

California Department of Public Health Weekly Facility COVID-19 Update Call August 18, 2020 8:00 am – 9:00 am

I. Welcome / Introduction:

II. Testing Taskforce Update:

State run testing sites Optum Serve and Verily will continue through September.

A recent RFP for mobile testing sites was distributed and applications have been received. We anticipate decisions made regarding these applications within the next 1-2 weeks.

The TTF has distributed Swabs: **7.4M** (+406k), Media: **5.5M** (+445k) and have 25 weeks of swabs and 11 weeks on Media in back up supplies.

We are also aware that the ID Now machine supplies will be opening up again and some supplies may be available again soon.

TTF continues to encourage entities to think beyond PCR testing to fulfill testing needs. For example, the antigen tests, best suited for symptomatic individuals within 5 days of symptom onset. Pooling for asymptomatic individuals. Test guidance and pooling guidance can be found on the TTF website Consider the right test for the appropriate situation at the right time.

III. Laboratory Update:

This past week several testing guidances were released.

CDPH released an updated guidance on the types of tests – molecular, antigen, and serology – that are available for COVID-19 testing; a link is provided in the notes. <u>https://testing.covid19.ca.gov/wp-content/uploads/sites/332/2020/08/COVID-testing-8.6.2020-FINAL-letterhead.pdf</u>. A CDPH guidance document on the use of antigen tests is forthcoming. Please note that a facility that performs only CLIA-waived tests must possess either a CLIA Certificate of Waiver or a Certificate of Compliance. Persons performing the point-of-care test must be trained in how to perform it, but there are no testing personnel requirements.

This past weekend the CDC released guidance on the use of antigen tests to diagnose COVID-19. This can be found under the Using Antigen Tests tab on the CDC COVID-19 Testing webpage. As part of this guidance, they have defined 3 categories of testing and their intent for use: Diagnostic, Screening, and Surveillance. The CDC guidance is quite descriptive, but basically they consider Surveillance testing as a

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public health tool to be used across a population and does not require testing in a CLIA compliant lab or with an EUA; surveillance results are not to be returned to the individual or to be used for patient management. Conversely, both Diagnostic and Screening testing, as defined by the CDC, are intended to detect COVID-19, whether in someone who is symptomatic or asymptomatic. Diagnostic and screening test results are to be reported to the individual and to public health, and must be performed with an FDA approved test in a CLIA regulated environment. The CDC Antigen testing guidance also provides information on advantages, uses, and limitations of antigen testing.

https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

The US FDA provided a new question and answer recommendation for healthcare providers on the use of testing ("screening") asymptomatic persons for COVID-19. Visit the FAQs page under the "General FAQs" heading. Essentially, if you (a healthcare provider) suspects COVID-19 in an asymptomatic individual, any FDA-approved test can be used. However, if you are ordering an authorized SARS CoV2 diagnostic test to be used off-label (outside the EUA) to screen asymptomatic individuals NOT suspected of COVID-19, the FDA recommends you consider these factors:

- 1. Data are limited on the viral loads in symptomatic vs asymptomatic people across demographics, different settings, and specimen types. Therefore, consider using a highly sensitive test, which is more likely to provide more accurate results, especially when results can be provided in a timely or rapid fashion.
- 2. If less sensitive tests, such as some POC tests are used, be aware of the performance of the test. You may want to consider serial testing when POC results are negative, such as repeat testing with a different test or with new samples collected on a different day.
- 3. Negative results in asymptomatic persons should be considered as presumptive negative and you should consider them in the context of clinical observations, patient history, and epidemiological information.

There are still only 2 Ag tests approved for diagnostic use, and CDPH continues to caution that there are limited data to guide the use of rapid Ag tests as screening tests on asymptomatic persons to detect or exclude COVID-19. The manufacturers have stated that when samples are collected with 5 days of symptom onset, these tests are reported to have positive percent agreement of 97% (Quidel) and 84% (BD Veritor) compared to RT-PCR. Since these tests are generally less sensitive than PCR tests, they may return a negative result when a more sensitive test such as PCR may be positive. Positive results are likely to be reflect an active infection, but negative results may not rule out infection.

