California Department of Public Health
Weekly Facility COVID-19 Update Call
November 17, 2020
8:00 am – 9:00 am

AT&T Meeting Recording: 1 (866) 207-1041
Access Code: 2136291
Available after 10am 11/17/2020

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

II. **Overview** — **Dr. Kathleen Jacobson**

- None Provided

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

Molecular Tests for SARS-CoV-2 Detection

There are many different nucleic acid amplification tests (NAATs) with FDA Emergency Use Authorization for the detection of SARS-CoV-2 viral RNA. There are real-time reverse transcription PCR [rRT-PCR] assays (e.g., the CDC rRT-PCR assay) which are approved for qualitative detection of viral RNA (vRNA), detected or not detected (positive or negative). There are many different rRT-PCR assays available and they are not equivalent or based on the same viral targets. Detection of vRNA targets from rRT-PCR assay is indicated as a measure of "Ct" or cycle threshold, which represents the amplification cycle number at which amplified target vRNA reaches the assay's minimum detection threshold (thus the term "cycle threshold" or Ct). A positive real-time PCR test result with a low ("early") Ct value does NOT necessarily correlate with viral load or indicate infectious virus. Therefore, a Ct value cannot and should not be used as a marker for transmissible virus. There is NO rRT-PCR assay for SARS-CoV-2 approved as a quantitative test and therefore laboratories cannot report out Ct values.

Other NAATs include transcription-mediated amplification (TMA, e.g., Hologic Aptima SARS-Cov-2) isothermal amplification (Abbott IDNow) or loop mediated isothermal amplification (LAMP). Neither TMA nor isothermal amplification assays utilize Ct values as a measure of viral RNA detection.

Below is a list of resources and references pertaining to COVID-19. Please see the section for Ct values for guidance on Ct value interpretation and utility.

General FAQs:

https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

COVID-19 Testing and Safety
https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-safety-practices.html

https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-testing-supplies-faqs-testing-sars-cov-2

Lab Reporting (CalREDIE Help Desk email: CalREDIEHelp@cdph.ca.gov)
https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html#what-to-report

https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-related-test-data-and-reporting-faqs-testing-sars-cov-2

https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf

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

https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html

https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html

https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf

https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory

HHS Webinar: Antigen Testing in Nursing Homes (Link)
On September 3, 2020 HHS hosted a webinar to assist states in their continued outreach on the roll out of COVID-19 antigen tests to long term care facilities. In this webinar test manufacturers, BD (view slides) and Quidel (view slides) walk through steps associated with performing the BD Veritor and Quidel Sofia SARS-CoV-2 antigen tests.

Ct Values

https://academic.oup.com/cid/advance-article-abstract/doi/10.1093/cid/ciaa1199/5891762?redirectedFrom=fulltext

https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-COVID19-Ct-Values.pdf

https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Interpreting-Results-of-Diagnostic-Tests

California Testing Task Force (Email: testing.taskforce@state.ca.gov)
https://testing.covid19.ca.gov/

CDPH Guidance Documents
https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Guidance.aspx

CDPH Lab Field Services (Email: LFSCOVID@cdph.ca.gov)

https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/COVID-19.aspx

State of California COVID-19 Information
https://covid19.ca.gov/

IV. **Healthcare-Associated Infections** **Dr. Erin Epson**

1. Yesterday CDPH released **AFL 20-86 Coronavirus Disease 2019 (COVID-19) Infection Control Recommendations during Holiday Celebrations**.

People at higher risk of severe illness or death from COVID-19 (such as older adults and people with chronic medical conditions) are strongly urged not to attend any gatherings; however, if higher-risk individuals do attend gatherings, CDPH provides infection control recommendations for residents, families, and facilities to safely celebrate the holidays in accordance with the CDPH Guidance for Private Gatherings, which include the following considerations:

1. **Community levels of COVID-19** – Consider the number and rate of COVID-19 cases in your community and in the community where you plan to celebrate. County COVID-19 tier information is available on the Blueprint for a Safer Economy website.
2. **Location of the gathering** – Gatherings that occur outdoors are significantly safer than indoor gatherings.
    - All gatherings (involving different households)[i] should be held outside. Attendees may go inside to use restrooms as long as the restrooms are frequently sanitized.
    - If an outdoor gathering is not possible, avoid crowded, poorly ventilated, and fully enclosed indoor spaces. Increase ventilation by opening windows and doors to the extent that is safe and feasibly based on the weather.
3. **Duration of the gathering** – Gatherings that last longer pose more risk than shorter gatherings. Gatherings should be two hours or less.

4. **Number of people at the gathering** – Gatherings with more people pose more risk than gatherings with fewer people. Gatherings should not include more than three households. This includes everyone present, including hosts and guests.
5. **Locations attendees are traveling from** – Gatherings with attendees who are traveling from different places pose a higher risk than gatherings with attendees who live in the same area. Higher levels of COVID-19 cases and community spread in the gathering location, or where attendees are coming from, increase the risk of infection and spread among attendees.
6. **Behaviors of attendees prior to the gathering** – Gatherings with attendees who are not adhering to social distancing (staying at least 6 feet apart), wearing a mask, hand washing, and other prevention behaviors pose more risk than gatherings with attendees who are engaging in these preventative behaviors.
7. **Behaviors of attendees during the gathering** – Gatherings with more preventive measures in place, such as mask wearing, social distancing, and hand washing, pose less risk than gatherings where fewer or no preventive measures are being implemented.

