



**California Department of Public Health
Weekly Facility COVID-19 Update Call
October 13, 2020
8:00 am – 9:00 am**

AT&T Meeting Recording: (866) 207-1041

Access Code: 7427345

Available after 10am 10/13/20

- | | |
|--|------------------------------|
| I. Welcome / Introduction: | Heidi Steinecker |
| II. Overview:
None provided. | Dr. Kathleen Jacobson |
| III. Laboratory Update: | Dr. Deb Wadford |

Antigen testing UPDATE: multi-analyte antigen test for both SARS-CoV-2 and Influenza A/B

Antigen tests for SARS-CoV-2 – EUA Point of Care Tests

- 1) Quidel Sofia SARS Antigen FIA assay (within 5 days of onset); *Influenza A/B test kit available*
- 2) BD Veritor System for Rapid Detection of SARS-CoV-2 (within 5 days of onset); *Influenza A/B test kit available*
- 3) Abbott BinaxNOW COVID-19 Ag CARD (within 7 days of onset); *Influenza A/B test kit available but requires reader*
- 4) LumiraDx SARS-CoV-2 Antigen Test (within 12 days of onset)
- 5) **Quidel Sofia 2 Flu + SARS Antigen FIA** (within 5 days of onset) – multi-analyte assay; Requires Sofia 2 instrument to read test results

FDA EUA List of Antigen Assays for COVID-19:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen>

Viral Testing to distinguish SARS-CoV-2 from Influenza Virus

- 1) Antigen tests for SARS-CoV-2 and influenza virus
 - Separate assays available for each virus (lower sensitivity in general than molecular assays)
 - One combination Flu A/B and SARS-CoV-2 Antigen test (Quidel Sofia 2 Flu + SARS Antigen FIA)
- 2) Molecular assays for both viruses (rapid or real-time RT-PCR) – based on nucleic acid amplification
 - Several FDA Emergency Use Authorization (EUA) assays available
- 3) Multiplex molecular assays that can test for both viruses in one test
 - Several EUA assays available <https://www.cdc.gov/flu/professionals/diagnosis/table-flu-covid19-detection.html> (not a complete list)

FDA EUA List of Assays for COVID-19:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

Test result reporting to include certain data elements for all SARS-CoV-2 lab results:

Critical data elements should be the primary focus for lab data reporting for COVID-19:

1. Test ordered – use harmonized LOINC codes provided by CDC
2. Device Identifier – use if LOINC codes do not indicate device/test kit
3. Test result
4. Test Result date
5. Accession #/Specimen ID
6. Age (or DOB)
7. Patient race
8. Patient ethnicity
9. Patient gender
10. Patient residence zip code
11. Patient residence county
12. Ordering provider name and NPI or CLIA (as applicable)
13. Ordering provider zip
14. Performing Lab name and CLIA number, if known
15. Performing Lab zip code
16. Specimen Source - use appropriate LOINC, SNOMED-CT, SPM4 codes, or equivalently detailed alternative codes
17. Date test ordered (date format)
18. Date specimen collected (date format)

QUESTION & ANSWER SEGMENT:

1. **CalREDIE Help Desk:** calrediehelp@cdph.ca.gov OR <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-HELP.aspx>
2. **Regarding the requirement to report SARS-CoV-2 results in 8 hours can be found as part of CCR Title 17 Section 2505:** link is at → [§ 2505. Notification by Laboratories.](#) (or: <https://tinyurl.com/y6r7puy8>)

Below is the subsection of 2505 with the text highlighted in yellow:

(2) The diseases or agents specified, with the exception of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), shall be reported within one working day after the health care provider or other person authorized to receive the report has been notified. **Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) shall be reported within eight hours** after the health care provider or other person authorized to receive the report has been notified. Laboratories shall transmit these reports to the state electronic reporting system or local electronic reporting system that is linked to the state electronic reporting system, except for acute HIV infection reporting which shall be reported by telephone (see (j) for specific acute HIV infection reporting requirements). Acute HIV infection shall be reported both by telephone and to the state electronic reporting system within one working day of identification. If reporting to the state or local electronic reporting system is not possible, reporting by electronic facsimile transmission or electronic mail may temporarily substitute for reporting to the state or local electronic reporting system. Laboratories shall also report by other means (e.g., electronic facsimile) if requested by a health officer or the Department. Laboratory findings for these diseases are those that satisfy the most recent communicable disease surveillance case definitions established by the CDC (unless otherwise specified in this Section).