IV. Healthcare-Associated Infections

1. As Dr. Hacker presented, this past weekend the CDC released guidance on the use of antigen tests to diagnose COVID-19, which defines 3 categories of testing and their intent for use: Diagnostic, Screening, and Surveillance. The CDC defines Surveillance testing as a public health tool to be used across a population and for which results are not to be returned to the individual or to be used for patient management. Conversely, CDC defines Screening testing as testing to detect COVID-19 in someone who is asymptomatic. and without known or suspected exposure to SARS-CoV-2, and its purpose is to identify persons who may be contagious so that measures can be taken to prevent further transmission.

Dr. Erin Epson

The CDPH All Facilities Letter 20-53.2, which was originally released several months ago, recommends regular "Surveillance" testing of skilled nursing facility healthcare personnel, which is more aligned with the category of testing that CDC is now defining "Screening" testing. As such, AFL 20-53.2 will be updated to align its terminology with CDC, and also to incorporate forthcoming CDPH guidance about the use of antigen tests that specifically addresses their use in SNF, as well as other clarifications that I have discussed on recent previous healthcare facilities calls.

2. CDC also posted a note to their guidance on the duration of isolation and precautions for adults with COVID-19. The note seems intended to clarify misinterpretation of their guidance to not re-test asymptomatic individuals within 3 months of a prior positive test to mean definitively that individuals were immune to reinfection for 3 months, and concerns that this misinterpretation would potentially lead people to not follow physical distancing and source control measures if they had (or thought they had) COVID-19. Rather, CDC is saying that we don't know for sure about immunity, but that because PCR tests can continue to be positive for prolonged periods without infectiousness, testing asymptomatic individuals is not recommended for 3 months. If a previously positive individual develops COVID-19 symptoms without another apparent cause, even if within 3 months of their prior positive test, CDC recommends considering re-testing for COVID-19. CDC recommends that all people, whether or not they have had COVID-19, continue to take safety measures to avoid becoming infected with COVID-19 (wash hands regularly, stay at least 6 feet away from others whenever possible, and wear masks).

Here's that CalOSHA guidance link to include in my transcript: <u>https://www.dir.ca.gov/dosh/coronavirus/Cal-OSHA-Guidance-for-respirator-shortages.pdf</u>

V. Remdesivir Update

Dr. Philip Peters

We have now received our sixth commercial distribution of remdesivir which has been significantly larger than previous distributions. The sixth distribution was for was 1,094 cases (or 43,760 doses) which is about three times as much as previous weeks.

A weblink will be posted later today on the CDPH guidance page with the distribution details. Link: <u>https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-</u>19/CaliforniaRemdesivirAllocationCommercial-8.10.20.xlsx

This larger allocation seems to have come closer to meeting the need for remdesivir but we are still interested in hearing if that is the case or not.

The Medical Health Operational Area Coordinator (or MHOAC) for each county has been getting informed of their allocation of remedesivir on Thursday and have to finalize allocations to hospitals by close of business Friday so at the end of the week is the optimal time to determine and communicate with your MHOAC the amount of remdesivir that your hospital intends to order from AmerisourceBergen. If you communicate to your MHOAC that you intend to order less than your

allocation of remdesivir, it allows time to reallocate to another hospital in California. If you do not inform the MHOAC then that product will be reallocated nationally.

VI. Question and Answer

Q: Is the Abbott ID NOW is used on an asymptomatic patient and is tested negative, would this be a presumptive negative? All patients coming in are being tested.

A: For screening asymptomatic individuals in the hospital with no known contact with COVID, then we are assuming the probability is low. The lab will not need to report as a presumptive negative, but the hospital will use their clinical judgement. The Abbott ID NOW is best used for symptomatic individuals, and there is a risk for false negatives for this device.

Q: Has the CalREDIE data process been fully validated?

A: Yes, the issues have been resolved. I would reach out to your local county about the reporting process.

Q: If there is a previously positive patient and is displaying symptoms, do they need to be tested for COVID?

A: CDC is recommending that they would be tested. If you have a recent recovered positive and they test positive, we would like to do full genome sequencing to gather more information.

Q: Does the current guidance allow for dental staff to swab?

A: The current regulation now does not allow dental staff to be used for conducting NP swabs.