



**California Department of Public Health
Weekly Facility COVID-19 Update Call
July 21, 2020
8:00 am – 9:00 am**

I. Welcome / Introduction:

Heidi Steinecker

II. Testing Task Force Update:

Dr. Kathleen Jacobson

As you are all aware there are increases in COVID 19 cases nationwide. Simultaneously states throughout the country have scaled testing. This has caused new constraints for testing in California. Prior to the 4th of July weekend California was consistently performing between 80-90,000 test per day. Then over the holiday weekend California hit an all-time high of 127,000 tests in a single day and now are consistently doing over 120,000 tests daily. This increase in testing in California and nationally has resulted in increased number of specimens that are going to labs, increasing the time for a patient to get an appointment to have a test, and markedly increased turnaround time to get test results back.

All of this impacts timely clinical care, implementation of contact tracing and ultimately inhibits our ability to control the COVID 19 epidemic here in California. The way this has been experienced on the ground is that testing supplies that are delivered to testing sites for collection have been limited – sometimes substantially. This has resulted in some testing sites having to close. Yet we know in California that we have over 400 high and medium throughput labs resulting in a potential capacity of 190-200 thousand tests per day if the sites ran 24/7. Or about 66,000 cumulative tests across all labs in an 8 hour shift.

So initially the TTF thought if we matched the organizations needing testing to the labs that still had capacity we could resolve the issues. In fact the TTF has a lab list that identifies over 50 of these labs which meet CDPH lab readiness criteria for COVID 19 testing for licensure, FDA Emergency Use Authorization, reporting to CALRedie (which is what allows us to implement contact tracing) and are registered with Lab Field Services and willing to contract to do more testing.

https://testing.covid19.ca.gov/wp-content/uploads/sites/332/2020/07/COVID-19-Testing-Task-Force-Lab-List-updated-07_16_20.pdf

However, we quickly learned that there were barriers to organizations matching with new labs. Many organizations had longstanding hardwired contracts with just a few of the major labs. Those labs are national labs and organizations have long term commitments to those labs. Additionally, some of the major labs were all using the similar testing platforms and those platforms were now starting to have reagent, and plastics (pipette tips, pipettes, trays) shortages. As well those labs were being overwhelmed with specimens beyond their current capacity—as you can see with CA alone, we

increased our testing by 40-50,000 tests a day. So the next question that surfaced was whether the larger labs could subcontract with some of the other labs that had capacity to run the tests.

So on Friday July 10th we invited the lab directors from over 200 labs to a meeting to discuss these issues and try to trouble shoot solutions. What we learned is that some of the larger labs were actually willing to subcontract with the smaller labs but they were running into a few challenges. Even if a lab does subcontract with another lab to do their tests, there is an initial processing of specimens (accessioning) that has to happen in the first lab. This process is timely and takes a significant amount of manpower. Yet there is a “no mark-up” clause that prevents labs from billing insurances for this initial process if they are preparing the specimen to go to another lab. So this is something the TTF is looking into to find solutions. Additional laboratory challenges were also brought to our attention.

This initial processing for labs (accessioning) as mentioned above takes a lot of time and manpower. But the time it takes can substantially decreased if the ordering and registering of specimens is done via online electronic registration process instead of a paper process that requires significant more time to accession which adds to turn around time and therefore delays results getting to patients and CALREDie further delaying contact tracing and epidemic control. **So laboratory directors across CA requested the TTF to urge all facilities to please register and order tests via the labs online registering platform.** When labs are getting tens of thousands of specimens a day this can have a substantial impact on speeding turn-around time if all facilities use these electronic registration and ordering processes.

We also learned that some labs could actually run more specimens, but they are facing workforce shortages. They actually have capable staff who could help process additional specimens, but their personnel level is too low to allow them to do so. However, the lab directors believe with appropriate supervision they could process the specimens. This would require executive order to do so. TTF has looked into this and have learned that there was a previous executive order placed in April to waive CA regulatory personnel requirements for the duration of the emergency based on federal CMS CLIA personnel requirements. To date the federal government has not yet lowered their requirements. The CDPH Lab Field Services is having weekly conversations with CMS CLIA to try to address this. Additionally, the TTF is working on a solution to this personnel requirement issue.

