APHL/CDC COVID-19 National PHL Call

May 13, 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 canceled APHL's ID Lab Con 2020 from August 11–13, 2020, in Atlanta, GA. APHL will reschedule this important event in 2021 and is looking at possible dates.

APHL also wants to bring to your attention that stock of Perkin Elmer extraction kits are currently available on the IRR. We understand that there have been a number of questions around supply allocation, which is also why we have Brad and Tammy on the call.

Federal Effort to Support Laboratory Supply Chain (*Brad Smith, CMS* and *Tammy Beckham, HHS)*

Over the last few weeks, the National Response Coordination Center (NRCC) taskforce has been working to scale up testing efforts across the US in the following four ways:

1. Distributing specimen collection supplies to states.
2. Working with manufacturers to ensure equitable distribution of laboratory testing supplies for states.
3. Assisting with the deployment of CDC personnel across the US.
4. Distributing CDC guidance.

The federal government is collaborating with manufacturers to produce swabs, transport media and collection tubes, with plans to distribute over 12 million swabs and 10 million vials of transport media during May and June. The NRCC has been working with FEMA regional offices to assign a central location in each state for delivery of these materials. States should develop a plan to distribute the supplies as they see fit. The allocation of supplies to each state was determined by their state testing goals. At a minimum, all states will be receiving enough supplies to serve 2% of their population.

Each state will be receiving a variety of swabs and media. Each state will get the same percentage of each variety based on their total allocation number. Certain states have requested more of certain types of materials, but at this time, the NRCC cannot accommodate different allocation requests.

There have been several questions about the swabs that US Cotton provided and the packaging that was used. Clarifying information has been sent out that indicates that these swabs are the FDA approved spun polyester swabs.

There are multiple types of transport media being provided to states, including sterile saline, VTM and MTM. Some states will be receiving multiple shipments of these supplies over the next week or two as distribution is scaled up. Distribution will transition to a weekly schedule.

The procurement of laboratory testing supplies is slightly different than specimen collection materials. The federal government is working with each state and the manufacturer to make sure they are provided with enough testing materials to test their targeted testing volume. There are multiple points of contact in both federal and state government that can be reached out to for additional information or assistance. The NRCC is also working to ensure the IRR stays stocked, as well as working with IRR to distribute Abbott ID NOW test kits to the PHLs.

SPHERES (*Duncan MacCannell, CDC*)
Duncan MacCannell, Chief Science Officer for CDC's Office of Advanced Molecular Detection, provided a brief overview of SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance (SPHERES). The new initiative was launched at the beginning of the month to support the SARS-CoV-2 response.

Updates to CDC EUA (*Laura Rose, CDC*)
CDC has submitted additional external lysis buffers to be added to the CDC 2019-nCOV Real Time RT-PCR Diagnostic Panel EUA. The new external lysis buffers are chemically identical to the current QIAGEN and Roche buffers, just manufactured on a different production line. Letters from the companies verifying that will be available on IRR's website as well as APHL's COVID-19 Laboratory Testing Resource.

The new QIAGEN and Roche buffers will be given alternative catalogue numbers in the IRR; CDC will get further information out in writing to states shortly. CDC submitted their EUA amendment request to FDA on May 3. The Instructions for Use should be updated soon. Effective immediately, these new lysis buffers may be used with the CDC SARS-CoV-2 diagnostic panel. Because these products are chemically identical to the original lysis buffers, CDC does not feel that a full verification with the new component is necessary and that lot to lot verification will suffice.

IRR Update (*Erica Guthrie, CDC*)
IRR will add the new extraction buffers to the IRR catalogue shortly. For QIAGEN, the new buffer will not include the carrier RNA. The IRR site will automatically redirect to the page for the new product once the current item runs out. For Roche, they are adding an additional production line, so IRR will get allocations from both the existing and new lines. They will be offered under a single catalog number, but IRR will let you know which version you receive for traceability. IRR is still reviewing Roche orders once per week.Please submit orders by Wednesdays at 8pm EST. IRR also encourages PHLs to consider alternative enzymes from Taqpath as there are several other companies with sufficient supply. Additionally, alternate QIAGEN extraction reagents are available, including the QIAamp Viral RNA Mini Kit and EZ1 Virus Mini Kit v2.0.

Beginning last week, there will be a uniform allocation of 50 Abbott ID NOW kits and 6 controls to each state. IRR and CMS are reviewing the current guidance on external controls and may update the guidance as more information becomes available.

FDA Update *(Tim Stenzel, FDA* and *Sara Brenner, FDA*)
On May 15, 2020 from 1-2 pm EST, FDA will host a Town Hall on the production and use of 3D-printed swabs and the COVID-19 response. More information and call details can be found on the FDA website. On April 11, 2020, FDA updated the templates for EUA guidance. FDA continues to update their FAQ page as well.

Note: FDA has not yet granted an EUA for the Hologic Panther TMA assay. However, Hologic has been granted permission to distribute RUO reagents in the interim and laboratories may implement the assay by conducting a bridging study and not a full validation as is normally required.

LOINC mapping has been posted on CDC's DLS website. Questions can be directed to Shield-labcodes@fda.hhs.gov.

Questions & Answers

Q: Who are the points of contact that labs can reach out to for additional information on the NRCC testing allocations?

A: At the federal level, states will be provided with specific points of contact from CDC, FEMA and for Specimen Collection and Laboratory Supplies. At the state level, the points of contact include the governor, the state health officer, the state epidemiologist, the State Logistics POC and the State Lab Diagnostics POC.

Q: For states that contain major cities, such as NYC, how will the allocation of supplies be determined?

A: The allocation is determined at the state level with one distribution site in each state. The NRCC expects states to work with their cities and counties to distribute the supplies equitably.

Q: Are the types of test and/or quality and performance characteristics of tests being considered when determining their allocation?

A: Point of care (POC) tests such as the Cepheid and ID NOW are in highest demand. There are also certain places where Cepheid is the only testing platform; those sites got the majority of Cepheid kits. For the ID NOW, IRR is distributing these to PHLs who can determine the most appropriate use case.

Q: Do you have guidance for states on how to distribute their allocation of ID NOW kits since PHLs are now responsible for distributing these materials to the entire state?

A: It is up to the states to determine the best allocation of ID NOW test kits including to those testing sites that did not receive one of the ID NOW instruments deployed by HHS This is a departure from previous guidance which indicated those kits were only intended for the issues delployed by HHS. PHLs may now distrubte the kits as best serves their state's testing priorities. There are multiple use cases for the ID NOW, for example, to rural hospitals or critical care sites, long-term care facilities, correctional facilities, for a new cluster of cases, etc. CDC has guidance on their website on POC testing.

Q: Do you have input from laboratorians on what materials are being sent to states? Are states able to provide feedback before materials are shipped?

A: All of the supplies being sent to states are FDA approved. Different laboratories may have different materials they are able to use with different states and it is up to the states to determine which location can use what supplies. NRCC provided each state an FAQ document that addressed this and other questions. APHL will continue to work with NRCC to provide clarifty on expectations, correct points of contact and ways to improve communication all around.

Q: QIAGEN DSP extraction reagents are still not available on IRR, are we able to get them directly from the manufacturer?

A: QIAGEN DSP extraction reagents continue to be a product that the IRR does not have. However, QIAGEN has an equivalent product that is available with the IRR, the QIAGEN EZ1 Virus Mini Kit v2.0.