APHL/CDC National PHL Call
2019-nCoV

April 15, 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 launched a telephone survey on April 13 that aims to better inform IRR on what materials laboratories are using for COVID-19 testing. As of April 14, 59/99 PHLs had responded. If you have not yet done so, please respond to APHL and complete the survey. We will be following up weekly with brief phone calls.

On April 15, the APHL Board of Directors met with FDA leadership to discuss serology testing and some of the concerns PHLs have. FDA has committed to working with other federal partners such as BARDA and NIH to evaluate and monitor the serology tests that are on the market. If PHLs have concerns about fraudulent serology tests, they can email FDA-COVID-19-Fraudulent-Products@fda.hhs.gov. When emailing the FDA, please also CC eoc@aphl.org.

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

CDC wants to emphasize the importance of the APHL phone survey; CDC will use the survey to help allocate resources to PHLs. CDC also wants to reiterate the importance of properly labeling specimens and their paperwork when shipping to CDC for testing. It is critical that CDC get two patient identifiers on the tubes and forms so that they do not have to reject specimens.

CDC has also updated their guidance on specimen collection; however, they continue to receive questions on swabs. CDC has not evaluated foam swabs directly and would usually defer commenting, but at this point, they do not see why foam swabs wouldn't work and encourage laboratories interested in using foam swabs to consult the FDA FAQ for further information. If the laboratory chooses to adopt foam swabs, CDC encourages them to do a small study on their usage before integrating them fully into their testing workflow.

IRR Update (*Erica Guthrie, CDC*)

As of April 9, IRR has added a number of new catalog items. IRR is currently working on adding an FAQ page under the quick links that will address a number of the questions they have been getting as well as list all of the products currently available on IRR related to COVID-19 testing.

IRR is also modifying the way they ship products to laboratories. In the past, everything went through their contractor in Virginia. In order to ship more quickly and avoid bottlenecks, some materials will now ship directly from the manufacturer in their original packaging. Laboratories will still order through the IRR and IRR will coordinate the shipment with the manufacturer on behalf of the laboratory. IRR has updated the prefix system to reflect these shipping changes: "ER" materials will ship from the old contractor site while other prefixes reflect new shipping sites. The new FAQ document will list all these prefixes and indicate where the product is

shipping from. Regardless of where the materials ship from, there should be a slip in the box indicating that the order is on behalf of IRR.

IRR also has a number of updates on specific materials and manufacturers:

- Roche: they still continue to have supply chain issues with their consumables. IRR is working to get additional materials allocated to the US.
- QIAGEN: they are continuing to send EZ1 kits to IRR as they become available. Right now they are focusing their capacity on the QIAamp line since it is easier and faster to scale up in the short-term. Again, as IRR continues to get materials they will release them for order.
- CDC testing kits: IRR has moved away from the Biosearch and IDT manufactured kits. The ER-35 primer/probe sets will again be distributed by CDC and will contain positive control. Laboratories that are using the old kits from Biosearch and IDT that do not contain positive control will still be able to order positive control a la carte from IRR, but moving forward positive control will be included in primer/probe kit orders.
- Swabs: IRR has started taking requests for swabs, which will come in packages of 100 (kitted with VTM), and hopes to start shipping shortly. Demand for these far exceeds supply so the number requested by each laboratory may not be immediately available.

Responses to Technical Questions (*Steve Lindstrom, CDC*)
Question: How to handle NP swabs with residual blood?
Answer: It is not uncommon for NP swabs to have a small amount of residual blood on them. CDC has not seen any issues with residual blood inhibiting the performance of the CDC assay.

FDA Update *(Tim Stenzel, FDA* and *Sara Brenner, FDA*)
FDA has authorized two additional serology assays on April 14: Chembio and Ortho-Clinical. The Chembio test is a rapid test while the Ortho-Clinical test is for high volume testing. Additionally, Abbott has notified FDA that they are working on an IgG assay.

FDA also authorized additional molecular tests this week in addition to granting the first EUA using saliva to Rutgers University. Rutgers modified the ThermoFisher assay in conjunction with the Perkin Elmer Extraction platform and has seen good performance with their saliva specimens. To date, FDA has seen mixed data on saliva, so they are not sure if the Rutgers EUA will be broadly applicable, but FDA has seen interest from manufacturers in adapting the Rutgers method into a home kit.

FDA also has updates on biosafety, serology and 3D printing:

- Initially the FDA FAQ said PrimeStore MTM transport media could be used with all of the EUA platforms, however, FDA recently discovered that the Hologic Panther utilizes bleach, which when mixed with MTM can produce cyanide gas. FDA warns to not use PrimeStore MTM with the Hologic Panther or Panther Fusion Systems.
- Abbott has been notified of sensitivity issues with ID NOW that appear to be associated with the use of VTM. Abbott is updating their labeling to remove the use of VTM from their test; laboratories should use the direct-swab pathway only when testing on the ID NOW platform.
- FDA is working with several other federal partners to offer manufacturers pursuing pathway D the option to have their tests evaluated at NCI. FDA hopes this will streamline the pathway to EUA for a number of these serology tests.
- FDA has been looking into 3D printing of testing materials, including swabs, and intends to provide guidance shortly.

