California Department of Public Health
Weekly Facility COVID-19 Update Call
September 1, 2020
8:00 am – 9:00 am

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

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

Another new Antigen Test became available last week the Abbott BinaxNow, rapid POC test became available. It has a sensitivity of 97.1% and specificity 98.5%. Recommended use is for symptomatic individuals within 7 days of symptom. The TTF immediately reached out to Abbott about getting CA access to these tests and learned that all 150 million tests to be produced by the end of the year have already been purchased by the federal government and thus we anticipate that CA will be on allocation for these tests.

On 8/24 an Executive Order was signed which allows CA Department of Consumers Affairs to work with CDPH to issue waivers permitting Pharmacists and Pharmacy Technicians to conduct CLIA waived COVID 19 tests to detect the presence of virus. Information can be found on the CA Department of Consumers Affairs website.

Finally, the TTF wants to bring to your attention the fact that CA has entered into a contract with a vendor Perkin Elmer who will open a statewide lab opening in November which will have the ability to perform 100-150K tests daily by springtime.

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

Antigen Assays to detect SARS-CoV-2

- There are now 4 SARS-CoV-2 Antigen (Ag) Assays available through FDA Emergency Use Authorization (EUA) and all 4 assays are approved as CLIA-waived tests (point of care).
  1) Quidel Sofia SARS Antigen FIA assay (within 5 days of onset)
  2) BD Veritor System for Rapid Detection of SARS-CoV-2 (within 5 days of onset)
  3) LumiraDx SARS-CoV-2 Antigen Test (within 12 days of onset)
  4) Abbott BinaxNOW COVID-19 Ag CARD (within 7 days of onset)
- These antigen tests are lateral flow assays designed to detect the nucleocapsid of SARS-CoV-2 virus, if present, from a patient's nasal swab 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)
  - All 4 tests require dry swab collection with NO transport media
  - All 4 tests recommend testing as soon as possible once the specimen is collected

Antigen tests, in general, 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.

Uses of antigen testing in nursing homes (CDC Guidance released on 8/27/2020)
https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html
This document guides the interpretation of results when antigen tests are used in the following circumstances:

- Testing of symptomatic residents and healthcare providers (HCP),
- Testing of asymptomatic residents and HCP in facilities as part of a COVID-19 outbreak response, and
- Testing of asymptomatic HCP in facilities without a COVID-19 outbreak as required by CMS recommendations.

Testing in other circumstances are likely to occur, such as testing asymptomatic residents and HCP who were exposed to persons with COVID-19 outside of the nursing home (e.g., recent hospitalization or outpatient services) or through other screening activities. The principles described here can be used to guide the interpretation of antigen test results in those situations.

Antigen tests should not be utilized to determine the duration of Transmission-Based Precautions nor when HCP can return to work. Test-based strategies are not generally recommended to determine duration of transmission-based precautions, nor to determine when HCP may return to work. If used, test-based strategies should rely only on real-time RT-PCR.

Select Guidance Links:

- 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

Considerations for Interpreting Antigen testing at SNFs:
https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf

IV. Healthcare-Associated Infections — Dr. Erin Epson

Last week, the Food and Drug Administration posted a new FAQ regarding SARS-CoV-2 diagnostic testing of asymptomatic individuals, which includes some specific considerations for such testing in congregate care settings such as skilled nursing facilities.

FDA states that that testing an asymptomatic individual suspected of COVID-19 by their health care provider because of a known exposure or working in a high-risk environment is within the authorized

indications for tests. Health care providers ordering an authorized SARS-CoV-2 diagnostic test to screen asymptomatic individuals not suspected of having COVID-19 are using the test off-label (outside the authorization). Therefore, when screening asymptomatic individuals, FDA recommends health care providers consider using a highly sensitive test, especially if rapid turnaround times are available. If highly sensitive tests are not feasible, or if turnaround times are prolonged, health care providers may consider use of less sensitive point-of-care tests, even if they are not specifically authorized for this indication (off-label). For congregate care settings, like nursing homes or similar settings, repeated use of rapid point-of-care testing may be superior for overall infection control compared to less frequent, highly sensitive tests with prolonged turnaround times.

If less sensitive tests, such as some rapid point-of-care tests, are used, health care providers should be aware of the performance of the tests and may want to consider different testing approaches, such as serial testing. "Negative" results should be considered as "presumptive negative," and health care providers should consider them in the context of clinical observations, patient history, and epidemiological information. Thus, if there is a significant new outbreak in a congregate care facility or high clinical suspicion of an infection in an individual resident, a negative point-of-care test should be confirmed with a highly sensitive molecular test (per CDC guidelines). It is not necessary to perform confirmatory high-sensitivity molecular tests on individuals with negative antigen test or other point-of-care test results if they are obtained during routine screening or surveillance.

This guidance from FDA is reflected in CDC's guidance on the use of antigen tests in nursing homes. CDPH's antigen testing guidance is forthcoming.

