APHL/CDC National PHL Call
2019-nCoV

April 1, 2020

Call Summary

Main Contact Emails

CDC Emergency Operations Center (EOC) Contact: 770-488-7100
APHL EOC Contact: eoc@aphl.org
APHL informatics technical assistance: informatics.support@aphl.org

Welcome (*Scott Becker, APHL*)

APHL is looking for submissions from laboratories to share on social networks, blogs etc. on their experiences working in the lab during the pandemic. If you have a story you would like to share please email it to eoc@aphl.org.

APHL continues to monitor the supply chain issues; if your laboratory is 24-48 hours out from running out of supplies, please let APHL know at eoc@aphl.org and we will try and do our best to help you.

Situational Awareness Update (*Joe Bresee, CDC*)

The current situation in the US as of April 1, 2020 is as follows:

- There are over 188,000 cases in the US, 15% of which have been diagnosed in the last 24 hours.
- New York state and New York City account for the majority of cases, however, 8 states have reported more than 1,000 cases in the past 24 hours.
- Some of the early jurisdictions with outbreaks, such as Washington state, are reporting lower proportions of new cases each day, which may indicate cases are slowing down.

The focus this week on the epi side is to modify surveillance to better capture the efficacy of community public health measures and to focus on what is happening in rural areas.

CDC Lab Team Updates *(Wendi Kuhnert and Brandi Limbago, CDC)*

Alternative transport media: CDC recognizes that the suitability of saline as an alternative transport media is not addressed in the instructions for use, however, CDC is deferring to the FDA FAQs, which state the FDA believes that saline is suitable. CDC has done some internal studies on the suitability of saline and does not have any concerns with this substitution.

Serology: CDC has develop a set of assays that use the SARS-COV-2 antigen and/or live virus that CDC has isolated to detect antibodies against the virus with no cross-reactivity against common coronaviruses. CDC has started to use these assays in contact case studies and plans on deploying them to larger studies; however, CDC is not planning to pursue an EUA for these assays since they are not for diagnostics. There is a larger US government effort to look at some of the serology tests on the market for the purpose of an EUA. Quest and LabCorp are also developing serology tests; APHL will communicate with laboratories once those go live.

Alternative PCR instruments: CDC has heard from several laboratories interested in using the Quant Studio instrument to run the PCR for the CDC assay. Right now the only authorized instrument is the ABI 7500 Dx. However, under enforcement discretion, CDC will not object to laboratories moving to the Quant Studio platform as long as the individual laboratory takes responsibility for verifying that the instrument works with the

CDC assay. Of note: CDC has not evaluated the use of Quant Studio with the CDC assay nor do they have the run parameters necessary for the instrument.

FDA Update (*Sara Brennen, FDA*)
States can continue to check the FDA FAQ for updated policies and guidance. If there are questions, please relay them to APHL at eoc@aphl.org. Of note: this week FDA allowed for the use of the Abbott ID Now platform to be used in patient care settings outside of the clinical laboratory, by prescription only.

CMS Update *(Regina Van Brackle, CMS)*
CMS recently issued Memo # QSO-20-21-CLIA regarding CLIA guidance during COVID-19. Note: Laboratories should follow the manufactures instructions for all tests, including quality controls. If the FDA has given an EUA for a specific test, laboratories must follow the approved instructions.

CDC Assay Responses to Technical Questions (*Steve Lindstrom, CDC and Laura Rose, CDC*)
Lysis buffer and stability: Once specimens are added to the lysis buffer, they are stable at room temperature until they are put on the extraction system if they are extracted the same day. If you are not running the extraction the same day the specimen is added to lysis buffer, the specimen in lysis buffer can be refrigerated at 4°C for up to one week. Once you are ready to extract, the samples should be brought to room temperature before running.

Updates to the EUA: The FDA has granted three additional master mixes for use with the CDC assay. These are not yet posted in the instructions for use on the FDA website nor are they available at the IRR yet. APHL will notify laboratories once more information becomes available. Also of note, the volume of VTM has been adjusted from 2-3 mL to 1-3 mL in the official instructions for use.

CDC Biosafety Update *(William Arndt, CDC)*
CDC recently updated their biosafety guidance. The main updates focus on new isolate and culture shipping recommendations; all COVID-19 samples should be packaged and shipped as Category B infectious substances.

CDC is also working on messaging for laboratories around the R mix cell line. Data has shown that a component of the cell line supports a lower level of viral growth. CDC recommends laboratories switch to a different cell line. Laboratories should validate whatever cell line they switch to.

