APHL/CDC COVID-19 National PHL Call

May 6, 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 continues to communicate with federal leadership to discuss and advocate for PHL supply needs. While the plan for distribution of testing supplies remains fluid, AHPL hopes to learn more in the coming days. FEMA has already started to deliver supplies to the central locations in states and Hologic plans to start distributing research use only reagents for the Panther TMA assay soon. State-level reagent allocation is being determined by White house; lab-level distribution is being determined by the state. APHL encourages all PHLs to take an active role in the development of state testing plans.

APHL will be hosting two webinars this week-- COVID-19: Biosafety on the Frontlines and ID NOW Platform: COVID-19. Please refer to Lab Alert #43 for more information.

Finally, APHL wants to remind states of the AIMS Laboratory web portal solution. PHLs should consider this opportunity, especially STARLIMS states, due to the ease of implementation; the APHL informatics team is available to support the adoption of the platform.

CDC Lab Team Updates *(Wendi Khunert, CDC)*

Effective 4/29/2020, the IRR will no longer be distributing swabs. States that placed orders with the IRR for swabs prior to that date will have their order fulfilled. FEMA will be distributing swabs to the states, some of which will arrive in bulk. CDC has updated their specimen handling guidance to include information on how to handle bulk swab shipments. The updated specimen handling guidelines also reiterate that when collecting nasal mid-turbinate, deep nasal or nasal swabs, both nostrils should be swabbed with the same swab.

CDC is working to update their website with additional guidance on point of care (POC) testing, including, but not limited to, the Abott ID NOW.

Finally, CDC has received several questions on the testing of asymptomatic individuals and whether that is covered under the CDC assay EUA. From the perspective of CDC, the language in the instructions for use is broad and covers both patients who meet either clinical criteria for COVID-19 and/or epidemiologic criteria (i.e. case contacts, travel history, public health investigations etc.). At this point, CDC does not have a lot of data on symptomatic vs. asymptomatic testing, however they believe that the CDC assay is sensitive enough to pick up most asymptomatic infections.

Summer Influenza Surveillance Update (*Rebecca Kondor, CDC*)

Becky Kondor, Research Microbiologist, Influenza Division provided a brief overview of the 2019-2020 influenza season in the US, as well as the National Influenza Reference Center (NIRC) submission procedures for this

summer. The NIRC guidance is the same as last summer, except that on May 11 submission will transition to a single NIRC: all 2020 summer surveillance samples should be shipped to the Wisconsin State Laboratory of Hygiene.

IRR Update (*Erica Guthrie, CDC*)
FEMA is now handling the distribution of swabs. Roche reagents and consumables remain in limited supply; IRR asks that PHLs please consider QIAGEN extraction reagents as an alternative since their supply chain is more stable. IRR is reviewing Roche orders once per week (please submit order by Wednesdays at 8pm EST). IRR also asks PHLs to consider alternative enzymes from Taqpath as there are several other companies with sufficient supply. For shipping information, IRR encourages PHLs to reference IRR's FAQ document, which specifies when PHLs can typically expect reagents to arrive after ordering. Items with an ER catalog number are typically shipped within two business days of the order.

FDA Update *(Tim Stenzel, FDA* and *Sara Brenner, FDA*)
FDA updated their serology policy in response to a number of concerns regarding fraudulent or underperforming tests. This change primarily effects kit developers and not laboratories; laboratories can continue to offer laboratory-developed tests (LDTs) with voluntary EUA submission. The new policy states that all kit manufacturers must submit an EUA within ten days of notifying FDA of their test or within ten days of the guidance update, whichever is later. FDA has also developed minimum performance metrics for serology tests. FDA has published a list of EUA authorized serology tests along with their performance metrics. FDA is currently in process of evaluating several additional serology tests with the NCI program. Once results are available and FDA has made a decision on the test, FDA will release the performance data on their website. FDA will be delisting pathway D tests if an EUA application is not submitted in accordance with the new policy or if the performance of test is not satisfactory.

