

APHL/CDC National PHL Call COVID-19

March 18, 2020



Call Summary

Main Contact Emails

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

FDA Hotline: 1-888-INFO-FDA

APHL EOC Contact: eoc@aphl.org

Welcome (*Scott Becker, APHL*)

Due to the ongoing COVID-19 outbreak and response, APHL will be canceling its June 2020 Annual Conference in Portland, Oregon. With the Annual Conference being canceled, APHL hopes that many laboratorians will be able to attend APHL's newest conference, [ID Lab Con](#), which is scheduled for August 2020 in Atlanta, Georgia.

Please note that over the weekend, several new emergency use authorizations (EUAs) were granted to companies including Roche, Thermofisher, Hologic and Quidel over the weekend. More information can be found on FDA's website on [FAQs on Diagnostic Testing for SARS-CoV-2](#).

Situational Awareness Update (*Stephanie Bialek, CDC*)

As of March 18, there have been 6,103 cases of COVID-19 reported across the US, an increase of 1,574 since the previous day. All 50 states are now reporting cases as well as the US Virgin Islands and Puerto Rico. Washington State, California, New York City and New York State have reported the largest number of cases and they are rapidly increasing in Louisiana, Illinois, and New Jersey. Approximately 20-30% of cases reported by states are requiring hospitalization and CDC is closely monitoring high-risk communities such as older individuals and long-term care facility residents.

CDC Lab Team Updates (*Wendi Kuhnert and Laura Rose, CDC*)

CDC is doing everything they can to procure reagents; there is a worldwide shortage of certain reagents. CDC is turning around reagents and sending them to states as soon as they receive them. However, the International Reagent Resource (IRR) is not receiving sufficient supplies to fulfill all of the current orders at one time. Currently, IRR does have sufficient quantities of positive control, master mix, human specimen control (HSC), and the PCR kits. The bioMérieux platform was approved over the weekend and CDC has placed an order for those materials which are expected to arrive at the IRR within the next 4-5 days.

When placing orders with the IRR, please note the following:

- IRR is shipping seven days a week. When placing an order, please indicate on your order form if your facility is available for Saturday delivery.
- IRR is unable to send shipments that require dry ice (e.g. extraction kits) on Sundays. This is due to the need for dangerous-goods handlers at the airports who are not typically working on Sundays.
- Please do not order materials for COVID-19 testing from the influenza side. This will not help you get your order faster and most likely when IRR does have stock, they will prioritize the COVID-19 supply shipments.

The [EUA for the CDC diagnostic panel was reauthorized March 15](#), which formalizes the enforcement discretions. The reauthorization includes, among other things:

- Removal of N3 from the EUA panel
- Removal of the either/or language in the intended use document regarding the use of the assay for clinical or epidemiological purposes
- Addition of six extraction instruments, which are listed on the [FDA FAQ page](#) with [new instructions for use](#) with the CDC assay (pages 12-13). Additionally, the instructions for use document also includes verification instructions for all newly approved platforms and instructions for the alternative approach to extraction controls.

Please make sure to review the [instructions for use](#), [letter of authorization](#) and the new FAQ sheet for [patients](#) and [healthcare providers](#).

FDA Update (Tim Stenzel, FDA)

Earlier today, APHL sent out information regarding the policy changes that went into effect on March 16th. For the full policy statement, please see the [updated FDA policy originally issued on Feb. 29](#) on diagnostic testing for COVID-19 in order to achieve more rapid testing capacity in the U.S.

In order to further expand testing access across the US, FDA put into place two new policies:

1. States can take responsibility for tests developed and used by laboratories in their states, similar to the action the FDA granted to the New York State Department of Health last week. **States can set up a system in which they take responsibility for authorizing such tests and the laboratories will not engage with the FDA.** As stated in the guidance, the system does not need to mirror that of New York. Laboratories developing tests in these states can engage directly with the appropriate state authorities, instead of with the FDA. These laboratories will not need to pursue an EUA with the FDA.
2. An expansion of the policy outlined in the Feb. 29th guidance. The policy was originally applicable only to laboratories that are certified to perform high-complexity testing consistent with requirements under the Clinical Laboratory Improvement Amendments. **Under the update published March 16th, the agency does not intend to object to commercial manufacturers distributing and laboratories using new commercially developed tests prior to the FDA granting an EUA, under certain circumstances.** The FDA is aware that numerous commercial manufacturers are developing tests for coronavirus with the intention of submitting an EUA to the FDA. During this public health emergency, the FDA does not intend to object to the distribution and use of these tests for specimen testing for a reasonable period of time after the manufacturer's validation of the test and while the manufacturer is preparing its EUA request where the manufacturer provides instructions for use of the test and posts data about the test's performance characteristics on the manufacturer's website. As noted in the guidance, the FDA believes that 15 business days is a reasonable period of time to prepare an EUA submission for a test whose performance characteristics have already been validated by the manufacturer.

FDA anticipates authorizing a number of additional EUA submissions over the coming days and weeks. FDA is also involved with other entities doing additional validations for swabs and media methodologies and hopes to have more information by March 20. Finally, FDA is working to add additional staff to their toll-free number support line. In the interim, if you do not get the answers you need, please contact Tim Stenzel directly at Timothy.Stenzel@fda.hhs.gov.

