

California Department of Public Health Weekly Facility COVID-19 Update Call June 23, 2020 8:00 am - 9:00 am

I. Welcome / Introduction: Heidi Steinecker

II. Overview: Ngoc Ly Le

III. Laboratory Update: Dr. Jill Hacker

PCR Testing for SARS-CoV-2 for Skilled Nursing Facilities

As mentioned on previous calls, AFL 20-55 requires skilled nursing facilities (SNFs) to report results of COVID-19 baseline testing to CDPH. To help SNFs and LHJs meet these requirements, the CA Testing Task Force maintains a list of CLIA-certified COVID-19 testing laboratories. The link is provided in the call notes. Please note that if SNFs have samples involved in outbreaks, not baseline or weekly surveillance, they are still encouraged to send their samples to their LHJ.

Sample Collection and Transport Media

We continue to receive questions regarding which upper respiratory swabs are best to collect and what transport media to send the samples in. A recent study from the University of Washington (Tu et al, 2020) showed nasal mid-turbinate swab specimens collected by the patient were 96% comparable to HCW-collected NP swabs, and self-collected nasal samples were 94.0% sensitive compared to NP swabs. It should also be noted that the CDC does not prioritize one sample collection site over the other.

Once a sample is collected, care must be taken to deliver it to the laboratory in the appropriate medium validated for the specific testing method being used. Not all transport media are universally accepted and there are some laboratory tests that require transport media NOT be used (i.e. using a dry swab).

COVID-19 Serology Updates

As of June 22, 2020, 20 serology tests have been granted EUA status. Details for each assay can be found on the <u>FDA's EUA website</u>. If you are currently using the serology test from ChemBio, please be aware that the EUA for this test has been rescinded and is no longer on this list.

The FDA has also published a <u>summary</u> of the performance characteristics for many of these serology tests granted EUA status as determined by several federal agencies (FDA, NIH, CDC, and BARDA) using a panel of known/established verification samples. The estimated sensitivity, specificity, positive predictive value and negative predictive value (assuming 5% prevalence) are provided for each test with respective 95% confidence intervals.

As mentioned previously on these calls, SARS-CoV-2 serologic assays are NOT approved for diagnosing acute cases of COVID-19 and therefore should not be used for decision making relating to patient management or care. PCR remains the best test to diagnose cases of COVID-19, both for symptomatic people as well as for asymptomatic people for whom you have a suspicion of COVID-19.

Point of Care Tests

For the Abbott ID NOW, we have received questions regarding false negatives in testing symptomatic patients, in addition to questions regarding false positives in testing asymptomatic patients. Regarding false negatives: a negative result does not rule out infection and may still need to be confirmed using PCR. Regarding false positives: This system requires the patient swab is swirled into the reaction mixture prior to running of the test, then the removal of the test cartridge afterwards. If a sample is indeed positive for SARS-CoV-2, both steps are potential causes of contamination for future tests. We recommend cleaning the machine after every positive result to minimize cross-contamination. For anyone using their system, Abbott representatives are available for refresher training or other consultation regarding proper use of the instrument.

The Quidel Sofia SARS Antigen FIA Assay is another POC test with EUA approval. Like the Abbott ID Now, negative results do not rule out infection and may need to be confirmed by PCR. The test limitations reported by Quidel clearly state that certain commonly used viral transport media have been shown to cause false positive results. As mentioned, care should be taken to ensure the transport medium is compatible with the testing method.

Select Guidance Links:

- Specimen collection: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
- Tu et al, NEJM 3 June 2020 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7289274/
- Abbott ID Now Maintenance and Cleaning video: <u>ID NOW Training Videos Rapid point of care diagnostics Abbott</u>
- Lab Safety: https://www.cdc.gov/coronavirus/2019-ncov/lab/fags.html
- FDA documents and guidance:
 - o EUA: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-situations-medical-devices/emergency-situations-medical-devices/emergency-situations-medical-devices/emergency-situations-medical-devices/emergency-situations-medical-devices/emergency-situations-medical-devices/emergency-situations-medical-devices/emergency-situations-medical-devices/emergency-situations-medical-devices/emergency-situations-medical-devices/emergency-use-authorizations">https://www.fda.gov/medical-devices/emergency-use-authorizations
 - o FDA Serology guidance: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance
- The California COVID-19 Testing Task Force: https://testing.covid19.ca.gov
- Laboratory list for SNF testing: https://testing.covid19.ca.gov/wp-content/uploads/sites/332/2020/06/COVID-19-Testing-Task-Force-Lab-List-updated-06-11-20.pdf

