APHL/CDC COVID-19 National PHL Call

May 27, 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*)

Over the weekend, HHS released their COVID-19 strategic testing plan to Congress. The plan discusses the response to date, testing supply needs, the need for flexibility in the regulatory process and lessons learned from our current work.

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

Update from HHS Assistant Secretary for Health (*Admiral Brett Giroir, HHS*)

The first COVID-19 strategic testing plan was released to Congress over the weekend. This plan lays the groundwork for the future of the response. HHS will be working with CDC to review the state testing plans; HHS wants to ensure that appropriate distribution and testing plans are in place, especially for underserved populations.

HHS continues to acquire and ship testing materials such as swabs and transport media to states. In May, HHS plans to ship 12.9 million swabs. Moving forward, HHS plans to procure 20 million swabs and 20 million tubes of transport media per month. HHS continues to try to direct manufacturing to the degree they can; HHS is working with Cepheid on the allocation of test cartridges, Abbott on the production of ID NOW kits, and Quidel on a plan to potentially procure Sofia 2 instruments.

Moving forward, HHS wants to work more with PHLs. HHS is considering is using PHLs as centers of excellence in evaluating new technologies or conducting translational research. Additional funding for limited instrumentation grants are also being considered.

CDC Serology Testing Efforts (*Lyle Petersen, CDC*)

On May 18, CDC began to pilot a large-scale antibody study of healthcare and other frontline workers in New York City and Detroit. The purpose of the study is to determine antibody prevalence among this population and to stratify the data by specific occupation, PPE usage and other factors. The sample size is 120,000 in New York City and 20,000 in Detroit. The study is utilizing the Ortho-Clinical Diagnostics IgG antibody test. Aliquots from each participant will be sent to CDC in case of future testing needs. CDC is adding Rhode Island to the pilot study in the next few weeks.

CDC Lab Team Update: CSTOR Overview (*Valerie Albrecht, CDC*)

CDC has developed a process to improve specimen submission- the CDC Specimen Test Order and Reporting (CSTOR) web portal. CSTOR is an online portal for infectious disease partners for specimen test orders, reporting and other supporting materials. Please see the slides for more information.

CDC EUA Updates (*Laura Rose, CDC*)
CDC plans to distribute a multiplex assay for Influenza A, Influenza B and SARS-CoV-2 this summer. The first EUA submission will have one PCR instrument (ABI 7500 Fast Dx), three extraction methodologies (QIAGEN EZ1, QIAGEN QIAmp Viral Mini Kit and Roche MagNa Pure 96) and three master mixes (two TaqPath master mixes and the Quantbio 1-step test mix). All research use only (RUO) alternative reagents added to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel will be included in the initial EUA request. CDC recognizes that not everyone's preferred extraction method is in the initial EUA but felt that earlier access for PHLs should be prioritized. Additional extraction methods will be added as amendments following the initial release.

IRR Update (*Erica Guthrie, CDC*)
IRR orders and processes remain the same. IRR is still reviewing Roche orders once per week; please submit Roche 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. QIAGEN DSP kits are the only products that remain temporarily out of stock.

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*)
The FDA has several updates to report:

- There have been questions about what FDA uses as comparator assays when it reviews EUA packages. For evaluation of direct antigen assays, FDA requires comparison to a high sensitivity assay. For molecular assays authorized early in the pandemic, when samples were not available, FDA allowed evaluation with contrived samples. Embedded in all letters of authorization is requirement for developers to, upon FDA request, test with designated reference material.
- FDA's Center for Biologics Evaluation and Research (CBER) has been working to create reference panels. This week, FDA plans to start a pilot program to send a small number of developers these reference materials with the intention to make this program widely available.
- The FDA FAQs have been updated. There are two new FAQs on data and reporting and the Beckman RNAdvance Viral XP has been added to the list of acceptable extraction platforms to use with the CDC EUA assay.
- FDA has removed 29 serology kits from the serology pathway D notification list.
- The May 15, 2020 town hall on 3D printed swabs is now available on the FDA website, including audio and other webinar materials.

Questions & Answers

Q: How is HHS comparing the different testing platforms? Many of the non-peer reviewed articles in circulation are confusing clinicians. Is there consideration of CDC or other academic affiliates performing additional testing review?
A: HHS will consider this proposal. HHS has also asked the FDA to start posting the sensitivity and specificity data for all EUA nucleic acid and antigen tests. HHS is also working with FDA on grouping tests by best use scenarios and specifying advantages and limitations of each test.

Q: Does HHS have any advice on how to better integrate electronic messaging in the medical community?
A: Now is a good time to push for additional funds and support for this effort. HHS would be interested in a short white paper on this topic if a PHL was willing to write one.

Q: Will the Roche MagnaPure lysis buffer be available through IRR?

A: The MagnaPure lysis buffer is available through the IRR as product number OR-2. The IRR FAQ lists all available products with links to their webpages for ordering.

Q: Will local laboratories be able to use the CSTOR web portal?
A: Right now, only state PHLs can onboard the portal, but CDC is considering expanding access to local laboratories at a later time.