California Department of Public Health
Weekly Facility COVID-19 Update Call
September 15, 2020
8:00 am – 9:00 am

I. **Welcome / Introduction:** **Dr. Erin Epson**

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

None provided.

III. **Laboratory Update:** **Dr. Jill Hacker**

Antigen Assays to detect SARS-CoV-2

- CDPH has released a guidance document on the use of antigen tests to diagnose COVID-19. This document provides some basic information on the performance characteristics of the four FDA approved SARS-CoV-2 Antigen (Ag) assays. These lateral flow assays can provide results in about 15 minutes. Three assays require a machine to perform or read the test. All four are approved for use on nasal swabs; the Quidel Sofia assay can also be used on NP swabs. All 4 tests require testing of a dry swab (without transport media) and are intended to be performed as soon as possible once the specimen is collected.
- As a reminder, 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, especially in a high risk setting or when used on asymptomatic individuals. Results should be considered in the context of clinical suspicion of disease and risk status of the patient.
- Please see the CDPH testing guidance for more information. A link is provided below.

Use of Saliva for testing for COVID-19

- There has been a lot of interest in the use of saliva for testing people for COVID-19. The FDA lists six laboratories that have received approval for high complexity molecular testing of saliva samples. One of these laboratories is registered on the CA Testing Task Force list of laboratories that perform COVID-19 testing.
- There are additional labs on the TTF list that indicate they can also test saliva. When the FDA relaxed certain requirements for laboratory-developed tests in mid-August, they opened the door for laboratories to validate saliva and other sample types not specifically listed in the EUA assay that they are using. Under this guidance, the testing laboratory does not have to submit their saliva validation to the FDA for approval; however, they would need to provide documentation to CMS inspectors if asked during a CLIA/CMS inspection. Thus, there are additional laboratories on the CA TTF list that have indicated that they can accept saliva, even though they are using an FDA-approved assay that is not specifically listed as approved for use on saliva.

- **What is the relative sensitivity of testing saliva compared with an NP swab?** There have been several published studies. In symptomatic people, when saliva is compared with an NP swab, the relative sensitivity or positive percent agreement (PPA) has ranged from 94-100%, depending on the test. The negative percent agreement (NPA) has ranged from 90-100%. A couple of studies have looked at asymptomatic people: in asymptomatic people, the PPA has been 84.6-94.6%, and the NPA has ranged from 99-100%.

Select Guidance Links:

- CDPH Antigen Testing Guidance: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/CDPH-Guidance-on-the-Use-of-Antigen-Tests-for-Diagnosis-of-Acute-COVID-19.aspx
- APHL Antigen Testing Guidance: https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf
- Considerations for Interpreting Antigen testing at SNFs: https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf
- HHS COVID-19 Testing in Nursing Homes Video: https://vimeo.com/457060061
- 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
- LumiraDx SARS-CoV-2 Antigen Test Instructions for Use: https://www.fda.gov/media/141304/download
- Abbott BinaxNOW COVID-19 Ag CARD Instructions for Use: https://www.fda.gov/media/141570/download

IV. Healthcare-Associated Infections — Dr. Erin Epson

CDPH released updated AFL 20-53.3 Coronavirus Disease 2019 (COVID-19) Mitigation Plan Recommendations for Testing of Health Care Personnel (HCP) and Residents at Skilled Nursing Facilities (SNF); this AFL supersedes AFL 20-53.2. This revision updates and clarifies testing guidelines to align with the Centers for Medicare and Medicaid Services (CMS) interim final rule on facility and resident COVID-19 testing and terminology from new Centers for Disease Control and Prevention (CDC) testing guidance, including the use of point of care (POC) antigen test instruments. I'm going to highlight a some of what has and has not changed:

1. The Surveillance testing for SNF HCP is now called Screening testing to align with how updated CDC testing guidance uses these terms; otherwise the different categories of testing (including Symptomatic and Response testing) have not changed, although the AFL now acknowledges that SNF that completed their baseline testing by June 30 do not need to repeat baseline testing.
2. The frequency of Screening testing for SNF HCP has changed. SNF without any positive COVID-19 cases are instructed to implement a minimum of weekly screening testing of all HCP, regardless of the percentage test positivity in their county. Per CMS, however, SNF in counties with >10% positivity are required to test more frequently, i.e., twice weekly.
3. The AFL now includes the color – red, yellow, and green – terms for defining resident exposure categories that inform placement, cohorting and PPE use.