Since we didn't get to have Q&A last week, I'd like to revisit CDC's updated infection control <u>FAQs</u> regarding testing in nursing homes as I'm guessing you might have questions about them. The first FAQ is whether residents or HCP who previously had COVID-19 confirmed by viral testing should be retested. The answer depends on:

- 1. how much time has passed since their initial illness;
- 2. what strategy the facility is using to determine when residents can discontinue isolation and HCP can return to work; and
- 3. whether the individual has developed symptoms after initial recovery.

Most individuals who recently recovered from COVID-19 are likely no longer infectious even if they continue to have a positive viral test (e.g., persistently or recurrently detectable viral RNA). When an individual has a positive test result <6 weeks after they met criteria for discontinuation of Transmission-Based Precautions or Home Isolation, it's possible they still have detectable viral RNA from their previous infection.

Residents and HCP who had a positive viral test in the past 6–8 weeks and are now asymptomatic may not need to be retested as part of facility-wide testing unless the facility is using a test-based strategy to determine if residents can discontinue isolation or HCP can return to work. Residents and HCP who had a positive viral test over 8 weeks ago should be retested as part of facility-wide testing, regardless of symptoms. Residents and HCP who had a positive viral test at any time and become symptomatic after recovering from the initial illness should be re-tested and placed back on the appropriate Transmission-Based Precautions or excluded from work, respectively.

Another FAQ is how to manage residents who decline testing. If a resident has symptoms consistent with COVID-19, but declines testing, they should remain on Transmission-Based Precautions until they meet the symptom-based criteria for discontinuation. If a resident is asymptomatic and declines testing at the time of facility-wide testing, decisions on placing the resident on Transmission-Based Precautions for COVID-19 or providing usual care should be based on whether the facility has evidence suggesting SARS-CoV-2 transmission (i.e., confirmed infection in HCP or nursing-home onset infection in a resident). Only residents who have a confirmed positive viral test should be moved to COVID-19-designated units or facilities.

Another FAQ we've received is regarding testing-based management of HCP with a known, high-risk exposure who will be allowed to work during quarantine:

In addition to continued universal source control and symptoms monitoring as for all HCP, consider early serial testing (e.g., starting at 3 days post exposure, and every 3-4 days thereafter during the quarantine period) so that you can identify positive HCP as early as possible and exclude them until return-to-work criteria are met.

FAQ regarding timing of COVID screening for hospitalized patients who will be transferred to SNF; in other words, how recent must the negative COVID be in order to admit to SNF/nursing home from the hospital?

Depends on turnaround time for test results. Ideally, the timing of obtaining the test should be as close as possible to the date of transfer but such that the result is known at the time of transfer to inform appropriate infection control measures and cohorting for a new admission at the SNF. Importantly, the SNF will still need to place that individual in an observation status for 14 days from the date of last presumed exposure (not from the date of the negative test); exception to this is the SNF resident who goes to the hospital ED for a non-COVID issue and is screened in the ED – wouldn't necessarily need that result back before the SNF resident goes back to their home facility, just be sure the result is communicated to the SNF.

V. Remdesivir Update

Dr. Philip Peters

California received its fifth shipment of 353 cases (14,120 doses) on June 19. This shipment is being distributed based on June 18 data for hospitalized patients with confirmed COVID-19. The next shipment - and the last shipment from Gilead's donation - will be during the week of June 29.

A link to the excel spreadsheet that details remdesivir distribution to each county is provided in the notes and is posted on the CDPH website on the guidance page (https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Guidance.aspx) under remdesivir.

https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/CaliforniaRemdesivirAllocationAndDistribution-6.19.20.xlsx

We expect to be receiving more information soon from Gilead and the US government on plans for remdesivir distribution for July and beyond.

VI. Question and Answer

Q: What do you recommend when a healthcare worker declines COVID testing?