CMS Update *(Regina Van Brackle, CMS)*
As a reminder, during this PHL emergency, CMS is exercising enforcement discretion. Laboratoriesdo not need a separate certificate for temporary testing sites provided that the primary site has a CLIA certificate and the work being done at the temporary site falls under the certificate. The temporary testing site can only perform testing consistent with existing certificate and under the CLIA lab director and they must follow the manufacturer's instructions and quality controls.

For tests categorized as waived, or point of care, laboratories only have to follow the manufacturer's instructions for quality control (IQCP does NOT apply). The Abbot ID NOW requires positive and negative controls to be run with each new shipment and once for each new trained operator.

On March 23, CMS issued survey (proficiencyt testing) prioritization guidance and will revisit the need to continue to prioritize surveys after 3 weeks. This prioritization will remain in effect until otherwise notified. Therefore surveys will continue in accordance with March 23 guidance.

HHS Diagnostic Taskforce (*Carl Newman, HHS*)
There are a number of statistics that HHS wants to share with PHLs:

- As of April 14, the US has performed 2.9 million COVID tests. Community-based testing sites have screened over 84,000 people and tested over 70,000 for COVID-19.
- HHS continues to work with IRR to secure materials, including the Abbott ID NOW test kits. To date, they have distributed over 500,000 tests and are trying to get an additional 30,000 tests to IRR for distribution each week.

Informatics Update *(Michelle Meigs, APHL)*
Lab Alert #36 contains links to two PHLIP encoding guidelines. The informatics group continues to work to keep up with and get ahead of manufacturer EUAs so that their tests can be included in the standardized encoding.

CDC would like laboratories to consider adding test-kit information to their messaging. Information on how to do this can be found in Lab Alert #36 and the APHL informatics team can provide assistance.

The electronic test order and result (ETOR) option is still open; there is an updated reminder in Lab Alert #36. To date, 18 PHLs are in the process of implementing. .

PHL Experience: Approaches to Addressing Biosafety Concerns with the Abbott ID NOW
Iowa State Hygienic Laboratory (Mike Pentella)
Iowa has deployed 13 Abbott ID NOW instruments, with two sites currently up and running. Before deployment, Iowa assessed the biosafety aspects of the instrument as it is an open platform to ensure splash and splatter risks were minimized. The Iowa PHL informed each deployment site that they needed to perform a risk assessment as well as evaluate where they placed the instrument. They suggested that the ID NOW be placed in a a biosafety cabinet (BSC), if available. For sites that did not have a BSC, they recommended placing the ID NOW on a benchtop away from other work and that the individual performing the testing should be in full PPE, including respiratory protection, and to work behind a splash shield. For the two sites that are testing, one has a BSC while the other is using the full PPE/splash guard method. They have not received any negative feedback from any of the 13 sites on these biosafety guidelines.

New York City Public Health Laboratory (Scott Hughes)
The NYC PHL received 15 Abbott ID NOWs and is still evaluating them. They have the same biosafety concerns as Iowa and would also recommend using the devices in a BSC. The NYC PHL also had concerns about the

receiving/elution buffer – there is little data on virus inactivation. They have also provided specific guidance on bio-waste and developed a training to show how to properly dispose of used cartridges.

Questions & Answers
CDC has a new workgroup that is evaluating how non COVID programs have been affected during the response. APHL would like feedback from PHLs about what critical, non-COVID-19 lab work is not getting done due to the response, and to let APHL know if they need assistance from CDC. CDC may be able to provide support for some non-COVID testing.

Q: Should PHLs do a full validation of pathway D serology tests before using the test in their laboratory? If during the validation testing or at any point in using a pathway D test it does not perform as specified, what should a PHL do?
A: Even though pathway D tests do not have an EUA, they are expected to be validated by the manufacturer and should perform as advertised. It is still prudent to do some level of verification before putting it into service, however FDA doesn't expect laboratories to do a full validation. If you experience any issue with a pathway D test you can report it to FDA through the MedWatch program.

Q: On last week's call a boil method for extraction was mentioned, has that laboratory shared the protocol yet and if so, can APHL share it?
A: APHL has posted the method shared by Mississippi PHL on our COVID-19 Laboratory and Training Resources site.

Q: When our laboratory goes to put in an order on IRR it will not let us add items to the basket, what is the issue?
A: If the item is listed as temporarily out of stock, it can't be added to your cart. IRR is not taking orders on materials that are out of stock/back ordered right now. IRR suggests looking at alternative reagents for other platforms if preferred is not available.

Q: Moving forward, will IRR stock sequencing reagents (e.g. for Illumina)?
A: IRR has received several inquiries for products and is considering these, however they do not have immediate plans to stock sequencing reagents.

Q: Is Iowa recommending N95 or regular masks for PPE when using the Abbott ID NOW?
A: Iowa is recommending regular masks as that is what is available at the sites. The splash shield will provide additional protection.

Q: We understand that there are a limited supply of Abbott ID NOW reagents, however, our laboratory put in an order for 500 kits and got 4.
A: IRR is currently receiving 200-400 kits total per week from Abbott; it is not possible to send 500 kits to any one laboratory at this time. HHS and FEMA are working ard to secure additional supply.

Q: Can clinical laboratories or hospitals order ID NOW materials directly from Abbott? Multiple states have heard that clinical sites and hospitals should order from the PHLs through IRR.
A: Clinical laboratories should go through the commercial market and order directly from Abbott. IRR is focused on providing reagents to PHLs. CDC will follow up with Abbott again to make sure this messaging is clear to their local sales representatives.