California Department of Public Health
Weekly Facility COVID-19 Update Call
August 4, 2020
8:00 am – 9:00 am

I. **Welcome / Introduction:** **Heidi Steinecker**

II. **Overview:** **Dr. Kathleen Jacobson**

The TTF continues to work on testing volume issues that are delaying turnaround times. We wanted to share with you that last week FDA granted Quest authority to utilize a new RNA extraction technique that will allow Quest to perform 150,000 tests per day this week and 185,000 tests per day by the end of August. Two of the six labs offering this new lab technique are in California; Quest's San Juan Capistrano and Valencia labs.

The TTF lab list has been updated and can be found on the Testing Task Force Website. https://testing.covid19.ca.gov/wp-content/uploads/sites/332/2020/07/COVID-19-Testing-Task-Force-Lab-List-updated-07_23_20-v7.28.2020-1.pdf. The TTF was asked to look into who can perform various swabs.

For self-collected nasal swabs these have the best outcome when performed in the presence of a trained healthcare worker. Of note observation of self-collection does not appear to be regulated under current law, and is not currently a regulatory issue.

The following individuals can perform NP swabs.

- Registered nurses can collect specimens using nasopharyngeal or oropharyngeal swabs.
- Nasopharyngeal or oropharyngeal swab collection is within the scope of practice for a licensed vocational nurse (LVN) and psychiatric technician (PT) as long as the LVN or PT:
    - Receives specialized instruction in the proper procedure from a registered nurse or licensed physician;
    - Demonstrates the requisite knowledge, skills and ability prior to performance of the procedure; and
    - Performs the procedure in accordance with a licensed physician's order.
    - Respiratory care practitioners are authorized under their scope of practice to collect specimens using swabs, including NP and OP swabs.
    - EMTs and paramedics are authorized by the Director of the California Emergency Medical Services Authority to collect nasopharyngeal swabs only for COVID-19 testing and only for the duration of the COVID-19 emergency. Additional information about the local option scope of practice allowing them to do this is available on the California Emergency Medical Services Authority webpage.

Supplies:

To date CA has distributed 6.2 million swabs and has an 18 week stockpile. 4.4 million media transport have been distributed and CA has a 4 week supply.

Finally, the TTF recognizes that in order to meet the current testing needs in CA, it will be necessary to embrace other testing technologies beyond PCR testing.

III. **Laboratory Update:** **Dr. Deb Wadford**

Antigen Assays to detect SARS-CoV-2:
There are currently two SARS-CoV-2 Antigen (Ag) Assays available through FDA Emergency Use Authorization (EUA): 1) the Quidel Sofia SARS Antigen FIA assay, and 2) the BD Veritor System for Rapid Detection of SARS-CoV-2. Both assays are approved as CLIA-waived tests (point of care).

These antigen tests are lateral flow assays designed to detect the nucleocapsid of SARS-CoV-2 virus, if present, from a patient's nasal and can provide results in about 15 minutes.

- The Sofia Ag assay allows for the collection of NP specimen using a nylon flocked NP swab (not supplied)
- Both tests require dry swab collection with NO transport media
- Both tests recommend testing as soon as possible once the specimen is collected

Antigen tests are not as sensitive as nucleic acid amplification assays such as PCR. Thus, positive results tend to be accurate, but a negative result should be interpreted with caution, and should be considered in the context of clinical suspicion of disease and risk status of the patient.
Indeed, negative results for the BD Veritor antigen test should be treated as presumptive negative, while negative results for the Sofia Ag test should be treated as presumptive if the specimen is collected beyond five days from symptom onset.

- NOTE: this detailed information is contained within the Instructions for Use (IFU) brochure and on the FDA EUA website for each test

If necessary, for clinical management or infection control, negative antigen test results should be confirmed using a PCR-based assay with FDA Emergency Use Authorization (EUA) for SARS-CoV-2 detection.

At this time, antigen tests are NOT recommended for screening of asymptomatic individuals or screening of healthcare workers, first responders and other essential personnel.

CLIA Waived SARS-CoV-2 Point of Care Antigen Tests:
As a reminder, 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.

CLIA waived assays, as defined by CLIA, are simple tests with a low risk for an incorrect result, but they are not error-proof.

Despite being CLIA waived, erroneous results may have serious health consequences. To decrease the risk of erroneous results, the test must be performed correctly according to the IFU, be conducted by

personnel who are fully trained to do the test according to the IFA, and must be done in an environment where good laboratory practices are followed to avoid cross-contamination and maintain safety.