For residents returning to facilities from holiday celebrations, facilities should screen returning residents for signs and symptoms of COVID-19 and immediately test and isolate symptomatic residents in a single room pending results. Skilled nursing facilities (SNFs) should quarantine residents returning to the SNF from visits to settings in communities with substantial or widespread transmission based on the Blueprint for a Safer Economy website (or gatherings with participants coming from communities with substantial or widespread transmission) in the yellow-observation area (in a single room, if available) for 14 days, and test at the end of the 14-day period before returning to the general population or green-unexposed area. SNFs must prepare to implement transmission-based precautions as needed for residents returning to the facility.

I'd like to emphasize that while this AFL provides guidance for skilled nursing facility residents who wish to celebrate with their families and friends, the CDPH Guidance for Private Gatherings is also relevant to all healthcare personnel who work in any setting. Healthcare personnel exposed and infected in the community are common sources of introduction of COVID-19 outbreaks among patients or residents and other healthcare personnel in healthcare settings, so it is critical that all healthcare personnel act responsibly and take all possible measures to prevent exposures both within and outside of work. These include consistent adherence to mask wearing, physical distancing, and hand washing; with increasing evidence that masks protect the wearer (in addition to those around them), mask wearing is more important than ever.

2. On Wednesday, during the weekly SNF webinar and call, we plan to present infection prevention and containment strategies for Candida auris, other multidrug-resistant organisms (MDRO) during the COVID-19 pandemic, including how implementation and reinforcement of basic infection control practices can reduce transmission of both MDRO and SARS-CoV-2. We have observed increasing incidence of C. auris and other MDRO during the COVID-19 pandemic primarily in higher-acuity long-term care settings, however, we have also observed outbreaks of these pathogens in short-stay acute care hospitals. Some of the key messages for all healthcare settings include:

- If no shortages, do not practice extended use or reuse of gowns and gloves
- Everyone must adhere, including physicians and ancillary staff

- Double-gowning and -gloving are NOT recommended
- Don/Doff WITH hand hygiene

3. Wednesday, November 18, kicks off U.S. AntibioticAwareness Week 2020. Sustaining antibiotic stewardship efforts is critical, especially now. AR continues to be a public health threat during the COVID-19 pandemic. You can find CDC's latest stewardship report: Antibiotic Use in the United States, 2020 update: Progress and Opportunities featuring COVID-19, 2019 AU data, and data from the 2019 National Healthcare Safety Network AU option report (PDF - 14 pages).

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

Updates on the emergency use authorization (or EUA) for the monoclonal antibody called bamlanivimab.

Bamlanivimab is an investigational monoclonal antibody that has been engineered to bind to and neutralize SARS-CoV-2 and prevent progression to severe illness. Clinical trial data in outpatients have shown that bamlanivimab use may reduce COVID-19-related hospitalization or emergency room visits in patients at high risk for severe disease. Clinical trial data in hospitalized patients, however, have not shown a benefit with bamlanivimab use, and it is not authorized for use in patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19.

Link for further information:
https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Bamlanivimab-Fact-Sheet.aspx

Fact sheet for healthcare providers:
https://www.fda.gov/media/143603/download

Clinical and logistical details:

- Authorized for use to treat of outpatient mild-to-moderate COVID-19 in adult and pediatric (at least 12 years of age and weighing at least 40kg) patients who met high-risk criteria specified in the EUA for progression to severe disease
- High risk is defined as at least one of the following conditions: BMI ≥ 35, chronic kidney disease, diabetes, immunosuppression (from disease or treatment), or age ≥ 65 years. Additional high risk criteria are defined for people ≥ 55 years of age and for people 12 – 17 years of age. Notably, pediatric patients were not included in the clinical trial and CDPH does not recommend pediatric treatment at this time.
- Bamlanivimab is not authorized for use in patient who are hospitalized with COVID-19 or who require oxygen therapy due to COVID-19. Treatment is also not authorized for asymptomatic patients. Bamlanivimab is indicated for patients with mild or moderate symptoms, including fever, cough, sore throat, malaise, headache, muscle pain, gastrointestinal symptoms, or shortness of breath with exertion.
- Bamlanivimab is administered by intravenous (IV) infusion over 60 minutes and may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis.

- Patients are clinically monitored during the IV infusion and observed for at least 60 minutes after infusion. There is the potential for serious hypersensitivity reactions, including anaphylaxis, with bamlanivimab administration (see full EUA prescribing information in the fact sheet for health care providers3). Infusion-related reactions (pruritus, flushing, rash, or facial swelling) were reported in 2.3% of patients who received bamlanivimab. These reactions were reported to be mild and all patients completed their infusions.
- Product is donated (no cost to state or clinical sites) but **costs for infusion services** would need to be covered by insurance or another mechanism
- As bamlanivimab is a new product the optimal settings for treatment are being developed and can include urgent care clinics, skilled nursing facilities, outpatient offices, FQHCs and other community clinics, patient homes via telemedicine and home health services, and community sites such as temporary medical tents.

