients we have set up rules that patients that have filled or refilled larger amounts recently and have documented diagnoses requiring the prescriptions will be able to continue refilling at their regular level. I outline the technical limits below.

In the retail setting, we will be following guidelines established by Caremark and other PBMs, as well as the states themselves. However, in the absence of clear guidelines we are also establishing limits on what any of our pharmacies will dispense of the affected products. For Chloroquine and Hydroxychloroquine we will be limiting initial prescriptions to a 10-day supply, and contacting doctors to file another script if a refill is requested.

So far nine states have taken action to limit the dispensing of Chloroquine and Hydroxychloroquine: Arkansas, Idaho, Louisiana, Nevada, North Carolina, Ohio, Oklahoma, Texas, and West Virginia. Each rule is slightly different, but the general consensus has been to limit both drugs to a single 10- or 14-day supply with an initial script and eliminate refills without a second prescription.

All of these measures are helpful in limiting overutilization of these critical drugs at this time, but further action from the administration could create greater protection that all diagnosed COVID-19 patients will receive treatment.

Albuterol Meter Dose Inhalers:

- Two per 30 days (200 inhalations per device) at retail or six per 90 days at mail. Applies only to inhalers and not nebulizer solutions or oral tablets.

Chloroquine, hydroxychloroquine, Kaletra and azithromycin:

- Chloroquine, hydroxychloroquine: 10-day supply, limit of one fill per 60 days
- Kaletra: 14-day supply, limit of one fill per 60 days
- Azithromycin 250 mg tablets, limit of 6 tablets or one blister pack of 6 tablets per five days; limit of one fill per 60 days.
- Limit of one fill of each product

Limits apply to claims from all pharmacies.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/21/2020 5:56:58 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: FW: CU portal language EU change 03 21 20 rev-db_HM.docx
Attachments: CU portal language EU change 03 21 20 rev-db_HM.docx

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Date: March 21, 2020 at 5:10:28 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>
Subject: FW: CU portal language EU change 03 21 20 rev-db_HM.docx

We just learned that Gilead are going live with this in 2 hours. Can we please set up a call to discuss.
Patrizia

From: Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>
Sent: Saturday, March 21, 2020 4:54 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Miele, Peter <Peter.Miele@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Murray, Jeffrey S <Jeffrey.Murray@fda.hhs.gov>; Sherwat, Adam <Adam.Sherwat@fda.hhs.gov>; Chan-Tack, Kirk <Kirk.Chan-Tack@fda.hhs.gov>; Akunne, Linda <Linda.Akunne@fda.hhs.gov>; Winestock, Karen <Karen.Winestock@fda.hhs.gov>; Kim, Christine <Christine.Kim@fda.hhs.gov>
Subject: FW: CU portal language EU change 03 21 20 rev-db_HM.docx

Debra Birnkrant, M.D.
Director, Division of Antivirals
Office of Infectious Diseases
CDER, FDA
301-796-1500 office
301-796-9883 fax

From: Diana Brainard <Diana.Brainard@gilead.com>
Sent: Saturday, March 21, 2020 4:50 PM
To: Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>
Subject: CU portal language EU change 03 21 20 rev-db_HM.docx

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/7/2020 9:08:04 AM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Conway, Kellyanne E. EOP/WHO [KAC@who.eop.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Hicks, Hope C. EOP/WHO [Hope@who.eop.gov]; Rinat, Ory S. EOP/WHO [Ory.S.Rinat@who.eop.gov]; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]
Subject: Re: Convalescent plasma program

Completely agree, Katie.

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Date: April 7, 2020 at 9:07:13 AM EDT
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Conway, Kellyanne E. EOP/WHO <KAC@who.eop.gov>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>, Rinat, Ory S. EOP/WHO <Ory.S.Rinat@who.eop.gov>, Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>
Subject: Re: Convalescent plasma program

(b) (5)

Sent from my iPhone

On Apr 7, 2020, at 8:57 AM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

(b) (5)

Just a suggestion. Thanks.

Best Regards,
Peter

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Sent: Tuesday, April 7, 2020 8:17 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Conway, Kellyanne E. EOP/WHO <KAC@who.eop.gov>; Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>; Rinat, Ory S. EOP/WHO <Ory.S.Rinat@who.eop.gov>; Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>
Subject: Re: Convalescent plasma program

+others.