FDA has updated their FAQ page to address the use of EUA authorized molecular tests for screening asymptomatic individuals. Manufacturers or laboratories interested in authorization for testing asymptomatic cases can contact FDA at CDRH-EUA-Templates@fda.hhs.gov to discuss study design or to submit their data.

Informatics Update (*Krista Kniss, CDC*)
CDC would like to remind all PHLs to map any LDTs or commercially available tests to their PHLIP messages. If you have any questions or need assistance, please reach out to Krista Kniss or the APHL informatics assistance team.

HHS/NRCC (*Tammy Beckham, HHS*)
Over the last few weeks, the NRCC taskforce has been working with manufacturers and states in order to help allocate testing supplies. Some states have already started to receive the swabs and media that has been sent out. CDC sent an email to the governors' offices, and it is expected to also go out to state health officials. This email included helpful documents including a PowerPoint with technical assistance information for states, an FAQ document, and point of contact information. The taskforce anticipates sharing more information with states in the next few days on supply allocation and the development of the state testing plans.

Questions & Answers
Q: How will Hologic kits be allocated to the states? Will Hologic kits come through the IRR?
A: Per the NRCC, states will get a certain allocation of Hologic kits. The amount of kits will be based on what laboratories have previously ordered from the manufacturer/the placement of the manufacturer's instruments in each state. These items will not be distributed through the PHL; Hologic will work directly with the receiving laboratories.

Q: Some clinical laboratories had their Hologic Panther orders cancelled, do you know why?
A: The NRCC recommends reaching out directly to Hologic to inquire why the order was cancelled. It could be related to the allocation for the state.

Q: Are the Abbott ID NOW devices that were given to the states property of the state or the end user?
A: The devices are the property of the end user.

Q: Is there an update on the boil-prep extraction method? We heard CDC was reviewing it.
A: CDC has been reviewing the Mississippi protocol and data and are considering an update to their EUA.

Q: Will the state be supplying Hologic Panther supplies to local laboratories?
A: Laboratories will get Panther supplies directly from the manufacturer but the allocation will depend on the state testing strategy.

Q: Is the CDC going to update their EUA to include the Quant Studio Dx or ABI 7500?
A: CDC is not presently seeking an amendment to add either of those instruments to their EUA. However, FDA has listed those instruments among those which laboratories may qualify for their own use. CDC will not object if a laboratory takes advantage of FDA's suggestion to use these alternative instruments.

Q: Is there an update on the usage of 3D printed swabs?
A: Information on 3D printed swabs will be forthcoming. FDA has been trying to determine what regulatory mechanisms, if any, are needed for these. FDA is not looking to stand up an EUA process for 3D printed swabs.

Q: Should laboratories continue to provide a disclaimer on test result reports for asymptomatic individuals?
A: FDA never required a disclaimer, but if you want to include one in the results, that is fine. Until there is more data, a negative result may not mean much for an asymptomatic individual.

Q: Will serology tests that are delisted be required to notify their customers? Will customers of delisted tests be refunded?
A: FDA will provide a list of delisted manufacturers on their website for transparency. As for refunds, FDA is unsure of how those will be handled. FDA would suggest contacting the manufacturer directly.

Q: Are there any approved PCR tests for asymptomatic individuals?
A: To FDA's knowledge, there are no molecular assays authorized for use specifically in an asymptomatic population.

However, the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel EUA Instructions for Use specifies that the assay may be used in accordance with CDC Testing Guidance, which allows for testing ersons **without** symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans.

Q: If the information communicated to CDC from the state designated POC is inaccurate, what is the process for updating that information for supply allocation purposes?

A: The PHL should communicate this information to the state diagnostics POC, including if the PHL is planning to add additional instrumentation that would affect supply allocation. The IRR will continue to operate as it has, and IRR allocations should continue to grow.

Note: APHL is attempting to get further clarification on who the Diagnostics POC is in each state and will communicate that to you as soon as possible.

Q: Will Cepheid kits be available to order through IRR?

A: There is currently a very limited supply of tests kits available for order through IRR. Currently the USAPI are being prioritized for receipt of that limited supply. CDC is working with Cepheid on procuring additional stock for IRR.