

APHL/CDC National PHL Call 2019-nCoV

February 19, 2020



Call Summary

Main Contact Emails

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Situational Update of COVID-19 (*Joe Bresee, CDC*)

We continue to monitor the spread of COVID-19. The rate of confirmed new cases in China has slowed a bit over the last week while other countries such as Japan and Singapore have seen an increase in confirmed cases. In the US, there are 15 confirmed cases, 13 of which are travel-related cases and 2 who were close contacts of travel-related cases. Currently, 42 states have reported PUIs to CDC (412 PUIs have tested negative, 58 are pending results), and over the last week the rate of new PUIs submitted to CDC has slowed.

There were 328 travelers repatriated from the Diamond Princess Cruise ship in Japan and sent to three quarantine sites in the US. Those travelers that tested positive before leaving Japan are being retested here in the US, and those results will be reported out.

As the US remains in the containment phase of the response, we are focusing testing on those individuals who meet the PUI case definition. CDC is working on a plan for sentinel community surveillance for COVID-19 and hopes to start testing outpatient clinic patients in a select few cities shortly.

COVID-19 EUA Update (*Steve Lindstrom*)

Due to the observed aberrant activity with the N1 and N3 components of the assay the decision was made to replace all of the primer and probe components with newly qualified reagents. These new reagents will undergo a heightened level of quality control testing before being released to public health laboratories. The strategy for release will be to push these new kits to laboratories that had already received the old kits. Once the new kits are received, laboratories will need to destroy the old lots of primers and probes before moving forward with testing. This will ensure that any performance issues we see going forward will be tied to the new lot. Once laboratories receive the new reagents, we ask that they repeat the verification and let CDC know the results of that verification process so that CDC can keep the FDA abreast of how the assay is performing.

CDC has received a number of requests from large states requesting that additional regional or local laboratories receive kits. The plan is to address these requests after labs that already received kits get the new reagents. CDC also defers the decision to add new regional or local laboratories to their state public health laboratory for authorization. Finally, CDC recognizes that we need to have a plan to bring on and qualify those new laboratories as well as to make a plan for the equitable distribution of reagents across states. CDC hopes to be able to develop these plans, get back to design qualifications and other EUA related activities shortly.

Questions & Answers

Q: What is the ability of CDC to test for COVID-19 in the interim of states having kits?

A: CDC has set up surge laboratories and does not currently have a backlog. In the main testing laboratory, CDC is currently able to test and report results within 24 hours of specimen receipt.

Q: Once laboratories do the repeat verification, do we have to send our results to CDC and then wait to initiate testing?

A: No, CDC is simply being asked by FDA to track the number of labs who qualify for informational purposes. Laboratories can make their own decision to initiate testing based on the results of their verification testing.

Q: Will CDC be making changes to the EUA to reflect the name changes to the virus and disease?

A: CDC recognizes that the COVID-19/SARS-CoV-2 nomenclature issue is similar to the HIV/AIDS naming convention and that “SARS” has a connotation that leads to thinking about select agents. For now, because the assay includes “2019-nCoV” in the labeling that will continue to be the language used for reporting. CDC acknowledges that any future changes to the EUA would need to be carefully considered and coordinated with states as there would be impacts on LIMS and electronic reporting of results.

Q: The new kits that are coming out, to confirm, are just a remanufacture of the reagents and not a redesign?

A: Correct, it is strictly a remanufacturing of the same reagents.

Q: For laboratories participating in sentinel surveillance studies, will CDC be manufacturing the same kits but relabeling them (RUO vs. EUA)?

A: This is an ongoing discussion and CDC hopes to have more information soon.

Q: For laboratories participating in sentinel surveillance studies, can CDC make another hand out with the test code and instructions for how you want laboratories to label the specimen boxes until they are able to do their own surveillance testing?

A: CDC laboratory and epidemiology teams will consider this request.

Q: Can we use laboratory-developed tests (LDTs) to test for SARS-CoV-2?

A: Since SARS-CoV-2 (nCoV-2019) has an EUA in place laboratories **cannot** use a LDT for testing.

Q: Does CDC anticipate making any changes to the core testing procedure during future EUA amendments?

A: At this time, future amendments will likely be focused on adding additional options such as more extraction platforms and master mix chemistries not on changes to the core procedure.

Q: Is CDC developing or planning to develop a serology assay?

A: There are no current plans to release a serology assay under EUA.

Q: Does CDC plan to reconcile the differences in specimen type collection between influenza and COVID-19 (i.e., for influenza NP/OP swabs can be placed in the same tube vs. COVID-19 where NP and OP swabs should be stored and tested separately)?

A: Any changes to acceptable specimen types would be on future EUA amendments, these are being considered.

Q: Was the N1 issue observed during verification or actual testing?

A: From the laboratories that reported to CDC, the issue was seen during verification.

Q: After laboratories perform the new kit verification, what level of documentation does CDC need?

A: CDC is still determining what information will be requested in conversations with FDA.

Q: IDT (Integrated DNA Technologies) has “CDC” primer and probe sets on their website, could laboratories use those for surveillance purposes?

A: CDC cannot speak to these kits or reagents; it would be up to the individual laboratory to determine the appropriate usage of these investigational reagents. Any results obtained using these reagents could not be

reported back on individual patients. There are ongoing conversations with FDA for all potential uses for the official test, and CDC appreciates everyone's patience as we work through the details.

Q: What quality controls are in place for the new primer/probe sets?

A: Since this is a product quality issue it is under FDA oversight and has to undergo heightened scrutiny and oversight. As the manufacturer, CDC is responsible for performing the QC testing. The testing will have to get FDA approval before new kits go out.

Q: As the new kits come out and are QC'ed by CDC, will they be coming with a certificate of analysis like laboratories get with other vendor supply kits?

A: The labeling on the new kits will agree with FDA guidelines. This may include quality control certificates, but CDC needs to work through the specifics with FDA.

Q: What is the anticipated timeline for release of the new reagents?

A: Given the heightened quality control over the new lot of reagents, CDC is unable to commit to a specific timeline for release at this time. However, they are doing their utmost to expedite the process and get them out as soon as possible.