CDC Assay Technical Updates (Steve Lindstrom, CDC)

In the current CDC PCR kits, some of the primers and probes are giving a bit of background from fluorescence from early cycles. New kits coming in the next few weeks will not have the high background issue. For the additional extraction platforms, the lysis buffers should be appropriate for the platform to be used.

Informatics Updates (Krista Kniss, CDC)

Almost all state PHLs have their PHLIP messaging up and running. Starting on March 20, Krista or someone from her team will be following up with each PHL with a brief summary of results CDC has received from them. PHLs should review these results and ensure that CDC has received all of the data that has been transmitted. CDC wants to ensure the numbers they are reporting out are correct.

PHL Experience: New York City (*Jen Rakeman, NYC PHL*)

The following is an update from the perspective of a community that is experiencing widespread transmission. Looking at influenza like illness (ILI) visits and pneumonia admissions, it is clear that flu season is over and COVID-19 is here. While reagent shortages have been widely discussed, the availability of personal protective equipment (PPE) or ventilators has not been addressed. NYC is projecting that they will run out of PPE before the peak of the outbreak. From the testing perspective, PPE is used for both specimen collection and testing. New York City is not recommending testing for anyone not sick enough to be hospitalized, which is being done to conserve PPE and supplies. The NYC public health community is continuing to push really hard to get the science ahead of politics in this outbreak.

Questions & Answers

Q: How did New York City determine that flu season was over? We are asking because there have been reports of co-infection with flu and COVID-19.

A: This determination was based on surveillance curves and testing. We saw the ILI activity return close to baseline before we saw it spike due to coronavirus.

Q: Following the FDA regulatory changes that went into effect Monday night, our state is trying to generate our own system to evaluate LDTs instead of sending everything through FDA. Once we have that system in place, how do we notify FDA and what is the vetting process, if any, of the state developed system?

A: The FDA notification is voluntary, but we encourage states who pursue this to notify FDA so that we can track it. Please email CDRH-EUA-Templates@fda.hhs.gov your submission.

Q: What does the FDA mean in the new regulatory guidance when they say states will “take responsibility” for approving these new LDTs? Will states assume the liability if the tests do not work?

A: For states that prefer FDA still be involved in reviewing LDTs, the guidance that was issued Feb. 29th is still in effect; LDTs can be developed according to those guidelines.

Q: Is CDC qualifying additional master mixes?

A: CDC is in the process of evaluating other master mixes for the assay and hopes to add additional options soon.

Q: What is the suggested volume of saline for swab transport?

A: FDA is looking into this.

Q: Is there a specific sterile saline product we can use for transport? Can laboratories make their own?

A: FDA is looking into this and will update the FAQ sheet once we have more information.

Q: What volume of lysis buffer do we use for the bioMérieux easyMAG?

A: Please refer to the FDA FAQ page.

Q: Can we use the HSC from another CDC kit for the COVID-19 assay (e.g. from the influenza kit)?

A: Yes, the [revised instructions for use](#) that were authorized on March 15 and posted to FDA website have instructions on this.

Q: If laboratories are replacing viral transport media (VTM) with saline, can they do this immediately or do they need to validate this substitution before use?

A: FDA and CDC are meeting to discuss this and will provide guidance shortly.

Q: Does the scope of the CDC test cover screening for organ donation?

A: It depends on what specimen types you are using and how the information from testing would be used. An important note is that negative results do not preclude infection with COVID-19 and need to be taken into consideration along with epidemiological data when making clinical decisions.

Q: Our state is running low on flocked swabs, can we go back to just collecting oropharyngeal (OP) swabs instead of nasopharyngeal (NP) swabs?

A: CDC has data that NP swabs are the most sensitive, but there are other acceptable specimen types that can be collected as well. Your laboratory should recognize that if you only use OP swabs you will not have the most sensitive site for testing. CDC and FDA are discussing the issue of swabs as well.

Q: Can laboratories make their own VTM?

A: CDC and FDA are okay with this, noting that it is best to run quality control (QC) on the VTM before use.

Q: Can you use the internal lysis buffer on the bioMérieux easyMAG instead of using an external lysis buffer?

A: CDC has data on the external lysis buffer showing that it inactivates the sample; CDC does not have data on the inactivation properties of the internal lysis buffer. If you want to look into alternatives, make sure that they are chemically the same as the external lysis buffer currently detailed in the instructions for use. Additionally, CDC strongly encourages that samples be inactivated prior to being loaded onto an instrument from both a safety and specimen stability perspective.

Q: Is CDC looking into multiplexing the assay?

A: CDC is looking into multiplexing the assay and hopes to have more information on this soon.

Q: Some local PHLs have been in queue to get QIAGEN EZ1 kits for weeks and have yet to receive any. Is IRR prioritizing states over local laboratories?

A: CDC is trying to get things out as fast as possible, however there is a worldwide shortage. There is some level of prioritization for urgent hot spots.