Additionally, TTF ultimate goal is to have all tests turnaround time down to 24-48 hours, however given the current constraints and in efforts to prioritize currently which specimens need absolute 24-48 hour turnaround time (hospitalized and under public health department outbreak investigations), the TTF wrote new Testing Prioritization Guidance for healthcare providers and public health departments. **In order to ensure these Tier 1 specimens get prioritized the laboratory directors have asked the TTF to also get the message out to all facilities asking them to ensure that those priority specimens are appropriately identified based on your labs requirements which may be a card, or a sticker or some other way to mark and identify these priority specimens.**

The TTF has also shared with the laboratory directors that by law they are required to transmit COVID 19 results to CALREDIE within 24 hours. For those labs not doing so TTF implored them to do so every 24 hours or if possible, even more frequently. For those already transmitting once every 24 hours TTF asked labs to increase their frequency of transmission to multiple times a day since that transmission

from the lab to CALREDie is transmitted to CALCONNECT and this triggers contact tracing. Ultimately this helps with in epidemic control.

The TTF has also looked into additional strategies to address the testing constraints including the possibility of the state of CA actually developing our own reagents and supplies such as pipette tips, pipettes and other plastics to ensure long term sustainability. However, what we learned is that the testing platforms used by some of the major labs have received their FDA Emergency Use Authorization using proprietary equipment and thus different supplies could not be used on these platforms as they are not open platforms. So TTF considered whether CA should develop its own testing platform and supplies. Simultaneously we learned of a company that had developed a new platform including reagents and supplies. Uniquely, when this testing platform and supplies applied for its EUA with the FDA it also applied for an EUA on another 20+ “open” testing platforms that would allow its supplies to be used on these additional platforms without having to go back for an additional FDA EUA approval. The TTF solidified a contract with this company last Friday July 17th. We are in the processing of first implementing this with the PHL in CA to expand their testing capacity since PHL are the first line of testing in outbreak investigations. Once PHL are adequately outfitted then it may be possible to expand beyond the PHL. Currently, the TTF is also working to solidify a deal with a transport media manufacturer since this has also been a challenging supply to obtain.

Finally, the TTF has already been looking into alternative testing including test pooling which could allow more specimens to be processed simultaneously. TTF previously wrote pooling guidance and had a few small labs studying pooling. As of last week a few of these labs had gone in for FDA approval and were awaiting its outcome, one of these labs (Westpak) shared their FDA pooling approval application packet with the TTF to share with other labs to assist them in writing their own approval applications and finally we learned yesterday that Quest received the first FDA approval for pooling and anticipate seeing more of the pooling applications approval packets to move through the FDA soon.

So, in conclusion the TTF will continue to work on supplies, personnel requirements, insurance no mark up, alternative testing and supply strategies. **What we ask all of you to do is- if possible contract with additional labs that have capacity to level load the volume throughout labs in CA, when registering patients for test orders and registration—use electronic registering to decrease the initial processing time for labs, and ensure that those individuals who are in Tier 1- hospitalized or under PHD investigation are marked according to your labs requirements to prioritize the specimens.**

III. Laboratory Update:

Dr. Deb Wadford

Updated Guidance from the CDC

As of July 17, 2020, except for rare situations, a **test-based strategy is no longer recommended** to determine when an individual with SARS-CoV-2 infection is no longer infectious (e.g., to discontinue Transmission-Based Precautions or home isolation). Dr. Epton will discuss this in further detail and I will now focus on antigen tests and their use as CLIA waived assays, in light of news that CMS (Centers for Medicare & Medicaid Services) plans to provide these tests to SNFs.

Antigen Assays to detect SARS-CoV-2

- Antigen tests can provide relatively rapid results; however, they are not as sensitive as nucleic acid amplification assays such as PCR. Thus, positive results tend to be highly accurate, but a negative result may be a false negative.

- Indeed, negative results by an antigen test should be considered as presumptive negative.
 - If necessary for clinical management or infection control, negative antigen test results should be confirmed using a molecular assay with FDA Emergency Use Authorization (EUA) for SARS-CoV-2 detection.
- Antigen tests are NOT recommended for screening of asymptomatic individuals or screening of healthcare workers, first responders and other essential personnel.
- The Association of Public Health Laboratories (APHL) has published a guidance document on the use of antigen tests. Link provided in these notes below.
 - <https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf>.

