

APHL/CDC National PHL Call 2019-nCoV

March 25, 2020

Call Summary



Main Contact Emails

CDC Emergency Operations Center (EOC) Contact: 770-488-7100

APHL EOC Contact: eoc@aphl.org

Welcome (*Scott Becker, APHL*)

APHL updates from the last week:

- On March 20th, APHL, in conjunction with ASTHO and CSTE, [published a letter that specified criteria for testing prioritization](#).
- APHL is updating its [webpage](#) with member-only resources
- APHL continues to monitor supply chain issues and material shortages. If you are experiencing issues (especially with Qiagen) please let APHL know at eoc@aphl.org.
- APHL participated in a teleconference with the White House and 150 other non-profits; supply chain issues were discussed on the call.

Legislative Update (*Peter Kyriacopoulos, APHL*)

An overview of the money allocated to the coronavirus response thus far (all of this is additive):

- \$10 million provided to states through the Epidemiology and Laboratory Capacity (ELC) agreement, and \$25 million through the Public Health Emergency Preparedness (PHEP) agreement
- First supplemental provided \$2.2 billion in aid, \$950 million in direct grants and cooperative agreements to CDC. CDC has 30 days to disburse funds to state and local health agencies.
- Second supplemental gave \$1 billion to entities providing healthcare services.
- Third supplemental has passed the senate and is now on the way to the house. The current senate version of the supplemental has \$4.3 billion in aid to CDC, with \$1.5 billion going to states and \$500 million for data modernization efforts.

Situational Awareness and Laboratory Update (*Joe Bresee, CDC; Brandi Limbago, CDC; and Kirsten St. George NYSDOH*)

Situational Awareness

- As of March 25 there are over 54,000 confirmed cases, 10,000 of which have been reported in the last 24 hours.
- Half the total number of cases from the last 24 hours come from either New York City or New York State.
- There are 9 -10 states that are in the acceleration phase of spread; there are very few states in the US without community spread at this point.
- Most new cases worldwide are occurring in the US and Europe.

CDC will be focusing the next few days on healthcare security and the evaluation of community mitigation measures. CDC wants to ensure that healthcare workers have the supplies and guidance to do their jobs. CDC also wants to look at the community mitigation data and see which strategies are working.

Laboratory Update

CDC recently received a new shipment of primer and probe kits manufactured by BioSearch that is larger than the previous kit (1,000 rxns/kit). CDC is also aware of the continuing supply chain issues around ancillary components and continues to work with manufacturers such as QIAGEN to increase their supply for public health laboratories (PHLs). If your state has particular issues or suggested strategies for how resources could better be allocated to your state and local laboratories, please let CDC know.

CDC is planning to make several updates to the emergency use authorization (EUA), including the addition of 3 new master mix options, which CDC hopes to submit to FDA by March 26. Once the new master mixes are approved, they will be available for ordering through IRR. CDC also updated the [guidance for specimen transport and approved specimen types](#).

When collection of a nasopharyngeal swab is not possible, the following are acceptable alternatives:

- An oropharyngeal (OP) specimen collected by a healthcare professional, or
- A nasal mid-turbinate (NMT) swab collected by a healthcare professional or by onsite self-collection (using a flocked tapered swab), or
- An anterior nares specimen collected by a healthcare professional or by onsite self-collection (using a round foam swab).
- For NS, a single polyester swab with a plastic shaft should be used to sample both nares. NS or NMT swabs should be placed in a transport tube containing either viral transport medium, Amies transport medium, or sterile saline.

If both NP and OP swabs both are collected, they should be combined in a single tube to maximize test sensitivity and limit testing resources.

Some of the reasons CDC has chosen to expand to these specimen types is to reduce the use of PPE (these new sample types require less PPE) and to allow for self-collection.

- CDC has also been reviewing alternative transport media options and swabs. Based on the initial data, it does not appear that saline negatively impacts the ability of the CDC assay to detect the virus and CDC lists viral transport medium, Amies transport medium, or sterile saline as acceptable transport media on its website.

Finally, CDC has received several questions on the appropriate storage conditions for the primer and probe sets. If your PHL has the CDC labeled kits that arrived lyophilized, the package insert has the storage and instructions for use; these are specific to the CDC labeled material. There are also RUO materials made by IDT and Biosearch that have different instructions for use made by the specific manufacturer; these should be used with their product. If you continue to have concerns about the CDC kits, please let CDC know, and if you have issues with the IDT or Biosearch products please let them know.

New York State Evaluation of alternative swabs and media

The New York State Department of Health (NYSDOH) is running several studies on alternative swabs and collection media. NYSDOH has collected roughly 500 specimens and anticipates a 25-30% positivity rate among the specimens. The specimen types include nasal swabs, saliva and NP swabs; nasal turbinates were not collected because of the limited supply of the specific swab type. NYSDOH anticipates publishing the data on the specimen type evaluation but will share the preliminary data with everyone as soon as it is analyzed. Of note, the initial data shows that saliva does not appear to be a good alternative-specimen type. NYSDOH is also working with commercial companies in the validation of their COVID-19 assays as well as working in-house on multiplexing the assay.

Informatics Update (Krista Kniss, CDC)

CDC is working on data visualizations of shared data to put on the CDC website. CDC is pulling data that comes through the PHLIP feed as well as other aggregate data that is reported to CDC from commercial laboratories and other sources.

FDA Update (Sara Brennen, FDA)

States can continue to check the [FDA FAQ](#) for updated policies and guidance. Please relay questions to APHL at eoc@aphl.org.

