APHL Laboratory Alert: COVID-19 All PHL Lab Call

March 4, 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*)

CDC started releasing newly manufactured kits that contain only N1, N2 and RP. Some public health laboratories (PHLs) have already received these and others will receive them soon from the International Reagent Resource (IRR). FDA's regulatory discretion announcement last week has allowed many PHLs to stand up testing, and APHL is tracking PHLs' verification and testing status. As of March 4, 2020, APHL is aware of 60 PHLs offering testing and several more coming online imminently. CDC will be releasing a daily map illustrating what states have at least one laboratory offering testing. This map will be updated on a daily basis, and APHL will work with you to update your status with CDC as rapidly as possible if it changes. If a PHL is receiving media or other inquiries about their status on this map, they are welcome to contact APHL at eoc@aphl.org, and our communications staff is happy to work with their PIO or others on talking points. Since our last national call, there was also an announcement from FDA allowing for testing prior to emergency use authorization (EUA) at clinical laboratories. We encourage PHLs to reach out to FDA or APHL's EOC inbox with questions as they arise.

CDC Situational Awareness Update (*Greg Armstrong, CDC*)

Globally, the epidemiology of COVID-19 has changed significantly in the last two weeks. Incidence has decreased in China, however there has been sustained transmission in South Korea, Italy, Iran and other countries. As of March 3, 2020, CDC was aware of 48 cases in the US from the groups of repatriated individuals. There are an additional 78 cases from 13 jurisdictions in 12 states. There have been 9 deaths (all in Washington), most of which were associated with a skilled nursing facility. The case fatality rate was 54% at this facility. Washington state (Seattle/King County and Snohomish county) and California

have identified larger outbreaks. In both Washington and California, healthcare facilities have been impacted with several hundred health care workers exposed.

CDC Kit Update (*Wendi Kuhnert, CDC*)

Redistribution Update

Late last week, CDC identified seven pilot PHLs to receive and verify newly remanufactured kits. These pilot PHLs were able to quickly turnaround verification and confirmed that the new reagents performed to the expected standards. CDC sent out approximately 45 new kits to IRR which were distributed to priority PHLs based on cases, funneling, repatriation, etc. CDC also procured two new kit lots from Integrated DNA Technologies (IDT) that are identical to CDC test reagents. Both lots passed CDC quality control, and 250 kits were moved to IRR early this week. These new kits will be sent today to 93 PHLs. CDC is also procuring an additional 2,000 commercial kits from two manufacturers and by the end of next week, the first 1,000 should go out. Some replacement kits will not have the positive control. Laboratories should use the positive control they already have. On a case-by-case basis, CDC can ship positive control material as needed. The EUA will be officially updated to reflect the removal of N3 and will include the new intended use to reflect updates to PUI guidance and surveillance testing.

Reporting and Referral of Presumptive Positive Cases to CDC

PHLs should notify CDC of presumptive positive cases to CDC prior to shipping specimens. As a reminder, it is critical that the specimen submission form 50.34 be filled out accurately. Both the COVID ID and Specimen ID **must** be on the form so that CDC can link them. APHL is developing a job aid for the 50.34 and hopes to release it next week.

Serial Testing of Positive Cases

Under the EUA, PHLs can use the CDC kits to perform serial testing for positive cases. If there is an issue with reagent supply, please contact CDC and they can provide testing support. CDC is working on additional guidance on serial testing as the response moves into the mitigation phase.

Clarification of FDA Regulatory Discretion (*Laura Rose, CDC*)

The enforcement discretion that CDC received by FDA last week has two parts: 1) FDA has authorized CDC to proceed with N1, N2 and RP as the primer and probes to be used for testing under the EUA and 2) FDA has provided authorization to proceed with testing anyone who meets either clinical **or**

epidemiological criteria for COVID-19. In the amendment to the EUA, all of these changes will be reflected in the letter of authorization and instructions for use.

IRR Update (*Erica Guthrie, CDC*)

IRR has been automatically generating orders for replacement kits. Additional inventory will be available soon so PHLs can resume normal ordering. Please only order reagents as you need them (do not stockpile). The new kits will have a new catalog number. Please hold off on placing additional orders for ER-35 as this is the old catalog number. The website will be updated this week to have the proper kit product page to reorder the CDC EUA kits. Please also note that the research use only (RUO) positive control (catalog number ER-37) cannot be used with this EUA, and therefore CDC will remove this item from sales orders. CDC is working on establishing a replacement for the positive control. Please allow the IRR team to focus on distribution of the remanufactured kits this week, and then they can start to fulfill product reorders.

Electronic Results Reporting Update (*Michelle Meigs, APHL*)

Out of 57 PHLs the informatics team is working with, 43 have completed successful data validation and are ready to send results to CDC. An additional 14 are in the validation process. An informatics FAQ document was distributed in APHL's Lab Alert #18. This Lab Alert included updated guidance on the removal of N3, message validation, updated COVID-19 terminology, encoding, and updated HL7 sample messages. For PHLs that have already verified their messaging, no re-validation is necessary. For PHLs in progress, they continue as is or update to validate with the new message. For PHLs that have not begun validation, use the updated guidelines. For PHLs that plan to include the COVID unique ID into their PHLIP feed, please each out to informatics help desk. A one-step validation will be required for adding this data element.