IV. Healthcare-Associated Infections:

Dr. Erin Epton

Yesterday CDPH released AFL 20-80 with recommendations for prevention and control of influenza in skilled nursing facilities (SNF) during the COVID pandemic, which links to the guidance document posted on the HAI program website as mentioned last week. We recognize and appreciate the challenges facilities will face with implementing the appropriate transmission-based precautions and determining resident room placement while avoiding movement of residents between COVID-19 cohorts. HAI staff are currently developing materials to provide webinars for SNF providers as well as for local health departments to review this guidance and address your questions more in-depth than we are able during these all facilities calls; we will provide updates on the scheduling of those webinar during the coming weeks. In the meantime, SNF should focus on optimizing influenza vaccination coverage among residents and all healthcare personnel.

V. Remdesivir Update

Dr. Philip Peters

Remdesivir Distribution and General Therapeutic Update for all Healthcare Facility Call

As stated last week, the directed allocations of remdesivir ended on Oct. 1st. If any hospitals are having trouble accessing remdesivir, feel free to contact CDPH. AmerisourceBergen is the sole distributor of remdesivir until at least December 2020 and contact information is included in the notes.

AmerisourceBergen can be contacted directly at 877-746-6273 or via email at remdesivir@amerisourcebergen.com.

As you have seen reported in the press, two companies, Regeneron and Eli Lilly, have submitted emergency use authorization (or EUA) requests to the FDA for their monoclonal antibody products. Monoclonal antibodies are engineered to bind to a particular region of an antigen. Monoclonal antibodies against SARS-CoV-2 bind to the receptor binding domain (RBD) and can prevent the virus from binding and entering human cells. Preliminary reports have indicated that monoclonal antibodies have clinical benefit for COVID-19 treatment. It is anticipated that clinical trial results will be published and that monoclonal antibodies will receive an EUA for COVID-19 treatment. At this juncture, all the monoclonal antibodies being tested for treatment are administered intravenously (prophylaxis indications are also being tested with subcutaneous administration).

If an EUA is granted for one or both of these products, initial supply is anticipated to be limited and we would also expect that the federal government will direct allocation as with remdesivir.

At the state level, the structure of these allocations will depend on the wording in the EUA. As monoclonal antibodies are anticipated to be most beneficial early in illness in people at high-risk for severe complications, an important part of the allocation will be to ensure that people at the highest risk for mortality have access. This would include older adults, residents of skilled nursing facilities and assisted living facilities, and communities of color (i.e., Latinx, Black, and Pacific Islander Californians).

Finally, as 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 which is www.cmadoocs.org.

VI. Additional Information

Wednesday Webinar, 3–4 p.m., October 14, Attendee Information

Register at: <https://www.hsag.com/cdph-ip-webinars>

Call-In Number: 415.655.0003 Access Code: 133 788 3426

NIOSH Seeking Sites to Receive Elastomeric (Reusable) Respirators

NIOSH recently published a Federal Register Notice (FRN): “A National Elastomeric Half Mask Respirator (EHMR) Strategy for Use in Healthcare Settings During an Infectious Disease Outbreak/Pandemic”

<https://www.federalregister.gov/documents/2020/09/14/2020-20115/a-national-elastomeric-half-mask-respirator-ehmr-strategy-for-use-in-healthcare-settings-during-an>.

This FRN is seeking a diverse group of healthcare organizations to participate in a deployment of EHMRs across the nation. This includes healthcare organizations such as:

- Hospital systems, individual hospitals, and/or specific hospital units (ie: emergency department, intensive care units)
- Outpatient care settings (ie: offices, clinics, home care, urgent care, rehab centers)
- Long term care facilities
- Skilled nursing facilities
- Dental practices

The deadline to respond to the FRN and express interest in participating is October 14th. Please feel free to forward this email to any organizations that may be interested in participating.

VII. Questions and Answers

Q: Would two rounds of sequential response testing qualify to shorten the duration of quarantine?