CLIA Waived SARS-CoV-2 Point of Care Antigen Tests

- CLIA waived tests may be performed at sites that possess a CLIA Certificate of Waiver. These sites are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
- Facilities performing only waived tests have no routine oversight and no personnel requirements. These sites are only required to obtain a CLIA Certificate of Waiver, pay biennial certificate fees, and follow manufacturers' test instructions.
- The two antigen tests currently with FDA EUA status are both considered CLIA waived assays meaning that, as defined by CLIA, these waived tests are simple with a low risk for an incorrect result, but they are not error-proof.
- Despite being a CLIA waived test, erroneous results may have serious health consequences. To decrease the risk of erroneous results, the test must be performed correctly, by trained personnel, and in an environment where good laboratory practices are followed.

A link to more details about CLIA waived assays is included in these notes.

Select Guidance Links:

- CDC guidance on CLIA Waived tests: <https://www.cdc.gov/labquality/waived-tests.html>
- Specimen collection: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>
- The California COVID-19 Testing Task Force (CA TTF): <https://testing.covid19.ca.gov>
- CA TTF “Find a Test Site” tool:
<https://www.arcgis.com/apps/Nearby/index.html?appid=43118dc0d5d348d8ab20a81967a15401>

IV. Healthcare-Associated Infections

Dr. Erin Epon

CDC has updated their guidance on the [duration of isolation and precautions](#) and the role of testing strategies for their discontinuation and return to work for infected healthcare personnel.

Essentially, CDC no longer recommends the test-based strategy except for persons who are severely immunocompromised (e.g., currently receiving chemotherapy, or recent organ transplant), and they are recommending a symptoms-based approach of 10 days after symptoms onset (or date of positive test for asymptomatic individuals) with lack of fever and improving symptoms for 24 hours (instead of 72 hours) for most individuals; extending the duration to 20 days can be considered for persons with

severe illness.

CDC cites available data that persons with mild to moderate COVID-19 remain infectious no longer than 10 days after symptom onset, and that persons with more severe to critical illness or severe immunocompromise likely remain infectious no longer than 20 days after symptom onset. Whereas recovered persons can continue to shed detectable SARS-CoV-2 RNA in upper respiratory specimens for up to 3 months after illness onset, replication-competent virus has not been reliably recovered in these individuals and studies have not found evidence that clinically recovered persons with persistence of viral RNA have transmitted SARS-CoV-2 to others. As such, CDC is recommending a symptom based, rather than test-based strategy for ending isolation of these patients, so that persons who are by current evidence no longer infectious are not kept unnecessarily isolated and excluded from work or other responsibilities.

In addition, CDC acknowledges that reinfection with SARS-CoV-2 has not yet been definitively confirmed in any recovered persons to date, and that if, and if so when, persons can be re-infected with SARS-CoV-2 remains unknown and is a subject of investigation. Persons infected with related endemic human betacoronavirus appear to become susceptible again at around 90 days after onset of infection. Thus, for persons previously diagnosed with symptomatic COVID-19 who remain asymptomatic after recovery, retesting is not recommended within 3 months after the date of symptom onset for the initial COVID-19 infection. In addition, quarantine is not recommended in the event of close contact with an infected person.

Importantly, this 3 month timeframe also now applies to [retesting of residents and healthcare personnel in skilled nursing facilities](#), where previously the recommendation was to retest as part of facility-wide testing after 8 weeks. Residents and HCP who had their initial positive viral test in the past 3 months and are now asymptomatic do not need to be retested as part of facility-wide testing; testing should be considered again (e.g., in response to an exposure) only if it is 3 months after the date of onset of the prior infection.

For persons who develop new symptoms consistent with COVID-19 during the 3 months after the date of initial symptom onset, if an alternative etiology cannot be identified, then the person may warrant retesting in consultation with infectious disease or infection control experts. Quarantine, isolation and transmission-based precautions, may also be considered during this evaluation based on consultation with an infection control expert, especially in the event symptoms develop within 14 days after close contact with an infected person.