(b) (5).

(b) (5)

Sent from my iPhone

On Apr 7, 2020, at 8:13 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

KelleyAnne, Joe and Katie,

The convalescent plasma program has ramped up and we are working hard to identify donors. There is a significant shortfall of plasma because of the need to identify additional donors. Donors will be identified through a Microsoft-built convalescent plasma recruitment application online.

(b) (5)

Thanks
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/19/2020 10:09:34 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: [EXTERNAL] FW: CBER Update

(b) (5)

?

Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 18, 2020 at 6:50:33 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: [EXTERNAL] FW: CBER Update

Ok. (b) (5) ?

Sent from my iPhone

On Apr 18, 2020, at 6:20 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Joe,

(b) (5)

The names of donors are below.

Thanks

Steve

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: April 18, 2020 at 5:51:32 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: [EXTERNAL] FW: CBER Update

Dear Commissioner,

Here are the names of three convalescent plasma donors in the area who might be amenable to coming over to the WH to help drive donations. Thanks!

Best Regards,
Peter

From: Gilmore, Shaun P <Shaun.Gilmore@redcross.org>
Sent: Saturday, April 18, 2020 4:47 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: Fwd: [EXTERNAL] FW: CBER Update

Hi Peter,

In response to your request for local CCP donors that would be willing to help promote CCP donations, here are the names and contact information for 3 who have said they would be interested.

Regards,

Shaun

Sent from my iPhone

Begin forwarded message:

From: "Sebok, Melissa" <Melissa.Sebok@redcross.org>

Date: April 18, 2020 at 1:04:59 PM PDT

To: "Gilmore, Shaun P" <Shaun.Gilmore@redcross.org>

Subject: RE: [EXTERNAL] FW: CBER Update

Hi Shaun –

I just heard back from (b) (6) and he is definitely interested. So here are the three who said yes:

(b) (6)

Please let me know if you need anything further on this. Thanks!

Best,
Melissa

From: "Marks, Peter" <Peter.Marks@fda.hhs.gov>

Date: April 17, 2020 at 5:02:44 AM PDT

To: "Gilmore, Shaun P" <Shaun.Gilmore@redcross.org>

Cc: "Young, Pampee (pampee.young@redcross.org)" <pampee.young@redcross.org>

Subject: [EXTERNAL] FW: CBER Update

Dear Shaun,

Could Red Cross help us identify a few donors who might want to volunteer to help publicize this endeavor? Thanks!

Best Regards,
Peter

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

Sent: Friday, April 17, 2020 7:58 AM

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

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: CBER Update

Peter,

I just got off a call with folks at the WH and stressed the need to increase our communication regarding plasma donations. They suggested that we have our collection centers identify people who have recovered and donated so that they could be on the WH podium with the President. Can you reach out and help with the identification of willing donors?

Thanks

Steve

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 5/20/2020 3:44:29 PM
To: 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=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]
Subject: Re: Nucleocapsid Protein Serology Tests vs Spike Protein Serology Tests

Really helpful.

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Wednesday, May 20, 2020 at 3:29 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Fauci, Anthony S (NIH)" <afauci@niaid.nih.gov>, "Redfield, Robert R (CDC)" <olx1@cdc.gov>
Subject: Fwd: Nucleocapsid Protein Serology Tests vs Spike Protein Serology Tests

FYI
Nice work by Jeff and his team.
Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: May 20, 2020 at 11:41:44 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Nucleocapsid Protein Serology Tests vs Spike Protein Serology Tests

(b) (5)

Jeff

From: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Sent: 4/12/2020 5:07:47 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: Suggest you get set-up as a customer with Hardy Diagnostics

(b) (5)

Sent from my iPhone

On Apr 12, 2020, at 4:55 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

(b) (5)

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 12, 2020 at 2:28:00 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Suggest you get set-up as a customer with Hardy Diagnostics

(b) (5)

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: April 12, 2020 at 2:14:56 PM EDT
To: Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Suggest you get set-up as a customer with Hardy Diagnostics

Well that is a really bad sign

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: Sharpless, Norman (NIH/NCI) [E] <norman.sharpless@nih.gov>
Sent: Sunday, April 12, 2020 2:12 PM
To: Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Cc: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Suggest you get set-up as a customer with Hardy Diagnostics

We heard from Hardy that they won't send us kit till May.