To assist states in their continued outreach with nursing homes, the U.S. Department of Health and Human Services (HHS) will host a webinar with BD and Quidel on September 3, 2020 from 12:00PM-1:00PM EST to walk through each manufacturer's training modules that are being utilized by the nursing homes. Each manufacturer will have a 30-minute time slot to present and answer any questions. Use the following link to register for the training:
https://bcg.zoom.us/webinar/register/WN_jjlkj-9JTMeLY_Hzao7JCA

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

Regarding remdesivir distribution, we have now received our eighth commercial distribution and for the first time the supply has exceeded the demand for remdesivir. We were allocated 1,000 cases (or 40,000 doses) but there was only demand for about 561 cases or 56% of what was available.
A weblink is posted on the CDPH guidance page with the distribution details.

Link:
https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/CaliforniaRemdesivirAllocationCommercial-8.24.20.xlsx

As we no longer have a shortage of remdesivir, for future calls I'll stop updating on the supply but will be available for questions.

There are three other clinical updates on therapeutics that I wanted to note.

First, the EUA for remdesivir was updated on August 28th to allow remdesivir use in patients who are hospitalized but not requiring oxygen. This patient group is often referred to as moderate illness and we reviewed the data from the JAMA publication last week that showed that 5 days of remdesivir was associated with a slightly faster clinical improvement but the absolute improvements were small and of unclear overall clinical significance. This level of evidence was enough to expand the EUA to allow the option to treat this patient group. Patients with more severe COVID-19 illness who are hospitalized and require supplemental oxygen are still the group with the biggest clinical benefit from remdesivir.

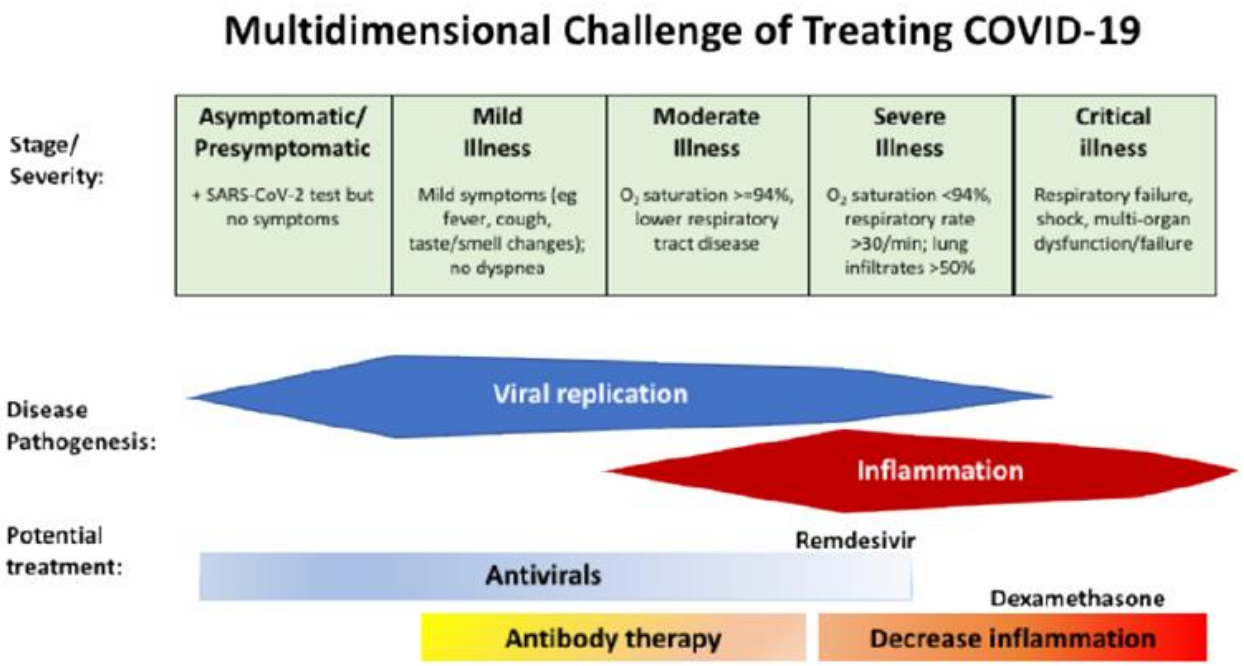
The link to the updated EUA is on the CDPH website and I've also provided a link in the notes.
https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/Fact-Sheet-Health-Care-Providers.pdf

Second, there was a request for more general information on therapeutics and I've attached a link to an article that summarizes the role of remdesivir in the context of other therapies in the meeting notes.

https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1132/5879440

The article presents a framework for considering treatment based on the stage or severity of illness that a person has. The stages in this framework are 1. Presymptomatic, 2. Mild illness (just symptoms), 3. Moderate illness with lower respiratory disease but not needing oxygen, 4. Severe illness requiring oxygen, and 5. Critical illness with respiratory failure (see figure below). Early in infection viral replication predominates so antivirals and antibody-based therapies may be important. Late critical illness can be characterized by an over-exuberant immune response and excess inflammation and the RECOVERY trial demonstrated that dexamethasone reduced mortality in hospitalized patients with COVID-19 with the greatest benefit in patients on mechanical ventilation. The trial also showed that dexamethasone does not improve outcomes – and may even lead to harm – in people who were not ill enough to require supplemental oxygen, highlighting the importance, as the authors say, of using the right drug "at the right time, in the right patient".