V. **Remdesivir Update**

Dr. Philip Peters

We have now shifted to the commercial distribution model for Remdesivir. California's first allocation of 354 cases (or 14,160 doses) of Remdesivir was distributed last week. The transition to this new distribution model seemed to go well. As of Monday (7/20) morning, the distributor, Amerisource Bergen, reported that Remdesivir had been shipped to 255 of the 263 hospitals that received an allocation. The other eight hospitals were still "in process" and we hope that the process should get more smooth moving forward. We haven't posted this first commercial allocation to the web yet but hope to do that soon.

We received good news that we will be receiving weekly distributions of Remdesivir instead of every other week, as such California has been allocated an additional 360 cases (or 14,400 doses) this week.

The federal website for Remdesivir distribution has been updated with new information including an FAQ on the commercial distribution process and a link to their website will be provided in the meeting notes.

Federal Remdesivir website: <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/remdesivir.aspx>

Federal allocation of Remdesivir to states:

<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/commercial-allocation-table.aspx>

To review the process one more time, we will now allocate Remdesivir weekly by county based on number of hospitalized patients with COVID-19 infection. The county MHOACs will then determine how much Remdesivir to allocate per hospital. CDPH will send that information to Amerisource Bergen who will contact each hospital with the amount of Remdesivir that they can order. Hospitals will place their order and be billed for the Remdesivir that is ordered. We are encouraging hospitals to order all of the Remdesivir that they are allocated until the supply starts to truly exceed the number of patients with clinical indications as we have been allocated a limited amount of medication and the number of patients being hospitalized in California continues to increase. If a hospital does not want all of the Remdesivir allocated, we ask that you to let your MHOAC and CDPH know as soon as possible so that medication can be reallocated to another hospital that needs Remdesivir. If we do not do this, the medication gets put back into the national supply and can't be used in California.

VI. Question and Answer

Q: Can Cal OSHA address the use of permanent markers being used on N95 masks?

A: We put out guidance based on NIOSH that the use of a marker voids the approval of a respirator. EMSA and Battelle conducted their own study and results showed permanent markers did not result in the degradation of filtration efficiency. Therefore, we have changed our position on that and haven't changed the website. We are going to permit permanent markers. We are looking at what the appropriate number of reuses are.

Q: What is the recommendation when a patient is screened upon entry to a facility and they are COVID positive?

A: When an individual entering a facility is screened positive for COVID 19, the individual should be placed in isolation and be source controlled with a facemask until they can be placed in the appropriate isolation room. Ideally you would have a designated COVID unit for positive individuals.

Q: According to AFL 20-60, individuals that test positive should not be included in response testing until after three months. It also says that in order to do response testing, you must test 100% of the population. If we aren't supposed to test positives for three months, then we are not able to test 100% of our population. Can you offer some guidance on that?

A: You would not need to continuously re-test positives. Positives would not need to be re-included in the response testing population until they've met the criteria to return to response testing population.

Q: If a staff member hasn't been in the building for two weeks and they test positive, is response-based testing necessary, and should they be part of the denominator?

A: No, if a staff member tests positive but they weren't in the building during the 14-day exposure window or near the building around the time of testing positive, that would not constitute as a potential exposure. We would like them included in the denominator to understand where they've been who they work for.

Q: If staff are not going to be in the building for two weeks, do staff need to be tested for response testing? Our Skilled Nursing Facility (SNF) is not a long-term care facility, but short term. An average stay of 10 days does not absolve us from the SNF category.

A: If staff are not in the building or potentially exposed, I don't see the reason to have them in the response testing. We do know that there are facilities where this goes around for a long time. For those that work intermittently and then come back, they would need to be included in response testing. I would say that having that testing information could be empowering. We're more in line to say if they're positive they can work with positive patients as long as they're asymptomatic.

Q: Can Cal OSHA please comment on the written guidance from June 5, 2020 for Childcare Facilities that might be interpreted for healthcare facilities and the use of a face shield without masking?

A: That is a recommendation strictly limited to the instruction of children in a classroom for pedagogical reasons. Children in early development need to be able to see their teachers face. In no way should it be taken that it's ok to wear a face shield without a mask in a healthcare setting.

Q: Regarding not being able to fit test your employees, if the mask you have says they have a crosswalk, what is your recommendation?

A: We consider that a new model, and we still recommend fit testing.