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
- BD Veritor SARS-CoV-2 Antigen Instructions for Use: https://www.fda.gov/media/139755/download
- Quidel Sofia SARS Antigen FIA Instructions for Use: https://www.fda.gov/media/137885/download
- The California COVID-19 Testing Task Force (CA TTF): https://testing.covid19.ca.gov
- CA TTF list of labs with testing capacity: https://testing.covid19.ca.gov/covid-19-testing-task-force-laboratory-list/

IV. Healthcare-Associated Infections — Dr. Erin Epson

Last week, CDPH disseminated an updated AFL 20-53.2 COVID-19 Mitigation Plan Recommendations for Testing of Health Care Personnel (HCP) and Residents at Skilled Nursing Facilities (SNF). This AFL updates testing and isolation guidelines, and HCP return to work criteria to reflect recent changes to the Centers for Disease Control and Prevention (CDC) guidance. The AFL also highlights the Department of Health and Human Services recent announcement of the dissemination of point-of-care antigen test instruments and tests to nursing homes in COVID-19 geographic hotspots, as Dr. Wadford discussed.

The updates include additional clarification about admission testing and quarantine. The purpose of testing and quarantining new admissions to SNF is to monitor the resident for the 14 days since the date of their last likely potential exposure outside the SNF, which could be in the community or in the transferring healthcare facility if that facility is having an outbreak. In general, we would not consider an acute care hospital stay to constitute an exposure unless that hospital is having a suspected or confirmed outbreak. The AFL includes criteria for assessing whether or not a transferring acute care hospital should be considered a site of potential exposure, for the purpose of determining whether to count acute care hospital days as part of the quarantine observation period from the date of last potential exposure for new admissions.

Residents that are being re-admitted to the same SNF after a hospital stay, ED or clinic visit where there is no suspected transmission would not be considered to have an exposure at that outside facility and so do not necessarily require testing and quarantine upon readmission to the same SNF. From a practical standpoint, the practice of quarantine in a separate observation area with use of full personal protective equipment for COVID following a hospital stay or outpatient visit for readmitted residents can lead to SNF residents remaining in the acute care hospital for longer than medically necessary because the SNF is unable to accommodate them in their observation/quarantine area. Rather than quarantine, SNF can consider periodically testing individuals who frequently leave the facility (for example, for dialysis).

I'd also like to clarify regarding the recommendation for response testing every 7 days until no new cases are identified among residents in two sequential rounds of testing. The rationale for this recommendation is that we consider two sequentially negative rounds of testing in residents to be evidence that transmission is no longer ongoing within the facility, because cases in residents are generally a result of transmission within the facility whereas HCP often acquire their infections in the community. So a facility that identifies new cases in HCP while there are no new cases among residents during response testing may still have contained transmission within the facility; new cases identified in HCP in this scenario with control measures in place would trigger additional response testing, but this could be done with contact tracing and a more targeted response testing of residents and HCP, for example, on the same unit where the new positive HCP was identified – will try to clarify this in the next update to the AFL.
Many local health departments require SNF to close to new admissions until transmission is contained, often as evidenced by two sequentially negative rounds of response testing among residents, although this is not intended to be the sole basis of determinations for closures to new admissions. A facility carrying out a diligent outbreak response, with no staffing or operational issues, and a well-separated observation area could likely safely take new admissions.

(From last week's transcript): I'd also like to briefly reiterate some of last week's update on CDC's new recommendation against use of the test-based strategy (2 tests 24h apart) to discontinue isolation and transmission-based precautions and return-to-work for HCP, except under special circumstances. Importantly, this test-based strategy was for discontinuation of isolation and precautions for known positive individuals, not a strategy for screening or surveillance of asymptomatic individuals. We continue to hear about SNF requiring 2 negative tests 24h apart for screening of new admissions, and this is not the correct use of this testing strategy; one test is sufficient, and as I've reviewed on previous calls, the results of the test obtained in the hospital on asymptomatic individuals for the purposes of SNF discharge do not necessarily have to be available at the time of SNF transfer, since these new admissions will be placed in an observation area in the SNF.

V. **Remdesivir Update** **Dr. Philip Peters**

We have now received our fourth commercial distribution of remdesivir which was 457 cases (or 18,280 doses). This fourth shipment brings the total remdesivir allocated to California in the last four weeks to almost 1,500 cases (1,471) and almost 60,000 doses (58,840).