4. The AFL indicates that SNF may use the Point of Care (POC) antigen testing instruments distributed by the Department of Health and Human Services for testing in the SNF in accordance with CDPH guidance. I'll describe how this guidance applies to the categories of testing in SNF, and whether confirmatory RT-PCR testing is indicated depending on the testing scenario and antigen test result, as follows:
    a. Symptomatic testing: POC antigen tests are most reliable when used on symptomatic individuals in settings with high rates of transmission to quickly identify and isolate contagious individuals.
        i. No confirmatory testing is needed for symptomatic individuals that test positive by POC antigen test; manage as confirmed COVID-19 positive.
        ii. Confirmatory RT-PCR testing should be done immediately for symptomatic individuals that test negative by POC antigen test; manage as suspected COVID-19 pending results of confirmatory testing.
    b. Screening testing of SNF HCP: POC antigen tests may be used for serial testing of individuals tested on a regular (e.g., weekly) basis.
        i. Confirmatory testing is optional for screened individuals that test positive by POC antigen test; manage as COVID-19 positive and consider confirmatory testing for HCP in SNF in areas with low transmission.
        ii. No confirmatory testing needed for screened individuals that test negative by POC antigen test as long as individual will continue to be tested regularly.
    c. Response testing of residents and HCP: POC antigen tests may be used for serial testing of individuals tested repeatedly during an outbreak when turnaround time for RT-PCR results is prolonged, e.g. >72 hours.
        i. No confirmatory testing is needed for response tested individuals that test positive by POC antigen test; manage as confirmed COVID-19 positive.
        ii. SNF should obtain confirmatory RT-PCR testing for response tested individuals that test negative by POC antigen test, and manage as suspected COVID-19 pending results.
5. The AFL includes additional reporting requirements for SNF conducting POC antigen tests under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate of waiver, which are subject to regulations that require laboratories to report data for all testing completed, for each individual tested. Per Title 17 section 2505 of the California Code of Regulations, any entity performing SARS-CoV-2 testing is required to report both positive and non-positive results to public health. There will be a link to a guidance from CDPH on reporting of these results to public health via the CalREDIE manual lab reporting module.

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

Regarding remdesivir distribution, we have now received our tenth commercial distribution and for the third week in a row, the supply has exceeded the demand for remdesivir. We were allocated 1,000 cases again and we ordered about 288 cases (or 11,512 doses) which is about 29% of what was available.

A weblink is posted on the CDPH guidance page in the "other" section with the distribution details.

Link:

https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/CaliforniaRemdesivirAllocationCommercial-9-07-20.xlsx

The only additional update is a reminder that the California Medical Association in collaboration with CDPH will be hosting a virtual grand rounds on October 13th at noon. The topic will be COVID-19 treatment and will feature an excellent speaker who will discuss cutting edge issues relevant to clinical providers. You can find more information on the CMA website and I've included a link in the notes as well:
https://www.cmadocs.org/event-info/sessionaltcd/CME20_1013_GRCOVID/t/Virtual_Grand_Rounds_COVID-19_Updates_in_Theapeutics

VI. **Question and Answer**

Q: Does the point of care testing have to be ordered by a licensed provider?
A: According to the AFL, point of care testing must be ordered by a licensed healthcare provider under their scope of practice.

Q: The AFL says we must test all our healthcare workers weekly, that means 100%?
A: Yes, that is correct. All healthcare personnel must be tested at a minimum of weekly.

Q: There are some differences in the positivity rate for CMS and the state, so which one do we follow?
A: The CMS positivity percentage does not exactly align with the state. However, since the testing criteria is a CMS requirement, I believe it is better to make facility decisions on testing frequency off the CMS positivity rate.

Q: What can be done if a facility cannot reach the 48-hour turnaround time?
A: The CMS memo does require a 48-hour turnaround time. If you cannot achieve the 48-hour turnaround, then facilities need document that they are making efforts to reach the 48-hour turnaround time.

Q: Is there going to be an updated guidance regarding visitor limitations?
A: There are two AFLs that have been released, one for hospitals and one more specific for SNFs. For hospitals, can interpret and create their own policies and protocols. So, if some hospitals feel comfortable with being able to have more visitors safely, then that is allowed. For SNFs, CMS may be loosening their very strict criteria.