Allocation of bamlanivimab for EUA use

Access to bamlanivimab is currently being coordinated by the U.S. government which has purchased more than 320,000 treatment courses and two phases of allocation are being planned. In phase 1, bamlanivimab will be allocated to hospitals and hospital affiliated locations only. In phase 2, bamlanivimab will be allocated to additional outpatient facilities.

For week one, California received an allocation of 4,040 doses and we expect to receive a similar allocation this week and at a regular cadence moving forward. During phase 1, CDPH is using acute care hospital data of the 7-day average of new COVID-19 admissions and conversions to proportionately distribute bamlanivimab to the counties' Medical and Health Operational Area Coordinator (MHOAC) per the established Multi-Agency Coordination Group (MAC Group) process. The MHOAC will allocate bamlanivimab within their county to hospitals (phase 1) and other facilities (phase 2). Based on this allocation bamlanivimab is shipped to hospitals by AmerisourceBergen. Details on the week one allocation are here:
https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/CA-Bamlanivimab-Allocation_11-13-20.xlsx

CDPH recommends prioritizing patients who had the greatest benefit in the clinical trial: patients who are > 65 years of age and patients with a body mass index (BMI) > 35. This prioritization includes residents of skilled nursing facilities (SNFs) and other long-term care facilities who receive regular testing for COVID-19 and are at high risk for severe COVID-19 illness.

VI. Questions and Answers

Q: Do we need to wear hospital grade mask?
A: Recommendation for source control applies to all healthcare personnel and that is defined broadly and that does include persons not directly involve in patient care, which would include dietary staff. A surgical or medical face masks is used for source control for all healthcare personnel.

Q: When transferring to SNF is it required to use Polymerase Chain Reaction (PCR) testing, or can we use antigen testing?

A: In general antigen testing is recommended for symptomatic individuals. In general, when considering using antigen testing for asymptomatic individuals that would really be in the special context of individual who are routinely being screened. The risk with using antigen testing is false positive which continues to be true at least for now. I concur that if antigen tests are being used for asymptomatic individual at a higher frequency, at least twice a week, you can overcome the decrease in sensitivity that has been associated with antigen testing. If there are concerns with not having enough face masks or testing supplies, you need to work with your Medical Health Operational Area Coordinator (MHOAC). We do have supplies at the state and use salesforce.

Q: If we get a positive on the antigen testing, then we can confirm with a PCR test?
A: Yes, for asymptomatic individuals the issue has been false positive. In symptomatic individual you would want to confirm with a PCR test.

Q: The 21-day and 28-day interval for the Pfizer and Moderna vaccine, are those minimum time intervals?
A: I believe we don't have anyone on the call to answer that. We can take that back to the vaccine taskforce and get answers for you.

Q: Clarification regarding All Facilities Letter (AFL) AFL20-38.5
A: We do not specify directly in the AFL when the visitor is the support person. If the question is whether you can have a support person serve the clinical role and the visitor then it would depend on A) what county they are in B) what tier that county is in C) on what capacity that visitation is happening and their ability to maintain physical distancing.

Q: Is there any consideration for Healthcare (HC) Workers, for allowing exposed healthcare workers to work and travel if they're asymptomatic and not positive?
A: The travel advisory is essentially recommending against non-essential travel at this point. I would reiterate my earlier comment that healthcare personnel would be encouraged to act responsibly and talk all measures to prevent exposure.

Q: For HC workers that are exposed to COVID at home or in the community, what are the mitigation efforts for spread?
A: There are provisions in the Centers for Disease Control and Prevention (CDC) guidance for management of potential HC personnel and for facilities that are needing to mitigate potential staffing shortages (includes provision for widespread community transmission) to allow potentially exposed HC personnel to continue working with rigorous application of screening and encouraging those who are showing symptoms to not show up to work, and use of source control at all times.

Q: Are Skilled Nursing Facilities (SNF) required to test?
A: All Skilled Nursing Facilities are required to do screening tests of all their healthcare personnel at a minimum of weekly once weekly throughout the state, but the Centers for Medicare & Medicaid Services (CMS) has a requirement for twice weekly testing for facilities in counties with high percentage test positivity (believe to be above 10%). Facilities in these jurisdictions would need to comply with more stringent of requirements.

Q: How can we take care of the cost not covered by CMS?
A: For reimbursement, the medication itself is free for now. Cost of infusion it could be in SNF settings my understanding is that it would depend on the current status of the person in the SNF. I believe it would be analogous to the way antibiotic infusion is approached. CMS has developed codes for reimbursement, but I understand it might not apply to some patients in SNFs. I think we are trying to figure out solutions to send to CMS or HHS to inform them of these barriers to help cover these ancillary costs.

Wednesday Webinar: 3–4 p.m., Attendee Information:
Register at: https://www.hsag.com/cdph-ip-webinars
Call-In Number: 415.655.0003 Access Code: 133 788 3426