The weblink is now posted on the CDPH guidance page:
https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/CaliforniaRemdesivirAllocationCommercial-8.03.20.xlsx

Now that the supply of remdesivir has increased somewhat and the hospitalizations for COVID have decreased slightly, we are interested in hearing if the supply is approaching the need for remdesivir or if there is still a significant gap in supply.

Overall for the state, the supply does not exceed the number of patients with clinical indications for treatment so we ask that you continue to work closely with your Medical Health Operational Area Coordinator (or MHOAC) to ensure the amount of remdesivir allocated to your hospital is the amount

of remdesivir that you intend to order from AmerisourceBergen. If you communicate to your MHOAC that you intend to order less then that remdesivir can be reallocated to another hospital in California. If you do not inform the MHOAC then that product will be reallocated nationally.

Finally a clinical update, CDC has partnered with the Infectious Diseases Society of America (or IDSA) to offer a new service to clinicians treating COVID-19 patients. Clinicians who have questions about the clinical management of patients with COVID-19 can call the main CDC information line at 800-CDC-INFO (800-232-4636). Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support.

A link to this program is provided in the meeting notes:

- Clinician On-Call Center: https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html?deliveryName=USCDC_425-DM33857.

VI. Question and Answer

Q: Will the state be allowing the use of antigen test to be used for screening at nursing homes and other facilities?

A: I believe the thinking is starting to change and we are starting to think outside of the box. We are beginning to look at that. It does make a lot of sense. We are not there right now but we are working on it.

Q: There are concerns being raised about the false positives rates with the Sofia test. Has anyone at CDPH heard about this at all?

A: Those false positives were the direct result of collecting the specimen and putting the swab in a Viral Transport Media (VTM). Because of that event, of the high false positivity rate, that the Quidel manufacturer and the FDA retested and reevaluated their test and came to the decision that VTMs are not to be used for these tests.

Q: Related to the reporting requirements of healthcare worker positives data that were updated from HHS and CHA. HHS does not have the requirement for that data but we are asked to submit them through CHA. Can someone comment on why there is a difference? Also last week, there was some discussion about outbreak reporting. We are already submitting all of our cases to Local and State Public Health. A lot of the epidemiology related cases are mitigated through the appropriate use of PPE. There is no mention of PPE use and whether that is a mitigation factor for reporting.

A: For you first question, as of date, we are asking for that to be reported as an unusual event across the board with all of our facilities. We need to be uniform in the data we are asking for. That's why it's in that data set. For you second question, the outbreak investigation and reporting threshold that I reviewed on last week's call were proposed by the National Council for State and Territory Epidemiologists and the Council for Outbreak Response and Healthcare Associated Infections. These are separate from the reporting that you mentioned in you first question. These are essentially

threshold recommendations at this point to help facilities investigate their own COVID-19 Cases that might be concerning healthcare associated transmission and reporting those to Public Health under Title 17 and as required for Licensed Healthcare Facilities under Title 20.

- The main questions was that there's nothing in the document sent last week's meeting about mitigating factors if appropriate PPE is being worn. Is that considered epi linkage or not? What is the definition of epi linkage as it relates to PPE would be helpful?
    - There are many factors. The use of PPE does mitigate the level of risk but does not eliminate it all together.

Q: A private employer is using the rapid Sofia test. They are seeing false positives. Are we seeing with the Sofia tests, a sort of residual antigen long after the people are not infectious and so we can disregard those or should we regard that as infectious?

A: That's exactly why we are not recommending the screening of asymptomatic people be done with antigen assays. I cannot give you further advise or suggestion.

Q: We are doing the 14-day quarantining for new admissions when they come from acute care because we are told from the hospital that have treated positive patients in acute care. Should we be actually be asking them if they have been on a COVID unit?

A: Those are setting where we would be a bit more concerned. We are recommending to be in communication with the hospitals for their practices and their COVID unit. It should be coordinated with your local health department.

Q: Can someone speak on the process that can be applied to the determination of hospital versus community onset and those patients who test positive between hospital day two and day 14?

A: This is the rationale for investigation. We would recommend evaluating for epi linkage. The thresholds recommend reporting those instances to public health. There are many factors.

Q: Are dentist and registered dental hygienists ok to be doing nasal pharyngeal swabs?

A: My understanding is that only registered nurses, LVNs, RNs, psychiatric technicians, physicians and in addition to that, EMTs and paramedics are authorized in California under EMSA. I have not heard anything about dental technicians. I will need to look into that.