APHL/CDC COVID-19 National PHL Call

May 20, 2020

Call Summary

Main Contact Emails

CDC Emergency Operations Center (EOC) Contact: 770-488-7100

CDC Respiratory Virus inbox: respvirus@cdc.gov

APHL EOC Contact: eoc@aphl.org

APHL Informatics Contact: informatics.support@aphl.org

Slides from the call are available here.

Welcome (*Scott Becker, APHL*)

APHL emailed the state PHL Directors with the respective points of contact (POC) for federal testing subject matter experts (SMEs), FEMA, CDC and state laboratory SME; please see Lab Alert #47 for additional information. If your state PHL Director did not receive this email, or if you have additional questions, please email eoc@aphl.org.

APHL appreciates your continued cooperation with the weekly phone surveys. The survey data is shared on a weekly basis with HHS, CDC, the White House and the IRR, among others, to prioritize supply orders, allocate supplies and inform the procurement strategy. The aggregate data is also shared with Congress and the media to demonstrate the PHL efforts in the COVID-19 response.

APHL has entered a partnership with Amazon to allow APHL member labs to access a special COVID-19 supply store created for first responders. Amazon designed the COVID-19 Supplies store as a service for healthcare and government organizations. Although some inventory is limited, they have hundreds of items related to protective apparel, disinfectants and diagnostic equipment. In order to purchase from the store, your lab must have an Amazon Business account (free to register) and you will need your lab's or agency's CCN (Medicare/Medicaid certification number) or NPI (National Provider Identifier) number. Links to the store and access instructions can be found in the Laboratory Director ColLABorate Community and Laboratory Alert #48.

Situational Awareness Update (*Joel Montgomery, CDC*)

As of May 19, 2020, the COVID-19 situation is as follows:

- Globally there have been more than 4.7 million cases and over 316,000 deaths.
- In the US, there have been more than 1.5 million cases and over 90,000 deaths.
- In the US, cases are slightly trending downward but this varies from state to state.
- The national rate of positivity has decreased from 15% in mid-April to 7% as of this week.

CDC Lab Team Update (*Vicki Olson, CDC*)

CDC is finalizing data for submission to the FDA for a new EUA for a multiplex influenza A, influenza B and SARS-CoV-2 assay. CDC plans to have this submission ready in the next week or two; further details are forthcoming. CDC is also asking that PHLs that have used MTM transport media with the CDC assay reach out to CDC with their data and experience.

IRR Update (*Erica Guthrie, CDC*)

IRR has added the new extraction lysis buffers that were described on last week's call to the IRR catalogue. For the QIAGEN buffer, the old catalog number (ER-33) has been replaced by ER-37. The new QIAGEN buffer will not include the carrier RNA. The new Roche extraction buffer will still be available under the OR-2 catalog number. Both IRR pages for the new extraction buffers will link to the manufacturer letters that indicate the formulation and manufacturing processes of these new products are equivalent.

IRR is still reviewing Roche orders once per week. Please submit orders by Wednesdays at 8pm EST. IRR continues to encourage PHLs to consider alternative extraction reagents; the QIAamp Viral RNA Mini Kit and EZ1 Virus Mini Kit v2.0 are well stocked.

Finally, if PHLs are collaborating with other laboratories in the state, please let IRR know so that we can work together to ensure the right amount of reagents are being allocated to the PHL.

FDA Update *(Tim Stenzel, FDA* and *Sara Brenner, FDA*)
On May 14, the FDA issued a press release on the Abbott ID NOW regarding its updated intended use and limitations. Of note, a negative result on the ID NOW is now a presumptive negative and should be reflexed to another molecular assay at the discretion of the provider. Abbott has agreed to work with the FDA on several post-market studies to evaluate the test's performance. If the post market performance does not meet the minimum 80% sensitivity, then FDA will take the appropriate action.

NRCC Update (*Jessica Roach, HHS*)
The NRCC Taskforce continues to work with states to distribute Abbott ID NOW and TaqPath kits. This week, each state (plus DC, Puerto Rico, New York City and LA County) will receive 54 ID NOW test kits and 3 controls; these should arrive by May 25 at the latest. The Thermo TaqPath reagents have already shipped and should arrive by May 22 for those who requested these supplies. The Taskforce will continue to follow up weekly on Thermo requests through June to confirm orders. After June, TaqPath kits should be available for purchase on the commercial market.

As a reminder, state testing plans are due to HHS by May 30, 2020.

Questions & Answers
Q: When can we expect the post-market Abbott ID NOW results to be available?
A: Abbott will publish the data as soon as the studies are completed.

Q: When will the NCI serology evaluation data be published?
A: These data will be published as soon as regulatory decisions are made. FDA has been working through a large number of submissions and will post results on the FDA website in the near future.

Q: Is the rapid boil-prep extraction protocol available? Have further evaluations on this method been performed?
A: Mississippi shared their rapid boil extraction method with APHL, and it is available on APHL's Laboratory and Testing Resources site. CDC is also looking at a heat treatment procedure and has submitted an amendment to their EUA (still under review at FDA).

Q: Is CDC looking at saliva as an alternative specimen type for their assay?
A: CDC is designing studies to examine alternative specimen types, including saliva. They will evaluate the performance of saliva before moving forward with an amendment to the EUA.

Q: For supply allocations from HHS, is it possible for states to find out what is being sent ahead of time?
A: States can reach out to their POCs using the contact list APHL shared earlier in the week.

Q: Is CDC developing a multiplex assay for influenza and COVID-19?
A: Yes, CDC is developing a multiplex assay for Influenza A, Influenza B and SARS-CoV-2 and an EUA will be submitted in the next few weeks.

Q: For the CDC multiplex influenza and COVID-19 assay, will CDC consider the KingFisher or Chemagic extraction platforms for the EUA?
A: CDC is exploring multiple platforms but will most likely move forward with single platform on the initial EUA and then bridge to others in the future.

Q: Is a physician's order required to run a COVID-19 EUA assay?
A: Currently all EUA assays require either a prescription for use , a statement regarding the restriction to sale by or on the order of physician, dentist, veterinarian or with the descriptive designation of any other practioner liscensed by State law. In other words, State licensing laws must be consulteted to determine who can order an EUA authorized COVID assay.

Q: Will states be notified in advance of ThermoFisher shipments?
A: Yes, states will get an automated email from ThermoFisher to the POC email address that was provided on the original spreadsheet. If you are not getting those emails, please reach out to your state's FEMA representative.

Q: Can local clinical laboratories request supplies from IRR?
A: No, at this time, IRR is focused on providing resources to state and local PHLs.