A: I am not aware of any guidance that allows for shortening the duration of quarantine.

Q: Would you be able to resend out the notice for the webinar?

A: We have it listed on the COVID-19 website. You can go to the skilled nursing facility homepage to see the log in information.

Q: What is the recommendation for visitor PPE for patients that are COVID positive. Should we have visitors wear a mask and wash their hands frequently or should we have them wear gloves and gowns?

A: This is normally a facility-based decision. We emphasize conserving PPE if possible.

Q: My second question is the side effects of the Battelle masks. The Massachusetts Nurses Association filed a complaint saying that a number of nurses are getting sick from these masks. Has there been anything similar being reported in California?

A: Cal OSHA guidelines no longer allow the reuse of decontaminated respirators.

Q: I had heard that if we use any of the point of care antigen testing, that we have to have the results in CalREDIE within 8 hours. I haven't seen this anywhere in writing. I thought that it was 24 hours. Can someone clarify which one it is?

A: The 8 hours is correct. I will find out where its written. It used to be 24 hours but now it is 8 hours.

Q: Earlier in the call, you mentioned the enhanced reporting requirements. The last we heard from our IT department, the state department was not ready to receive this data. Has that changed and is there a contact person that we can reach out to for questions?

A: I would recommend contacting CalREDIE help desk. They would be able to assist with your question.

Q: My question is about AFL 20-75. It clearly states that it is for licensed healthcare facilities. Should we be using these recommendations or is there some other guidance for reporting purposes for potential outbreak investigations in the ambulatory setting?

A: There are a set of thresholds that include various ambulatory settings. Those will likely be available in the coming weeks.

Q: What were the two pharmaceutical companies that you said earlier that were requesting EAUs?

A: Regeneron and Eli Lilly. Regeneron is a combination of two monoclonal antibodies and Eli Lilly is a single monoclonal antibody.

Q: Has there been any change in the screening requirements for employee screening?

A: I'm not aware of any changes to the screening process.

Q: My question is regarding the October 6th communication from CMS. They noted that as of October 19th, there would be six optional fields added related to influenza. Are there any plans to update Smartsheet? When can we expect see them show up in the Smartsheet?

A: There is ongoing discussion to add influenza to the daily reporting. There is no timeframe for that.

Q: We have not received the vaccine survey. Is it still pending distribution?

A: The vaccine survey went out last night. We are aware of some issues with it. If you are having problems, you can contact the CHCQ Duty Officer for any questions about the survey. As for the webinar information, you can find it on AFL 20-50.1. We have our AFLs posted on the CDPH website.

Q: Comment for the Testing Task Force: It's taking us 3 to 6 days to get results from Quest. We know there are other options available for lab testing but we have pre-existing integration of Quest lab in our EHR. We have also received an Abbott ID Now testing machine but we are having a problem with getting reagents.

A: Thank you for sharing that. When did the problems start with Quest?

Q: It's been happening all along. Back in July, the delay was much longer. It's improved but we are still having wait times of 3 to 6 days.

A: We will reach out to Quest to find out what is going on. In regards to the Abbott ID Now reagent issue, that is a national issue. I would suggest reaching out to Abbott.

Q: Are we supposed to report in CalREDIE when using the Abbott Tests?

A: The Abbott BINAX testing is the one that is used with the App. You record the barcode and run the tests. The Abbott BINAX testing is not recorded in CalREDIE at this time. You need to report to California through a different system.

Q: Can you comment on the value of the rapid tests for asymptomatic individuals. There are comments that the false negatives are likely a low transmission risk. Any thoughts on that?

A: Currently the recommendation is to utilize those tests for symptomatic individuals. There has been a lot of information in the literature about utilizing these types of tests in higher frequency testing. There has been good modeling in the literature that shows that even with a slightly less sensitive test, if you test more frequently, you can prevent outbreaks. The concern is the false positives. I am in talks with Nevada to try to understand it better.

Q: Do you feel the same with the old Abbott ID Now tests?

A: That is a PCR test. It has its issues with false positive. It has always been used in an asymptomatic individual as sort of a prescreening for surgical usage.

Q: To Dr. Epson: Can you repeat your recommendation on PPE for visitors?

A: They must adhere to facility procedures for transmission-based precautions.