Informatics Update *(Krista Kniss, CDC and Michelle Meigs, APHL)*
To date, there are 58 PHLs sending data through the PHLIP feed; 180,000 messages were sent in March alone. The technical assistance team has been working across partners to gather all LOINC information for new assays. In the next few days APHL will be providing updated encoding guidance as well as specific guidance for ensuring messages continue to flow through the PHLIP feed. As a reminder, anyone implementing a new assay should reach out to CDC and APHL to make sure that they receive proper informatics support as there is a small data validation step to make sure your data is getting parsed correctly at CDC.

PHL Experiences
Specimen Pooling in Nebraska (Pete Iwen, Nebraska PHL)
In order to mitigate existing reagent shortages, Nebraska implemented pooled testing of specimens. This method is common in laboratories performing STD testing as well as in some blood donation screening laboratories. Nebraska engaged a statistician to look at the state's data to determine the pool size and limit for when this method could no longer be used given the community infection rate. Due to the relatively low rate of infection in the population (<5%), the Nebraska PHL found that it could effectively pool five specimens together, using 50 µl/specimen and be able to accurately report out results. If the pool is negative, they report all individuals as negative and include a comment on the report that the specimen was group tested. All positive

pools are split out (deconstructed) and each specimen is re-extracted and re-tested. The Nebraska PHL recognized that this may pose issues with the FDA and CMS around CLIA and the EUA. Ultimately the Governor gave full authorization to use pooled testing and the FDA notified the PHL that they would not object to pooling specimens as long as the positive rate is below 10%.

Pooled testing increased the Nebraska PHL's capacity to test from 100 to 300 specimens a day, reduced reagent usage by 50%, decreased turnaround time to 24 hours, and reduced staff time. However, some limitations of this method include the possibility of missing high Ct samples, the requirement for low population incidence, and no savings on the amount of swabs or PPE needed. To address the sensitivity issue, Nebraska is starting to look for late amplification in the 40-45 Ct range.

Wisconsin's Approach (Allen Batemen, WSLH)

The Wisconsin State Laboratory of Hygiene (WSLH) has a multi-pronged approach to their COVID-19 response: diversify their supply chain, increase throughput, offer STAT testing, and automate testing where possible. The WSLH currently has six extraction platforms validated, is in the process of validating high throughput options, has a plan to implement the Cepheid for STAT testing (and possibly Abbott ID Now), is working on multiplexing the CDC assay as an LDT, and is considering the Hologic Panther for automation. The WSLH has also built strong collaborations with other large clinical laboratories in Wisconsin through newsletters, webinars, and sharing residual specimens, which has helped bring testing to more laboratories across the state.

Questions & Answers

Q: The QIAGEN instructions for use say to elute into 60 µl but the CDC EUA instructions for use say 100 µl: is there any reason we cannot use 60 µl? If we can use 60 µl, do we need to do a full validation or can we do another study to prove efficacy?
A: Following QIAGEN's isnturction to use 60 µl should produce acceptaible results but that is now how CDC has run the assay. You will need to verify this change with a bridging study in your laboratory; the FDA FAQ gives some guidance on bridging studies and the FDA will also follow up with APHL on some specific citations.

Q: Is CDC performing serial-clearance testing?
A: CDC has information on this on their website; CDC has both test-based and symptom-based strategies for the discontinuation of transmission-based precautions in healthcare settings. If there is a need to do clearance testing and for some reason your laboratory is not able to perform it, please contact CDC and they will discuss an approach with you.

Q: Our laboratory has been approached about using an alternative lysis buffer that is salt-based rather than guanidinium-based, is that an acceptable alternative?
A: No. The guanidinium buffers are required as CDC has data that demonstrates their ability to inactivate virus while other buffers do not necessarily inactivate virus at particular titers. CDC is evaluating other guanidinium-based buffers for use.

Q: Our laboratory is interested in the King Fisher extraction platform, what do we need to do to validate the instrument? Do we need to submit our own EUA to the FDA?
A: You do not need to submit an EUA to the FDA if you follow the Instructions for Use for the Thermo Fisher TaqPath™ COVID-19 Combo Kit EUA. Your laboratory can do a bridging study, validate the instrument according to your own internal protocols and if it works, move forward with testing.

Q: What types of saline (phosphate buffered, normal etc.) are acceptable for specimen transport?
A: Normal saline, sterile saline and/or phosphate buffered saline are acceptable; they should be interchangeable.