A: Try to understand why the individual is refusing testing. Perhaps the type of specimen collection may be an issue, so offer other options. Provide information on how testing can protect the individual, their family, and community. Ultimately, the facility's Occupational Health program is responsible for responding to this situation.

Q: How will quantitative PCR testing be used for testing in isolation, for either patients or HCP?

A: This depends on which PCR you are using. All PCRs being used are real time and should be comparable to each other. There is no specific CDC guidance on the use of quantitative PCR as opposed to other types of PCR testing when determining whether isolation could be discontinued. We do not have quantitative thresholds to determine if a patient can be removed from isolation.

Q: Once surveillance testing is in place at SNFs, will the hospitals and emergency rooms need to keep testing patients admitted from SNFs that were not admitted for COVID?

A: We know that many hospitals are screening SNF residents upon admission that present to the emergency room or hospital for a brief admission where no clinical concern for COVID is present. Depending on the length of admission, the patient might be ready for dismissal back to the SNF if test

results are still pending. For new SNF residents, it is important that the test results be known at the time of transfer in order for the SNF to perform effective control measures.

Q: Cal OSHA guidance prohibits the use of using a permanent marker on N95 masks. Their guidance also instructs not to reprocess N95 masks used during an aerosol generating procedure. Has there been any modification to that guidance?

A: We do not have a Cal OSHA representative present right now, but we believe the concern for using permanent markers on N95 masks could somehow result in an unsafe product. We have found no research to indicate otherwise, so we referred that guidance. We will follow up with Cal OSHA to confirm. Regarding the reprocessing of N95s after use with an aerosol generated procedure, a higher level respirator is required for those procedures.

Q: Is there guidance for previously diagnosed COVID positive patients returning to a facility for elective procedures when aerosol generating procedures are involved? Does that guidance differ at all for immunocompromised patients?

A: We recommend the use of the test-based strategy as a conservative approach. If possible, you can defer elective procedures in order to obtain two sequentially negative tests for immunocompromised patients.

Q: People in the community have asked who they can contact if they observe a business not following proper COVID guidelines?

A: They can always reach out to local county public health office. Contacting local law enforcement is another option to let them know about a severe health concern. Many counties will issue a citation.

Q: We currently have limited reagents. What is most appropriate use of Abbott ID Now? Can we use it in our SNF screening?

A: Abbott ID Now should not be used for asymptomatic screening, so it probably would not be appropriate for screening asymptomatic patients to be discharged to SNF. It can be used for individuals admitted with symptoms potentially consistent with COVID to inform action for immediate infection control and isolation procedure. If you use Abbott ID Now to test a symptomatic person and get a negative result, you will need to follow up with another type of test.

Q: Can you address the surge we see in community spread?

A: When we use the term surge, we are referring to a surge in hospitalization. Case numbers will continue to rise because we are increasing testing, but we are also seeing an increase in community spread as the economy opens. The hospitalization and increased use of ICUs and ventilators are key indicators for how much space is available to accommodate patients adequately. We still have Alternative Care Sites (ACS) available if needed.

Q: I have a SNF employee that is extremely concerned because they had a needle stick with a COVID positive patient. I am trying to communicate to this employee what her risk for becoming infected is in terms of blood or body fluid transmission. Do you have a resource I can direct her to?

A: We are not aware of any guidance related to this. It could be theoretically possible, but the bigger concern would be routine bloodborne exposures. Have the HCP monitor their symptoms.

Q: Upon new admission to our SNF, we are following protocols. If a patient is asymptomatic and has previously tested negative for COVID, am I required to wear an N95, or is surgical mask acceptable?

A: The recommendation for newly admitted residents in the observation period is to use full PPE as if they were COVID positive. If a facility has shortages and known COVID positive individuals present, respirators should be prioritized. But with adequate supply, including extended use practices, the preference is to continue to use an N95 during the observation period.

Q: Our facility conducts employment exams which require the use of spirometers. OptumServe is still requiring nasopharyngeal swabs, although guidance indicates other swabs are acceptable. Is there any reason for that or will they change their position?

A: I would like to discuss the spirometer use with our occupational health partners. The testing taskforce webpage may offer some guidance regarding OptumServe.