CLIA and CMS Responses to Questions (Regina Van Brakle, CMS)

- State PHLs are being approached by other laboratories that want to perform COVID-19 testing; can any laboratory perform the test?
 - *No, laboratories need a CLIA certificate to perform COVID-19 testing.*
- Do laboratories need to validate alternative swab types or media before they use them?
 - *CMS will be issuing formal guidance on this in the next few days.*
- Do state executive orders suspending requirements for CLIA lab testing override federal CLIA rules?
 - *No. States can have rules that are more stringent than CLIA but not less. States with more stringent rules can suspend those requirements that are above CLIA but they cannot suspend CLIA.*

CDC Responses to Technical Questions about the CDC Assay (Steve Lindstrom, CDC)

CDC has received several technical questions this week from laboratories:

Extraction system lysis buffer:

- The lysis buffer used with the assay must be guanidinium-based for stabilization and inactivation of the specimen. If you are interested in alternative lysis buffers, you need to carefully evaluate the chemistries of the buffer for guanidinium content.
- In previous studies with other viruses and this buffer, the specimens were stable for months. While CDC doesn't have stability data just yet on this specific virus, CDC thinks that samples will be stable in the lysis buffer for at least a week at 4°C. Of note, make sure the buffer has not crystalized in the fridge before proceeding through extraction.

RLT buffer:

- CDC has not yet evaluated the RLT buffer. CDC is looking at other extraction kits.

Sensitivity and Specificity:

- Given that this is an EUA, the data on sensitivity and specificity are limited. However, the [instructions for use](#) do give clinical performance data beginning on page 39. The clinical performance data were evaluated against genetic sequencing and viral culture.

Biosearch RUO kits

- Several laboratories have asked what the rehydration volume is for Biosearch RUP kits as it is not indicated in the package insert. If you are using the Biosearch RUO kits, 1.5 ml of water is required for reconstitution. Because these are primer and probe sets, multiple freeze/thaw cycles are not recommended.

Inconclusive results

- Per the package insert, if a laboratory has one target with a high Ct positive and the other target is negative, the laboratory can repeat the test and, if necessary, recollect a specimen for testing. If laboratories experience a pattern of inconclusives or if they are getting results where one target is negative and the other is positive with a Ct value less than 35, they can contact respvirus@cdc.gov and CDC will work to get some sort of validation panel to the laboratory so they can evaluate the situation. Inconclusive is an acceptable result to report; this result happens regardless of the assay when you have low viral load in the sample.

VTM guidance

- The VTM guidance of 3 mL in the instructions for use is guidance, not a requirement. When CDC updates the instructions for use, they will change the VTM guidance to 1-3 ml, which should allow for flexibility.

PHL Experience: Washington State (*Romesh Gautam*)

The Washington State PHL has been performing testing since February 28th. They were able to ramp up capacity very quickly and are now able to perform tests on over 400 specimens a day using the CDC assay. There are currently about 35 staff members involved in testing, 7 days a week. They are processing samples from 6 am to 11 pm, which allows for social distancing in the laboratory as well as flexibility for the staff who have home responsibilities. Over the past few weeks the Washington State PHL has been working with Microsoft to develop an electronic test ordering system, which they hope will be live by the end of the week. Additionally, they have had two CDC fellows deployed to the PHL, which has been immensely helpful. Over 2,500 tests have been performed to date and they continue to reach out to try and figure out how to increase their capacity.

Questions & Answers

Q: Our laboratory has seen both N1 and N2 aberrant activity; does CDC have any guidance on when a sample goes from a weak positive to negative upon testing repeat?

A: CDC expects to see this result when samples have a low viral load; the interpretation of this result is one that the laboratory will have to make. A negative result does not preclude infection and CDC has put out additional [guidance on time-based isolation without repeat testing](#) in order to conserve resources. Of note, in cases where the patient has a productive cough, sputum can be more positive than other sampling sites, so CDC recommends collecting sputum for further testing.

Q: Does CDC have any guidance on pooled testing?

A: Pooled specimen testing has not yet been evaluated by CDC, however, CDC cautions against pooling specimens as there is an inherent dilution factor that occurs with this method.

Q: Are we able to use Aptima unisex collection kits? Can we use saline for transport of NP/OP swabs?

A: CDC has not yet addressed particular manufacturers of swabs but CDC has described the necessary characteristics a swab should have. If the Aptima swabs meet those characteristics they should be fine. Saline is an acceptable alternative transport medium for all specimen types.

Q: CDC has said that saline is an acceptable alternative transport media while CMS said they will be issuing guidance on this shortly, what should laboratories do?

A: CMS will be releasing guidance in the next day or so that will address this issue.

Q: Is the saline that is approved for transporting specimens 0.9% or 0.85%?

A: CDC uses 0.85%, others have used 0.9%; those differences in concentration don't seem to make a difference.

Q: Our laboratory has received an influx of requests to evaluate serology tests that are not currently being categorized by FDA. CLIA says they are high-complexity tests; will there be FDA guidance coming out on who can perform these tests?

A: APHL will follow up on this question.

Q: What import certification is needed on the swabs coming from China?

A: APHL will follow up on this question.

Q: Will the CDC assay EUA be relaxed so that laboratories can use the ABI Fast in addition to the ABI Dx?

A: CDC does not plan on evaluating any additional platforms at this time.

Q: What is the specificity and sensitivity of CDC EUA assay?

A: The assay [instructions for use](#) detail the clinical evaluation data starting on page 39 that address performance data available for the assay.