APHL/CDC COVID-19 National PHL Call

June 3, 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 has several announcements:

- APHL will be announcing the date for the virtual APHL 2020 conference soon. The member assembly, which usually takes place during the annual conference, will be held at the top of the June 17th COVID-19 National PHL call.
- Last week APHL leadership met with HHS to discuss the utility of antigen testing. APHL has added a question on antigen testing to the weekly survey and plans to have an antigen considerations document available in the near future.
- On June 1, 2020, FDA issued an amendment for the Abbott ID NOW COVID-19 assay. Negative results are now considered presumptive and should be reflexed to another molecular platform if signs and symptoms dictate.
- For at least the month of June, these calls will remain weekly.

Situational Update (*Joel Montgomery, CDC*)

The current COVID-19 situation is as follows:

- Worldwide, there have been more than 6.2 million cases of COVID-19 and over 300,000 deaths.
- The Pan American region has the greatest number of cases; Europe has the greatest percent of cases.
- The US has surpassed 1.8 million cases and 105,000 deaths. The number of confirmed cases is decreasing in 18 states, remains stable in 17 states and is increasing in 18 other states. As of June 2, 2020, 67,000 healthcare workers have been infected with 331 deaths.
- The US has performed over 17 million tests with an overall positivity rate of 12.2%.

CDC Lab Team Update (*Wendi Kuhnert, CDC*)

CDC is working with FDA on an amendment to the EUA that will allow additional testing flexibility, including the updated lysis buffers (chemically identical to the current QIAGEN and Roche buffers, just manufactured on a different production line). These changes should be final and posted in the next few days.

CDC Influenza/SARS-CoV-2 Multiplex (*Dave Wentworth, CDC*)

Dave Wentworth, Chief, Virology Surveillance and Diagnosis Branch, presented on the CDC SARS-CoV-2/influenza multiplex assay, "FLU SC2". Advantages of the multiplex assay include a three-fold increase in testing capacity compared to the current panel and the ability to identify co-infections. The assay will target conserved and expressed regions of the viral genomes – the M gene for influenza A, NS gene for influenza B, and existing targets plus the 3' terminus of SARS-CoV-2. There will be a single manufacturer for primers and probes (IDT) and they will be provided in a two-tube kit format (one tube for all primers, another tube for all probes).

CDC is currently drafting an EUA submission for FDA. The initial assay will be for use with the ABI 7500 Fast Dx, two rRT-PCR enzymes kits (Taqpath and Quantabio-1 step), and three extraction platforms (QIAGEN EZ1, QIAGEN QiAmp viral mini kit, and Roche Magna Pure 96) using upper or lower respiratory tract specimens. The EUA will include guidance for bridging to alternative extraction platforms.

IRR Update (*Erica Guthrie, CDC*)
IRR has observed a slow-down in the pace of ordering. Many laboratories have moved to a biweekly schedule of ordering; IRR encourages laboratories to place orders in anticipation of testing needs in order to maintain a steady distribution of orders. Most orders have been shipping within one or two days of receipt.

IRR's current stock of 96-well plates come in sleeves that are 10x larger than usual. These are used in a 1:2 ratio with the sealing film. The QIAGEN AVL lysis buffer with no carrier RNA (IRR catalogue number ER-87) is used in a 1:11 ratio with the EZ1 kits.

Roche reagents are still in limited supply; IRR will continue to try and distribute them equitably so that everyone receives some of their order.

Note: For July 4th shipments: IRR will not ship temperature-sensitive reagents after June 30, 2020. Please keep this date in mind as you plan your ordering over the next few weeks.

FDA Update *(Tim Stenzel, FDA and Sara Brenner, FDA*)
On June 1, 2020, FDA released an amendment to the Abbott ID NOW EUA. New instructions for use and an updated letter of authorization are available on the FDA webpage.

The FDA has now authorized 15 serology tests. A list of the authorized serology tests with links to their instructions for use can be found on FDA's emergency use authorization page. For the serology assays undergoing evaluation by NCI, they will have a separate NCI report on the serology performance page along with any final regulatory decisions.

As FDA previously noted, certain types of transport media are not compatible with all testing platforms. Media containing guanidine thiocyanate can react with bleach on certain platforms leading to the formation of cyanide gas. Prime Store MTM, Zymo DNA/RNA shield, and the Spectrum collection device should NOT be used with the Hologic Panther or Panther Fusion systems (or any other system using bleach). Some transport media is not be distributed with the proper labeling and FDA is working with manufacturers to rectify this. Please see the FDA FAQ for a full list of alternative collection recommendations and their limitations.

NRCC Update (*Jessica Roach and Rachel Kellogg, HHS*)
The NRCC Taskforce updates are as follows:

- The Federal Government continues to distribute swabs, transport media, Thermofisher TaqPath reagents and Abbott ID NOW kits to PHLs for use and distribution within their states. The Taskforce is still working with manufacturers on forecasting supply production over the next year.
- FEMA will continue to ship MTM through the month of June. These shipments will contain the cautionary guidance on MTM usage on certain platforms.
- The taskforce is currently reviewing the state and local jurisdiction testing plans that were submitted on May 30. The taskforce will have feedback for states and jurisdictions by late next week. Testing plans for July will be due June 15.

Questions & Answers
Q: Do laboratories need to submit a new EUA if they wish to use a different sample type (i.e. saliva) than what is included in an existing EUA?

A: FDA would not require and EUA for a laboratory developed test for using saliva. However, FDA would encourage EUA submissions as they have observed variable performance with saliva. Laboratories can evaluate saliva in parallel using an EUA approved specimen type. FDA recommends a minimum of 30 samples to ensure you can achieve a comparative performance of at least 95%. Additional information can be found in FDA's Molecular Diagnostics Template for Manufacturers.

Q: When does CDC anticipate the SARS-CoV-2/influenza multiplex assay being released?
A: CDC has not yet submitted the full EUA to FDA for review. CDC does not have a definite timeline but hopes to have the materials to FDA for review by mid-June, with approval by mid-late July. FDA will make this a top priority for review.

Q: Is there data available on testing of asymptomatic individuals using less invasive specimen types, such as nasal swabs?
A: FDA is working on a template update for validation recommendations for asymptomatic usage. If a developer wants to make a claim about performance in the asymptomatic population, they should seek an EUA.

Q: Will the multiplex SARS-CoV-2/influenza assay replace the existing SARS-CoV-2 assay? Will the multiplex assay be available through IRR?
A: CDC envisions both the original assay and multiplex assay being available for a while; one may be eventually phased out depending on usage. The multiplex assay will be distributed through IRR.

Q: Would CDC propose a new testing algorithm during flu season for influenza/SARS-CoV-2?
A: CDC is working with APHL's Influenza and Respiratory Pathogens Subcommittee to identify what guidelines may be needed.

Q: Has there been consideration for a review of false-positives from the GeneXpert, similar to the review and updated amendment of the Abbott ID NOW?
A: FDA monitors complaints and anything submitted to the MedWatch program. Aside from the ID NOW, FDA has not seen consistent complaints with any of the EUA authorized molecular devices. FDA is not aware of any issues with the Cepheid GeneXpert producing false positives. If you have observed issues, please let FDA know.