Norman E. Sharpless MD
Director, the National Cancer Institute

On Apr 12, 2020, at 12:54 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

Per the lead reviewer and Deputy Division Director, the company's data looks good. The company provided (b) (5), (b) (4)

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

From: Sharpless, Norman (NIH/NCI) [E] <norman.sharpless@nih.gov>
Sent: Sunday, April 12, 2020 11:47 AM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Suggest you get set-up as a customer with Hardy Diagnostics

I am told we heard about this one and requested kits last week. I don't think they have arrived in FNL yet but can make this one a top priority when we receive.

Norman E. Sharpless MD
Director, the National Cancer Institute

On Apr 12, 2020, at 11:43 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

We have a pre-EIJA in house. The manufacturer is Autobio, a Chinese company (b) (5), (b) (4)

(b) (5), (b) (4) Hardy is distributing the antibody test for Autobio in the US (b) (5), (b) (4)

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

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Sunday, April 12, 2020 8:22 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>
Subject: FW: Suggest you get set-up as a customer with Hardy Diagnostics

(b) (5)

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

From: Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>
Sent: Saturday, April 11, 2020 9:24 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: FW: Suggest you get set-up as a customer with Hardy Diagnostics

Another lateral flow coming on the market

Anti-SARS-CoV-2 Rapid Test

Rapid Results - 15 minutes for a readout

Sensitivity at >= 15 days after onset of symptoms

- IgM – 95.7%
- IgG – 99.0%

Specificity

- IgM – 99%
- IgG – 99%

From: Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>
Sent: Saturday, April 11, 2020 4:13 PM
To: Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Josh Fine (joshua.fine@tunnellgov.com) <joshua.fine@tunnellgov.com>; Newman, Carl I CIV DTRA CT (USA) (b) (6)@mail.mil>
Cc: Hargarten, Eric (CMS/CMMI) <Eric.Hargarten@cms.hhs.gov>
Subject: RE: Suggest you get set-up as a customer with Hardy Diagnostics

Hi team, any thoughts on this?

From: Kellogg, Rachel (HHS/OASH)
Sent: Friday, April 10, 2020 3:39 PM
To: Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Josh Fine (joshua.fine@tunnellgov.com) <joshua.fine@tunnellgov.com>; Newman, Carl I CIV DTRA CT (USA) (b) (6)@mail.mil>
Cc: Hargarten, Eric (CMS/CMMI) <eric.hargarten@cms.hhs.gov>
Subject: FW: Suggest you get set-up as a customer with Hardy Diagnostics

Antibody test that will supposedly be granted an EUA early next week.

(b) (5)

From: Christopher Catani <CataniC@hardydiagnostics.com>
Sent: Friday, April 10, 2020 3:30 PM
To: Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>
Subject: RE: Suggest you get set-up as a customer with Hardy Diagnostics

Rachel – our antibody kit, getting FDA EUA, early next week.

Anti-SARS-CoV-2 Rapid Test

Please get your order in soon.

Chris

Christopher Catani, MT (ASCP), RM (ACM) |
Director of Sales & Marketing, Corporate Vice
President
Phone: 805.346.2766 ext. 5696

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From: Christopher Catani
Sent: Friday, April 10, 2020 12:09 PM
To: 'Rachel.Kellogg@hhs.gov' <Rachel.Kellogg@hhs.gov>; Eddie Yubeta <YubetaE@hardydiagnostics.com>
Subject: Suggest you get set-up as a customer with Hardy Diagnostics
Importance: High

Eddie – please assist Rachel, she’s with the Federal Government, Health and Human Services.

Thanks
Chris

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/12/2020 5:07:11 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Suggest you get set-up as a customer with Hardy Diagnostics

Perhaps we can discuss?

