

APHL/CDC National PHL Call 2019-nCoV

March 11, 2020



Call Summary

Main Contact Emails

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

APHL EOC Contact: eoc@aphl.org

APHL update (*Scott Becker, APHL*)

This weekend APHL's Board of Directors met and decided to present the following recommendations to FDA and CDC for consideration:

- Releasing PHLs from sending presumptive positives to CDC for confirmation
- Releasing PHLs and CDC from performing confirmations for other clinical labs, other than first 5+/- as per immediate in use guidance to clinical labs
- Requesting immediate consideration for use of high throughput extraction instrumentation
- To allow NP/OP single tubes to gain an increase in patient throughput and conserve reagents

As of today (as far as we know) three of these four items have been resolved.

- Releasing PHLs and CDC from performing confirmations for other clinical labs, other than first 5+/- as per immediate in use guidance to clinical labs
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We know that the fourth item is in process.

- Releasing PHLs from sending presumptive positives to CDC for confirmation

APHL has been fielding many questions from the government, from partner organizations and the media on laboratory capacity in the US. This is true of public health capacity as well as general laboratory capacity in the US. To that end we have a few things planned:

- Later today APHL will be distributing a list of CLIA certified labs that we acquired from CMS. The list excludes CLIA –waived laboratories and we hope it will be helpful in identifying laboratories that have the potential to bring on testing for COVID-19. CSTE will be sharing this list with their membership as well.
- APHL also plans to field questions to our member labs to try to ascertain information on PHL capacity. The mechanism for fielding these questions is still being determined but we are very mindful of your current workloads and are absolutely taking that into consideration as we make our plans. More information will be available later this week.

Finally, we are all well aware of the current limited supply of ancillary reagents and we understand the amount of stress and concern that creates. To help our friends in the IRR manage your orders we have a few very critical asks:

- Try to funnel your orders through IRR if possible. Ordering directly from the manufacturer when their inventory is limited creates additional delays as they attempt to manage inventory.
- Try to consolidate your orders to IRR and not input multiple orders. This creates extra administrative burden and causes further delays.
- Direct your questions and concerns to IRR customer service rather than specific individuals.

If you have significant concerns or suggestions about how APHL can keep you better informed of the ancillary reagent situation, please let us know. We want to make sure you have the information you need while still giving CDC and IRR the space to work as quickly as they can to address these issues.

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

Over the weekend, [CDC updated their collection and specimen handling guidelines](#), which included the option of placing NP/OP swabs in a single collection tube at the time of collection. CDC hopes this change increases throughput and decreases the laboratory-testing burden. CDC is currently discussing moving to a single swab and will let APHL know once a final decision is made so that that information can be disseminated to public health laboratories. CDC also wants to reiterate that you should be placing reagent orders through IRR and that laboratories should be placing a single order versus multiple smaller orders. If your full order cannot be completely fulfilled at first, you do not need to put in another order for the remainder; your original order will eventually be completed. Of note, if your laboratory is able to get a Saturday delivery, please put this in your order comments.

EUA Amendments

CDC submitted three amendment requests to FDA over the past week:

- On March 5th CDC requested that N3 be formally removed from the EUA panel, that the either/or language in the intended use document regarding the use of the assay for clinical or epidemiological purposes be added and that Biosearch Technologies and IDT be added as manufacturers of the product.
- On March 7th CDC requested that four additional automated extraction options be added to the EUA. Additional information on these instruments and reagents can be found on the [FDA website](#). Currently, these new instruments are under enforcement discretion.
- On March 11th CDC requested that negative human specimen material or contrived human material be approved for use as Human Specimen Control (HSC) for the assay. This approach for HSC was added to the [FAQ document on the FDA website](#). CDC also requested permission to use the research use only (RUO) extraction reagents from QIAGEN as opposed to the IVD reagents that are currently in the instructions for use. QIAGEN has given CDC a letter that specifies that certain RUO products are chemically identical to the IVD reagents and that the RUO reagents would be suitable alternative. Once CDC has final approval for usage of the RUO materials we will let laboratories know.

Reagent Availability

[IRR currently has enzyme and RT-PCR reagents in stock](#); stocks of extraction kits are limited. IRR is working closely with QIAGEN to make sure that inventory needs are met. When ordering from IRR, please consolidate your orders. If you have placed an order, received it, and now need more reagent, place another order. Please do not place multiple orders back to back before you even receive the materials from your first order, this disrupts the system's ability to properly track what each laboratory has requested and can push states farther back in the queue.

FDA Update (*Tim Stenzel, FDA*)

One week ago, FDA released new guidance on laboratory-developed tests (LDTs). They have also updated their [FAQs](#) to include information on additional instrumentation, HSC and additional lot qualified primers and probes that can be purchased from [IDT](#) or [Biosearch Technologies](#).

Post Mortem Testing Guidance (*Sarah Reagan-Steiner, CDC*)

On February 21st CDC posted interim guidance on PUI post-mortem specimen collection (with and without autopsy). CDC is working to optimize the testing procedure for these specimens and to also get additional information on virus isolation from these specimens out to laboratories. Sampling instructions and information on ordering tests from CDC can be found [here](#). Laboratories may test NP or OP post mortem specimens using the CDC assay. If a laboratory collects post mortem swabs but are unable to test, the swabs can be sent to CDC. Refer to the guidance for more specific instructions on shipping.