Questions and Answers (Q&A)

Q: Should both naspharyngeal (NP) swabs and oropharyngeal (OP) swabs be tested? For positive cases, does CDC want PHLs to send serum?

A: The EUA covers testing NP swabs, OP swabs and sputum. CDC has been testing both NP and OP swabs and recommends testing both as mixed results have been observed between the two. PHLs can send serum to CDC, but CDC will not report results back since serum isn't included in the EUA.

Q: PHLs expect an increase in testing, can NP and OP swabs be combined to conserve resources?

A: Combined testing of NP and OP swabs is not allowable under the current EUA. However, CDC is looking into this and assessing the viability of combining the two.

Q: If NP, OP and sputum are all submitted for a PUI, should all three be tested? How should samples be prioritized?
A: CDC has seem some cases where the NP/OP that were negative and sputum is positive. That said CDC encourages PHLs to work with your epidemiologists to determine testing prioritization.

Q: Can clinical laboratories use viral transport media (VTM) as the transport media for shipping NP/OP swabs?
A: Yes.

Q: Will FDA's enforcement discretion be sufficient for CMS or CLIA?
A: CDC and FDA have discussed the N1/N2 enforcement discretion with CMS, who did not express any concerns about the documentation at this time. The EUA amendment will make the changes official. In the meantime, CDC has requested that FDA upload the instructions for use as an addendum to the existing EUA.

Q: Which IDT kit lots are qualified to be approved for use under the EUA?
A: CDC and APHL will follow up on this. The approved lot numbers should be posted on IDT's website soon.

Q: How many reagent kits can a PHL order at this time? Will there be enough kits?
A: IRR is distributing on a case-by-case basis. Initially one kit per PHL until the supply is sufficient. Do not stockpile kits. There are additional reagents in the pipeline, so only order what is needed currently. There are 337 kits in stock right now, 2,000 coming in a few weeks from commercial suppliers and an additional 600 from CDC's internal manufacturing process.

Q: Is a higher-throughput extraction platform such as the Roche Magna Pure 96 going to be added to the EUA?
A: CDC is working on additional platforms to add to the EUA and hopes to include this as soon as possible. CDC needs to ensure the inactivation step on the Magna Pure is adequate for this virus and has started those studies.

Q: With the FDA EUA expansion, can PHLs validate their own extraction methods?
A: PHLs can approach FDA for securing authorization for modifications to CDC's approach. FDA is willing to discuss that. However, CDC does have plans to add additional extraction platforms to the EUA.

Q: The QIAGEN EZ1 reagents are on backorder, does CDC have any information about this?
A: None of the IRR reagents are on backorder. PHLs are welcome to order any ancillary reagents they need through IRR (except the old replacement kit with catalog number ER-35 and RUO positive control ER- 37). Post-call update from APHL: QIAGEN also does not report any backorders. However, they are manually approving orders and placing limits on single orders for inventory management purposes. APHL recommends calling your local QIAGEN sales representative and making it known that you are a public health laboratory to get orders manually approved and released. Please let APHL know if you have any issues at eoc@aphl.org.

Q: For clinical labs that send their first 5 positives to a PHL for confirmation, will PHLs also need to send to CDC for confirmation? Is there a timeline to eliminate need for PHLs to confirm their positives with CDC?

A: CDC hopes to remove the requirement for confirmation at CDC as soon as possible. CDC plans to submit new data to FDA to demonstrate that confirmation testing is not needed. There may be data requests from public health laboratories to assist in this process.

FDA has stated that PHLs do not need to send specimens submitted from a clinical lab for confirmation on to CDC once the results are confirmed in a public health laboratory unless CDC is going to require it. APHL recognizes that this is still a bit unclear and will continue to try to achieve firmer resolution. However, our primary focus is going to be on getting the confirmatory testing requirement removed as soon as possible.

Q: Should PHLs still forward positive case serial testing specimens to CDC?
A: Since PHLs are up and running, they are welcome to perform serial testing at their PHL. If PHLs choose to send serial specimens to CDC, they will test them. There are ongoing conversations at CDC about best practices for serial testing. APHL will provide updates as they become available.

Q: For serial testing of presumptive positive cases, can PHLs propose a change to the sampling schedule?
A: CDC is in discussion about the testing required during the mitigation phase of the response. Please hold off on making any changes as CDC may have an update soon.

Q: What is expected turnaround time with confirmatory tests with CDC?
A: CDC will provide results within 24-48 hours.

Q: What is the guidance around rapid flu testing on PUIs for rule out?
A: APHL is working to get clarification on this.

Q: Can PUI samples be sent through the pneumatic tube system?
A: Please refer to CDC's updated laboratory biosafety guidance for COVID-19.

Q: What are the recommended specimens for cadaver testing?
A: Please see the following guidance posted by CDC as a reference for postmortem specimen collection and submission from deceased persons under investigation (PUI) for COVID-19: Interim Guidance for Collection and Submission of Postmortem Specimens from Deceased Persons Under Investigation (PUI) for COVID-19, February 2020

Q: Is the PUI ID still needed from CDC, or can the local jurisdiction generate the ID?
A: PHLs should follow the PUI guidance. CDC has deferred to states to come up with COVID ID.