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 12, 2020 at 12:54:00 PM EDT
To: Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Suggest you get set-up as a customer with Hardy Diagnostics

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(b) (5)

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ADM, US Public Health Service
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Cc: Hargarten, Eric (CMS/CMMI) <eric.hargarten@cms.hhs.gov>
Subject: FW: Suggest you get set-up as a customer with Hardy Diagnostics

(b) (5)

From: Christopher Catani <CataniC@hardydiagnostics.com>
Sent: Friday, April 10, 2020 3:30 PM
To: Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>
Subject: RE: Suggest you get set-up as a customer with Hardy Diagnostics

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Director of Sales & Marketing, Corporate Vice
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Phone: 805.346.2766 ext. 5696

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Thanks
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(b) (5)

(b) (5)

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/6/2020 5:37:22 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Finger sticks

Thanks. We wanted to make sure that we didn't run out of supply.
S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 6, 2020 at 5:35:58 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Finger sticks

We used any in Africa.

Sent from my iPhone

On Apr 6, 2020, at 5:29 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

FYSA

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 3, 2020 at 1:16:36 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: Finger sticks

(b) (5)

Please let me know if you need anything else.

From: Shuren, Jeff
Sent: Friday, April 3, 2020 7:55 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: Finger sticks

(b) (5)

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

(b) (4)

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, April 3, 2020 7:29 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: Finger sticks

Thank you
Does anyone have the firm info on IgM IgG time course?

(b) (5)

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

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, April 3, 2020 7:26 AM

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

Subject: RE: Finger sticks

FYSA

- Diagnostics
 - CDRH authorized an EUA for BD for their molecular test. This is a high throughput test run on the BD MAX instruments which are in place in 365 labs across the US. BD will distribute 30,000 tests/week and could ramp up to 50,000 tests/week.
 - CDRH authorized the addition of Northwestern's LDT to the umbrella EUA. This is a molecular test designed and run in the hospital lab.
 - The State of Connecticut notified FDA that they will take responsibility for oversight of LDTs in their state.
 - CDRH updated the website FAQ with additional information regarding swabs, media, instruments.
 - CDRH met with a representative from the Army to answer questions regarding testing military members.

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

Date: April 3, 2020 at 7:24:33 AM EDT

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

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

Subject: RE: Finger sticks

I would like info on the manufacturers or just the type of devices we need.

I don't know this industry at all.

I do Central Lines, not finger pricks

Brett P. Giroir, MD

ADM, US Public Health Service

Assistant Secretary for Health (ASH)

200 Independence Avenue, SW

Washington, DC 20201

Office Phone: 202-690-7694

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

Sent: Friday, April 3, 2020 7:20 AM

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

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

Subject: Finger sticks

Brett,

Your question about the lance for performing the finger stick is a good one. This appears to be a Class I device so we wouldn't have insight or tracking of the supply chain. Jeff's team is happy to provide your team with information regarding the manufacturers. Please let us know.

Steve

<[Detailed_R&L_Info_By_Product_Code FMK \(Blood Lancets\)_With_Contacts Info.xlsx](#)>

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 [Joseph.J.Grogan@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) @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.Lenihan]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: "Serology test"?? COVID-19

Got it (b) (5)
(b) (5)

Jeff

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@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. (b) (5)

(b) (5)

(b) (5)

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 <Joseph.J.Grogan@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 <Joseph.J.Grogan@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

(b) (5)
(b) (5)

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

(b) (5)

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" <Deborah.L.Birx@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 (yenpottinger@gmail.com) <yenpottinger@gmail.com>; 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

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: 829-471-9186

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 [Deborah.L.Birx@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 <Deborah.L.Birx@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 over (b) (4) tests to labs across the US. Please feel free to call with any questions. 224-430-0870.

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: 4/15/2020 1:40:26 PM
To: McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@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 <Joseph.J.Grogan@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: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 4/7/2020 5:08:54 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
Subject: Re: COVID 19 Rx Options as of Mar 19 2020.pdf

Thank you.

