APHL/CDC COVID-19 National PHL Call

April 29, 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

Welcome (*Scott Becker, APHL*)

APHL is creating a light version of the Epidemiology and Laboratory Capacity (ELC) guidance document to aid PHLs with developing their ELC CARES applications. APHL is also developing a joint document with CSTE on public health considerations for serology testing, as well as organizing a webinar with Abbott regarding the ID NOW. If there are other documents or products PHLs would like to see, please let APHL know.

APHL would like to thank everyone for being responsive to our weekly COVID-19 testing survey calls. These calls are important as they are helping to inform regional supply needs and prioritization.

PHL COVID-19 Capacity Summary (*Lorelei Kuriski, APHL*)

APHL has been reaching out to 100 PHLs on a weekly basis to gauge their COVID-19 laboratory capacity and capabilities and help inform supply prioritization. To date, there has been an 88% response rate. APHL is working on a dashboard that will be available soon to display the information collected. The full data summary can be found here.

Situational Awareness Update (*Greg Armstrong, CDC*)

The current situation in the US is as follows:

- As of April 28, 2020, the US has surpassed 1 million cases, with 57,000 deaths.
- The overall trend of cases in the US is down slightly, however, these trends vary by state. There are 12 states where the incidence of disease is coming down, 17 states where the trend is unclear, and 22 states in which incidence is still increasing.
- The US is performing 150,000 tests each day.
- The national rate of positivity has decreased from 20% (April 21) to 15% (April 28).
- CDC's National Syndromic Surveillance System Biosense platform and the National Hospital Surveillance Network have been useful at both the national and state level to track trends in COVID-like illness and healthcare utilization.

CDC Lab Team Updates *(Brandi Limbago, CDC)*

CDC has been participating in the state calls to address testing and reagent needs. These calls are focused on the entire state and are not specific to PHLs.

Although plans to expand IRR have been discussed on previous calls, final decsions have not yet been made. PHLs should continue to work through IRR for their reagents and reference the IRR FAQs for the list of currently available reagents and supplies.

CDC just learned that the swab allocation process is moving back to FEMA. Public health laboratories should be in touch with their FEMA contact to learn more about how the process will work in your state. CDC will be removing swabs from the IRR catalog on April 29, 2020: orders received through April 29, 2020 will be fulfilled.

CDC is evaluating a boil-prep extraction method and is planning to submit data to the FDA for an amendment to the EUA very soon.

IRR Update (*Erica Guthrie, CDC*)
As a reminder, IRR has posted an FAQ under "quick links" on the IRR website. FAQ #12 provides a full list of IRR supplies for COVID-19 testing with links to the product pages. The table also lists where items are shipping from and the frequency of shipments. Abbott ID NOW and Roche reagents will be reviewed once per week. Please place your orders by the following deadlines:

- Abbott ID NOW: orders due Tuesdays at 8 pm EST.
- Roche Reagents: orders due Wednesdays at 8 pm EST.

IRR will be consolidating the number of communications sent to PHLs. Moving forward, PHLs will get three emails regarding orders from IRR: one automatic email confirming the order is received, one email confirming what items from the order that IRR is able to fulfill, and one email from the vendor when the materials ship.

FDA Update *(Tim Stenzel, FDA* and *Sara Brenner, FDA*)
FDA has updated their FAQ page to include several new EUA authorizations as well as an additional extraction option. On April 28, 2020, FDA also issued a new "umbrella" pathway for serology tests that are being evaluated by the multi-agency partnership at NCI. Additional information, including the performance metrics being used to evaluate these tests, can be found here. FDA is still investigating the best way to publicly release the testing data on these serology tests.

FDA is continuing to work on data harmonization under the SHIELD project. If laboratories are interested in participating, please email shield-labcodes@fda.hhs.gov.

Informatics Update *(Michelle Meigs, APHL)*
Since March 1, 2020, nearly 500,000 HL7 messages have been sent through the PHLIP feed. APHL and CDC are still available to help migrate laboratories onto the PHLIP feed or to upgrade their HL7 messaging.

APHL continues to work with CDC on coding; there are 31 PHLIP codes currently available and the list will be continually updated as new assays roll out. If your laboratory has coding or implementation questions or needs assistance validating your messages, please email informatics.support@aphl.org.

APHL is enrolling the next cohort for the laboratory web portal connection project that will begin May 8, 2020. States that are interested can contact informatics.support@aphl.org or Michelle Meigs directly for more information. The implementation process has been simplified to two options:

- Option 1 (non-STARLIMS states): batch upload route. There is an upload function from the laboratory web portal to your LIMS system. This route will take 12-15 days to implement and does require a bit of laboratory and IT staff time.
- Option 2 (STARLIMS states): bi-directional sync service. This is an extension of your existing LIMS system and is an automated sync service.

PHL Experience
Pixel Home Collection Overview (*Brian Krueger, LabCorp*)
Brian Krueger, Associate Vice President, Technical Director, R&D, provided an overview of LabCorp's COVID-19 testing implementation and the recently approved Pixel collection kit for at-home testing. The slides from the presentation are available here.

Platform Diversification and Mobile Testing (*Tony Tran, Washington DC Public Health Laboratory*)
Tony Tran, Director of the Public Health Laboratory at the DC Department of Forensic Sciences, provided an overview of the DC PHL's testing implementation timeline and methods, in addition to discussing some of their unique approaches to testing, which include walk-up testing and a mobile testing unit.
The slides from the presentation are available here.

Questions & Answers
Q: Is CDC looking into saliva as a possible specimen type for use with the CDC assay?
A: CDC has not yet looked at saliva as an alternative specimen type. FDA guidance allows laboratories to conduct bridging studies if laboratories are interested in using saliva as a specimen type.

Q: Has CDC looked into the difference between analytical and clinical sensitivity for COVID-19? Has CDC ever looked at the sensitivities of the various swab types for COVID-19?
A: CDC has not published data on the sensitivities of different swabs for COVID-19. The list of acceptable swab and VTM types on FDA's website is based on the reality of the situation with supply shortages, not an ideal testing environment. If there is substantial concern regarding sensitivity, CDC recommends laboratories use the most sensitive collection site for testing. NP and OP swabs combined have the best sensitivity, but if only collecting one specimen type, NP is the most sensitive.

Q: The current EUA is approved for symptomatic patients; how are we supposed to test asymptomatic individuals?
A: We do not currently know the asymptomatic carrier rate or have regulatory data for this. Developers that want to claim test use on asymptomatic patients should provide data to FDA. In the meantime laboratories should follow the assay's intended use claims as outlined in the instructuions for use.

Post-call clarification from CDC: For the CDC assay, the intended use was specifically crafted to permit testing on people meeting clinical AND/OR epidemiologic criteria for testing. This was specifically to allow testing of individuals who do not meet the clinical definition. For the CDC assay, people do not have to be symptomatic to be tested. If they do not have symptoms, they simply must have an epi link of some sort. Some of the other EUA assays are more restrictive but CDC's allows for a bit more flexibility.