CDC Assay Technical Updates (*Steve Lindstrom, CDC*)

CDC has been working to answer several questions they have gotten over the past week. In regards to the new extraction platforms, CDC is working on getting out new verification guidance and anticipate it being very similar to the current guidance. [CDC has also provided updated storage guidance](#), especially when shipping to CDC. Of note, since these are clinical specimens, they ship category B to CDC. Finally, CDC is working to finalize guidelines for testing at commercial laboratories and the confirmation testing that public health laboratories will do in support of that effort.

Informatics Updates (*Michelle Meigs, APHL and Krista Kniss, CDC*)

We currently have 54 public health laboratories sending production level data to CDC through their PHLIP feeds with an additional three laboratories in progress. [Laboratory Alert #22](#) has guidance on how laboratories can send the new combined specimen types in their PHLIP feed; this information can also be found on the [APHL FAQs](#) page. As a final note, although it is an optional field, it is desirable that laboratories look into including the COVID 19 number with their PHLIP data. If laboratories need help implementing the optional field, they can contact the [APHL informatics help desk](#).

PHL Experience: California (*Deb Wadford, California PHL*)

California has seen at least three repatriation events across three different military bases in three different counties. California has also had at least three different cruise ship events, all of which have had positive COVID-19 cases. As of Tuesday, California had 157 laboratory confirmed cases, 50 of which are travel related (24 from cruise ships), 30 were person-to-person related, 29 were community acquired, and 24 are under investigation. Additionally, the state has successfully monitored more than 10,000 returning travelers for signs of illness. California is a decentralized state in respect to public health laboratories with the Viral and Rickettsial Disease Laboratory (VRDL) serving as the state viral reference laboratory. VRDL works with 21 state laboratory public health partners, which allows the state to spread out the ability to test to local sites. Out of the 22 PHLs in the state, 18 are currently able to test for COVID-19 and we expect an additional two laboratories to come online with testing in the next week. California is currently only testing verified PUIs; we are not testing asymptomatic cases or testing already confirmed positive individuals (serial testing). The testing volume per day across the 18 laboratories in the state is currently 300 - 500 tests. At VRDL, the number of tests performed per day ranges from 50 to 70. Reagents permitting, the 18 laboratories in the state are prepared to perform 1,000 - 1,500 tests per day.

The arrival of the Grand Princess 2 in California is a good example of a successful public health response. VRDL staff received 89 specimens from 45 passengers for testing at 6:00 pm at night. By working in teams, they were able to accession, aliquot, extract and test all of the specimens by 1:30 am, and by 2:30 am, the laboratory was able to report out the results. Of the 45 passengers under investigation, 21 were positive for COVID-19.

Questions & Answers

Q: What is the stability of whole blood for use with the assay?

A: Whole blood should not be used with the CDC assay. The collection of serum from positive individuals for serologic testing may be desired in some cases. CDC and APHL will seek further guidance from the CDC epidemiology team for additional information.

Q: Is the bioMérieux NucliSENS easyMAG platform going to be added to the EUA for extraction?

A: CDC does not have inactivation data on the easyMAG. There are not plans to include it at this time.

Q: When will the new extraction platforms be added to the EUA?

A: CDC has submitted an amendment to FDA to update the instructions for use to include all of the new extraction platforms listed on the FAQ document. CDC and FDA are not able to provide a timeline for the update. The additional extraction platforms are currently eligible for use under enforcement discretion.

Enforcement discretion: FDA will not object to laboratories going forward and doing the activity that has been requested while the amendments are under review.

Q: What is the CDC plan for HSC usage?

A: Additional HSC options are covered in the [FDA FAQ document](#).

Q: How many laboratories have submitted EUAs/how many laboratories do you anticipate will submit their own EUA?

A: There are currently ~20 laboratories that have notified FDA that they have completed validation and are able to test for COVID-19. FDA expects the number of laboratories to increase dramatically.

Q: How much longer will CDC require PHLs to send presumptive positives to CDC for confirmation testing?

A: CDC is hoping to drop this requirement shortly. Once it is no longer a requirement, we will communicate this to laboratories.

Q: Can NP and OP swabs be combined into a single tube once they are received at the laboratory?

A: No, NP and OP swabs must be placed in the same VTM or UTM tube at the time of collection. They should not be combined after the fact at the laboratory. Combining the samples in the laboratory introduces the possibility of diluting a positive specimen, reducing the overall sensitivity of the assay.

Q: For autopsy lung specimens, do you want the outer surface swabbed or the inner surface?

A: CDC is working to get additional information and APHL will include the answer in a subsequent follow up.

Q: Regarding commercial laboratory testing, does a commercial laboratory need to send their first 5 positives and first 5 negative specimens for confirmation in every state for which they perform testing or do they only need to complete the confirmatory testing process once?

A: Commercial laboratories only need to confirm their first 5 positives and first 5 negatives. They do not need to have specimens confirmed in multiple states.

Q: Is CDC considering extending the 72-hour storage limit on refrigerated specimens?

A: CDC does not currently have any data to support this extension at this time but will consider this issue.

Q: Has CDC updated their testing guidance on test of cure on previously positive patients?

A: [Please refer to the CDC website for this guidance](#). The CDC Epidemiology Taskforce is currently working on refining guidance for serial testing. If your state goal is containment, then serially testing of previously positive patients would be appropriate. If your state goal is mitigation, then serial testing may not be performed and

previously positive individuals will wait a certain amount of time after symptoms have resolved to be cleared. CDC and APHL will provide updates as needed.

Q: If one of the items under enforcement discretion gets objected to or removed after FDA review, what should laboratories do?

A: FDA does not anticipate this occurring at this date.

Q: If our laboratory experiences detection issues in the NTC of N1, do we report these results?

A: Yes. Any issues with the assay or reagents should be reported to respvirus@cdc.gov.