Sent from my iPhone

On Apr 7, 2020, at 8:31 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

I thought you all might want to see this URL related to therapies.
thanks
Steve

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Date: April 3, 2020 at 12:57:28 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: COVID 19 Rx Options as of Mar 19 2020.pdf

Public list of ongoing trials. jw

><https://www.biocentury.com/clinical-vaccines-and-therapies><

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 4/1/2020 12:32:04 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: FW: Materials for 12:30 PM meeting
Attachments: 04-01_RDV_Strategic_Update_vFF[1].pdf

From: Thomas, Ashley <Ashley.Thomas@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 12:02 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Materials for 12:30 PM meeting

Ashley Thomas

Executive Assistant to Dr. Janet Woodcock
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
WO 51, RM 6131
(301) 796-6413

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/26/2020 2:48:50 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: HESI Testing Proposal

Thanks

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 25, 2020 at 6:04:55 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: HESI Testing Proposal

We tried that almost no takers. The governors are going to have to make them.

Sent from my iPhone

On Apr 25, 2020, at 3:30 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

My apologies. I am going through my inbox now.
Wanted you to be aware.
Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 24, 2020 at 1:34:10 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: HESI Testing Proposal

Dr. Cyril Pettit, Executive Director of the Health and Environmental Sciences Institute, wanted to pass along a draft proposal from them and some of their colleagues on a national testing program for consideration by the WH TF, or interested members, and, hence. One of their proposals involves leveraging non-CLIA certified labs to expand testing capacity. I'm sharing it with you in case it would be informative for the TF's deliberations.

<CalltoAction-v5cleaner.docx>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/30/2020 6:33:31 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; 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-]
Subject: Fwd: Serology Studies in Germany

Interesting information from Germany

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 30, 2020 at 5:46:27 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Serology Studies in Germany

FYSA regarding serology studies being conducted in Germany, including status of tests to be used for those studies. This is the follow up to what I sent you last week (b) (5)

(b) (5)

From: Hoshi, Ryan <Ryan.Hoshi@fda.hhs.gov>
Sent: Thursday, April 30, 2020 3:17 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Louati, Claudia (FSN)* <Claudia.Louati@fda.hhs.gov>; O'Leary, Brendan <Brendan.O'Leary@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: FW: PLEASE REVIEW >> Meeting Notes - Call with Prof. Krause

(b) (5)

(b) (5)

(b) (5)

Thank you,
Ryan

Ryan A. Hoshi, Ph.D.

International Policy Analyst | Center for Devices and Radiological Health | ryan.hoshi@fda.hhs.gov | phone 240.402.5242 | mobile

(b) (6)



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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/23/2020 5:37:27 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; 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=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: Re: Serology Test Calculator

We've approved 4 EUAs and will probably approve another 4 in the next 24-48 hours. We'll have the NCI data to add into the mix. We're moving along on the consortium which can really help us gather data on testing performance and results

Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 21, 2020 at 4:06:03 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>
Subject: Re: Serology Test Calculator

(b) (5)

Deb

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Tuesday, April 21, 2020 at 3:23 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Fauci, Anthony S (NIH)" <(b) (6) @niaid.nih.gov>, "Redfield, Robert R (CDC)" <olx1@cdc.gov>, "Giroir, Brett (OS)" <Brett.Giroir@hhs.gov>
Subject: Fwd: Serology Test Calculator

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 20, 2020 at 6:26:14 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Serology Test Calculator

Attached is a very rudimentary calculator that you are welcome to share with the WHTF/HHS serology WG to calculate the positive predictive value and negative predictive value of individual serology tests and the use of two tests by plugging in the known or estimated sensitivity, specificity, and population prevalence of COVID-19 (b) (5)

(b) (5)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/22/2020 12:55:26 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: OWS Tx Update - 21MAY2020
Attachments: OWS_Weekly WH HHS briefing materials_v3 - TX only.pptx

FYI

From: Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Date: May 21, 2020 at 8:43:15 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: OWS Tx Update - 21MAY2020

Dr. Hahn,

Attached please find a weekly update on the therapeutics workstream within Operation Warp Speed, led by Dr. Woodcock. Dashboard pages are up front with some more detailed pages in the appendix. We have not been requested to share these with the WH yet, but wanted to have them ready and give you a chance to review in the event the request came down tomorrow or over the weekend.

The password for the file is (b) (6)

Please let us know if you have any feedback. Thanks,

Kevin Bugin, MS, PhDc, RAC
Director, Special Programs
CDER/OND

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/14/2020 8:42:19 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: CDC/FDA Serology Test Document

FYSA

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: May 14, 2020 at 8:39:57 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: CDC/FDA Serology Test Document

Maybe (b) (5)

(b) (5)

Jeff

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Thursday, May 14, 2020 8:24 AM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: CDC/FDA Serology Test Document

Jeff and Anand

(b) (5)

thoughts?

Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: May 13, 2020 at 11:57:10 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: CDC/FDA Serology Test Document

Here's the draft document with testing recommendations and the "cheat sheet".

Jeff

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 5/5/2020 6:16:52 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: Re (b) (5), (b) (4)

THANK YOU

From: "Marks, Peter" <Peter.Marks@fda.hhs.gov>
Date: Tuesday, May 5, 2020 at 5:52 AM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Grogan, Joseph J. EOP/WHO" <Joseph.J.Grogan@who.eop.gov>
Subject: RE (b) (5), (b) (4)

Dear Ambassador Birx,

(b) (5)

Best Regards,
Peter

From: Marks, Peter
Sent: Monday, May 4, 2020 8:57 PM
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Subject: (b) (5), (b) (4)

Dear Ambassador Birx,

Just to get back to you after speaking to several different individual vaccine development experts familiar with this area. They all consider the (b) (5), (b) (4)

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

(b) (5), (b) (4) It is felt that (b) (5), (b) (4)

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

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

Very happy to discuss this further if you would like. Have a good evening.

Best Regards,
Peter

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Monday, May 4, 2020 4:43 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>

Cc: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>

Subject: Re: (b) (5)

(b) (5)

From: "Marks, Peter" <Peter.Marks@fda.hhs.gov>

Date: Monday, May 4, 2020 at 1:36 PM

To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>

Cc: "Grogan, Joseph J. EOP/WHO" <Joseph.J.Grogan@who.eop.gov>

Subject: RE: (b) (5), (b) (4)

Dear Ambassador Birx,

It was my pleasure to bring you up to date, and I really am looking forward to keeping you and others fully updated as things progress.

In response to your question (b) (5), (b) (4)

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

Just to follow-up on another question from the other day, some of those vaccine experts not (b) (5), (b) (4)

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

Hope that information is helpful. Please feel free to contact me at any time. If you ever need to reach me urgently:

Work cell (b) (6)

Personal cell (b) (6)

Home phone (b) (6)

Best Regards,
Peter

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

Sent: Monday, May 4, 2020 11:11 AM

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

Cc: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>

Subject: (b) (5), (b) (4)

Peter

Thank you for taking the effort to bring me up to speed last week – you were incredibly patient.

(b) (5)

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 4/25/2020 12:44:02 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: John P RADM USN JS J4 Polowczyk [john.p.polowczyk.mil@mail.mil]; Gaynor, Pete [pete.gaynor@fema.dhs.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Kushner, Jared C. EOP/WHO [jck@who.eop.gov]
Subject: Re: MOFCOM new policy on export Medical supplies

Huge. Thank you

Sent from my iPhone

On Apr 25, 2020, at 12:42 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

I'm sure you all are aware of this good news.
Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 25, 2020 at 10:14:29 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: MOFCOM new policy on export Medical supplies

FYSA

From: Sutton, William <William.Sutton@fda.hhs.gov>
Sent: Saturday, April 25, 2020 10:07 AM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>; Hoshi, Ryan <Ryan.Hoshi@fda.hhs.gov>
Cc: Sutton, William <William.Sutton@fda.hhs.gov>; Marrero, Felix <Felix.Marrero@fda.hhs.gov>; King, Lisa M <LisaM.King@fda.hhs.gov>
Subject: FW: MOFCOM new policy on export Medical supplies

Good morning all,

Some good news overnight coming out of China. The Ministry of Commerce (MOFCOM) published an update to China's export policies that went into effect on April 1 and April 10. In short, if the manufacturer has FDA registration, they **are not** required to also have NMPA registration certification for the medical products used for the COVID-19 response. The shipper must signed a declaration that the medical product meets the foreign country's requirements. China Customs will then verify the registration information on the MOFCOM list.

The announcement is in two parts:

1. Non-medical masks
2. COVID-19 virus test reagents, surgical masks, medical protective gowns, ventilators, and infrared thermometers

With help from Lisa King (CDRH R&L), I ran these reports last week and the LES at the FDA China Office transmitted the spreadsheets to CCCMHPIE.