Finally, I'd like to highlight that the California Medical Association in collaboration with CDPH will be hosting a virtual grand rounds next week on September 8th at noon. The topic is Transmission, Testing and Masks: creating a culture to curb COVID-19 and will feature some excellent speakers to 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_0908_GRCOVID



Ref: Gandhi, CID, 2020

VI. **Question and Answer**

Q: I have a distinct-part SNF that's part of a critical access hospital. T~~T~~here ~~is~~ are no new positive ~~presentence~~ patients or staff, how will we handle weekly testing now?
A: We would consider HC personnel to be any staff that enters the facility that can be exposed or can expose other staff members. I would say yes, the testing/routine testing of your SNF HC Personnel should include those that also work in the critical access hospital that could enter or visit the SNF.

Q: Do I have to do two rounds of testing for employees every week?
A: ~~Yes,~~ CMS ~~did~~ released a new update that defines frequency testing for HC staff as reflected by the county positivity rate in the ~~next~~ prior week. For facilities in counties with medium COVID activity level as defined as 5-10% the testing becomes once a week. For counties that have a positivity rate greater than 10% test HC workers twice a week, assuming all testing material is available and can be turned around. All depends on county positivity rate, where your facility is located. You can find this info on the updated county monitoring on the CA Covid-19 webpage or you can work w/ LHD to figure out specifics.

Q: Regarding expanded EUA for Remdesivir, what you didn't talk about is the impact using this medication in critical access setting. We believe that this is going to create a shortage of the drug. Wondering if CDPH has thought of something for that.
A: The level of evidence that's required is relatively low compared to FDA. That's my understanding of the EUA was brought in to give clinicians more options to use the drug. In a patient group w/ moderate illness there is a recommendation not to treat, whereas people who require supplemental oxygen there is high level of support and recommendation to treat those patients. Also, a high-level

recommendation where there is a shortage of Remdesivir patients that require oxygen will be placed higher on priority list for Remdesivir.
Q: Results from antigen can be used less than 48 hours, so does that mean we'll be able to use our antigen testing for screening?
A: I would defer questions around when CMS will expect these changes to be implemented or into effect to our state survey agency. You are correct with positivity rates in the county that exceeds 10% and that doesn't necessarily correlate with the red or purple tier. Testing frequency per CMS is twice a week. If the 48 hours turnaround time can't be met due constraints, t~~. T~~he facility should have documented efforts that turnaround time wasn't able to be 48 hours. In the scenario of testing asymptomatic SNF personnel in no outbreak setting and you are not able to get 48 hours testing then yes you can use antigen~~, however, if you receive a positive testing then you would need to use the PCR confirmation testing~~.

Q: Can CDPH accept or make a blanket waiver to help alleviate some of the burden to get physicians orders for testing?
A: Need to circle back to get input from state survey agency/regulatory ~~committee~~colleagues.

Q: Is CDPH going to release some guidance on the Abbott testing machine?
A: CDPH is forthcoming, however, there is FDA guidance.

Q: Would the CDPH approve or recommend allowing the use of altering clinical guidance?
A: The issue is the molecular assay that has EUA are all qualitative and none are quantitative and for anyone to authorize that it would require a large paradigm shift that CDPH isn't ready for.

Q: Testing based upon positivity rate. Just for clarification the guidance was waiting for a CAHAN for QSO for CA, but earlier you had stated that you should possibility wait for clarification then earlier you spoke about CMS. I'm wondering if there's going to be more guidance put out by CDPH/CA, looking for more guidance on this.
A: We can discuss if a CAHAN or All Facilities Letter ~~is needed to speak~~ on the ~~CDC recommendation~~CMS requirements is needed and how ~~the~~ our regulatory ~~committee~~ colleagues at LNC will look at that. Your comments around the testing frequency, certainly we appreciate that it's a large undertaking, I'll just clarify here the impact you said on your ~~residence~~residents. The testing is to be done to HC personnel and not residents. There is CDPH guidance forthcoming on the use on rapid antigen testing as a potential option for carrying out the testing. It's not specified in the CMS memo which type of testing is expected. For the facilities that are being required to test twice a week, this is the caveat of testing when 48-hour turnaround time is available, if a facility can't then they need to document that and communicate that with their surveyor.

Q: Dental question on swabbing, can it be the dental assistant?
A: The nasal swab can be done by a trained healthcare provided and that is not under regulation for who the trained provider must be.