I will monitor this in real-world use and with consultation with Mission China. I have two calls on Monday night with Beijing. If I receive additional information over the weekend, I will share with all.

Have a great weekend!

Bill

Bill Sutton 萨盾

International Program and Policy Analyst, Medical Devices

国际项目和政策分析官员 (医疗器械)

FDA China Office

Office of Global Policy and Strategy

U.S. Food and Drug Administration

美国食品药品监督管理局驻华办公室

Tel: +1 (240) 478-1639

William.Sutton@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

From: (b) (6) (Beijing) (b) (6)@state.gov>

Sent: Saturday, April 25, 2020 8:58 AM

To: Simonds, Robert J (CDC) <rxs5@cdc.gov>; Sutton, William <William.Sutton@fda.hhs.gov>

Cc: (b) (6) (Beijing) (b) (6)@state.gov>; Gabrel, Celia <Celia.Gabrel@fda.hhs.gov>; Shaw-Dore, Vanessa <Vanessa.Shaw-Dore@fda.hhs.gov>; Robinson, Latasha A <Latasha.Robinson@fda.hhs.gov>

Subject: MOFCOM new policy on export Medical supplies

Dear RJ:

Julia and Bill from FDA China Office worked hard to coordinate with CCCMHPIE on the medical supplies export. Today, MOFCOM published an announcement. This will be very helpful for the Embassy tasks.

The MOFCOM and GACC and NMPA issued announcement to further strengthen the quality of export medical supplies. The Chinese version is available at ><http://www.mofcom.gov.cn/article/b/e/202004/20200402958960.shtml>< .

1. Strengthen the supervision on export non-medical use masks quality.

Since April 26, 2020, all masks for non-medical use shall meet either Chinese quality standards or the overseas countries quality standards.

MOFCOM confirmed the list of firms who gained overseas certification or registration as non-medical use masks (update at web >www.cccmhpie.org.cn<); list of unqualified non-medical use masks in domestic market provided by NMPA (updated by NMPA at >www.samr.gov.cn<); the importer and exporter joint statement when non-medical use masks export firm submit declaration to Customs (attachment 1), confirm the product meet either Chinese quality standards or overseas countries quality standards, the importer accepts the quality standards and will not use the

product for medical use; Customs will verify and release according to MOFCOM firm list. For the firm which is not in the NMPA list, Customs will accept declaration and then verify and release.

For purchase order signed before April 26, 2020, the importer and exporter joint statement (attachment 1), electronic or written, shall be provided when apply for declaration.

2. Further orderly the export of medical supplies.

Start from April 26, 2020, the firms whose products gained oversea countries certification or registration on COVID-19 virus test reagents, surgical masks, medical protective gowns, ventilators, and infrared thermometers shall submit written statement (attachment 2) when apply for declaration. The firm statement commits the products meet import country or region's quality standards and safety requirement. The Customs will verify and release according to the list of firms who gained oversea countries' certification or registration (update at web www.ccmhpie.org.cn) provided by MOFCOM.

The above export product quality supervision measures will be updated along with the trend of this pandemic.

Thanks.

(b) (6)

Sent via the Samsung Galaxy S8, an AT&T 4G LTE smartphone

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@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=0f1ab650905f424381ffbddd983419fcd-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" <Deborah.L.Birx@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 <Deborah.L.Birx@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)

Jeff

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 <Deborah.L.Birx@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)

Thanks for any info you could provide.

Steve

From: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Sent: 4/21/2020 1:41:42 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: RE: FYI: Information request to ANSM on CV risks from chloroquine/hydroxychloroquine

Give me a call when you can.

(b) (5)

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, April 21, 2020 1:40 PM
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Subject: RE: FYI: Information request to ANSM on CV risks from chloroquine/hydroxychloroquine

Yes and I called (b) (5) and left him a message.

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 21, 2020 at 1:33:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: FYI: Information request to ANSM on CV risks from chloroquine/hydroxychloroquine

Anything from the new York data yet?

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, April 21, 2020 12:24 PM
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Subject: FW: FYI: Information request to ANSM on CV risks from chloroquine/hydroxychloroquine
Importance: High

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: April 21, 2020 at 12:15:50 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: FW: FYI: Information request to ANSM on CV risks from chloroquine/hydroxychloroquine
Importance: High

FYI

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Tuesday, April 21, 2020 12:14 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: FYI: Information request to ANSM on CV risks from chloroquine/hydroxychloroquine
Importance: High

From: Kim, Sarah <Sarah.Kim@fda.hhs.gov>

Sent: Tuesday, April 21, 2020 11:34 AM

To: Booze, Kristen <Kristen.Booze@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Subject: FW: FYI: Information request to ANSM on CV risks from chloroquine/hydroxychloroquine

Importance: High

Fyi, French Health Ministry is planning to issue a press release on HCQ/CQ for COVID-19 and cardiotoxicity (attachment below). Their message is in line with the DSC. I've shared this with OCOMM and OND leadership, so they are aware.

Thanks,
Sarah

From: Eby, Michelle <Michelle.Eby@fda.hhs.gov>

Sent: Tuesday, April 21, 2020 10:12 AM

To: Kim, Sarah <Sarah.Kim@fda.hhs.gov>

Cc: CDER OSE OCT <CDEROSEOCT2@fda.hhs.gov>

Subject: FYI: Information request to ANSM on CV risks from chloroquine/hydroxychloroquine

THE INFORMATION AND ATTACHMENTS IN THIS EMAIL IS BEING SENT TO YOU UNDER THE TERMS OF OUR CONFIDENTIALITY ARRANGEMENTS AND IS NOT TO BE SHARED OUTSIDE OF FDA.

Hi Sarah,

Last Monday, we asked EMA for info on a press release from ANSM (Health Ministry of France) on risks from chloroquine/hydroxychloroquine for COVID-19. EMA initially sent two presentations in French. When I asked if English translation was available, EMA sent me a draft of their pending communication. See attached document which they shared under our confidentiality agreement.

Their message is pretty consistent with ours.

You may already have a copy of this (or perhaps they will be sending soon as I understand that they share with us before publication).

I don't know where our draft DSC is in clearance. Feel free to share with OND.

Thanks, Michelle

Michelle Eby, B.S., Pharm.D, CCRP.

Outreach and Communication Team

Office of Surveillance and Epidemiology

FDA-Center for Drug Evaluation and Research

Bldg 22, Room 4422

Office: 301-796-4714

Email: Michelle.Eby@fda.hhs.gov

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 [Deborah.L.Birx@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 <Deborah.L.Birx@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.

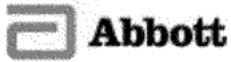
Below is the guidance sent to FEMA along with our data.

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.

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 224-430-0870.

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: 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 <Deborah.L.Birx@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 <Deborah.L.Birx@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 <Deborah.L.Birx@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" <Deborah.L.Birx@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 ship 150K tests upon approval. Make another 432k by 3/23 and another 432k by 3/26. And then in April 1MM tests / week.

So far as of 3/22 we have made the 150K tests and physically shipped 149k.
We have 110 Hospital/Labs that have our analyzer. 94 of them said yes, they will purchase tests, 76 have already placed a purchase order (which totals 890k) and 27 accounts have received tests and have began testing.

We did make the 432k tests from yesterdays commitment and we will begin to ship those.
Robert B. Ford
(510) 452-7181

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 make significant progress over the weekend, but as you have probably seen I have not been able to submit the EUA today as per our internal plan. After reviewing the hour by hour plan, I feel very confident this will be submitted this Thursday the latest. The team has informed me that there has been a lot of

contact with the FDA reviewer over the weekend also. We will follow the same protocol as we did with the high throughput system and share/submit parts of the studies as they become available.

We have also initiated a serology test on the 13th, to develop a high throughput IgM and IgG for antibody detection. Our plan is to be able to start shipping those tests to all of our lab and hospital customers by end of April.

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On a final note, a good portion of the high throughput analyzers that we got approval for the COVID-19 test are hooked up to the AbbottLink system. So we have real time information about the amount of tests conducted and results etc. As soon as I have a report tomorrow, if you are interested I can share with whoever is appropriate.

Best,

Robert B. Ford
(510) 452-7181

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