California Department of Public Health
Weekly Facility COVID-19 Update Call
November 3, 2020
8:00 am – 9:00 am

AT&T Meeting Recording: (866) 207-1041
Access Code: 4307061
Available after 10am 11/03/20

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

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

None provided.

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

https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html
The CDC updated its POC testing guidance on October 14th, including:

- The types of CLIA certificates and how to apply for one.
- A reminder that only tests that have received FDA EUA are authorized for use in POC settings, and that these POC tests currently are authorized for use on *symptomatic* individuals.
- However, CLIA continues to temporarily permit the use of POC antigen tests on asymptomatic people.

To minimize the chances of inaccurate or unreliable results, be sure to follow the specimen collection and handling guidance as well as the manufacturer's instructions on when and how to perform the test.

Antigen tests

As you are likely well aware, POC antigen tests are being used in various clinical settings. Since these tests generally are less sensitive than PCR tests and were developed and approved for use on symptomatic people, the CDC is working with different laboratories and groups to assess the real-world performance of some of these tests. At least one study is being written up, and we hope that the data will be publicly available soon. If you are performing your own assessment and are willing to share your data, CDPH and the CDC would welcome the opportunity to learn from your experience.

The CDC guidance for the use of SARS-CoV-2 Antigen Testing in Nursing Homes was updated on October 23rd.
https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html

The FDA EUA recommends that negative POC Antigen tests be considered presumptive. In fact, some negative results are required to be reported as "presumptive negative"; this information is included in the manufacturers' instructions for use.

When should an antigen test be considered a false positive?

A point-of-care test should be considered a possible false-positive when a positive test result appears inconsistent with the clinical situation (e.g., a positive antigen test in an asymptomatic person who does not have risk factors and resides in a community with lower COVID-19 prevalence).

CDC confirmatory testing recommendations

Consider the test characteristics and probability of infection.

- Test sensitivities vary between the available antigen tests. Know the performance characteristics of the test being used on your patient population.

Confirmatory RT-PCR testing after a positive antigen test result is not recommended in situations where the person being tested has COVID-19–like symptoms or had recent close contact with someone with SARS-CoV-2 infection (e.g., in an outbreak situation).
When a confirmatory test is pursued, consider these points:

- Use real time RT-PCR as the confirmatory test.
- Nasopharyngeal (NP) swabs have a higher sensitivity than other specimen types and are the preferred specimen for confirmatory PCR testing.
- If the person is unable to tolerate a NP swab, then a swab of the anterior nares or mid-turbinate may be substituted, although the sensitivity may be reduced.
- Perform the confirmatory PCR test within 2 days of the initial antigen test. Tests performed >2 days apart should be considered separate tests, and discordant results may be due to changes in viral dynamics.

If discordant test results suggestive of a false positive antigen test are identified, facilities and health departments should notify the test manufacturer and the FDA.

Finally, a reminder that no test is 100% sensitive or 100% specific, which means that false positive or false negative results can happen, especially when incidence of disease is low. As well, it is very important for this disease, which has both public health and potentially serious health ramifications, to remember that proper specimen collection and transport or shipping conditions, as well as proper technical training of POC testing personnel are important variables to ensure testing integrity.

U.S. FOOD & DRUG ADMINISTRATION

Potential for False Positive Results with Antigen Tests for Rapid Detection of SARS-CoV-2 - Letter to Clinical Laboratory Staff and Health Care Providers

Today, the U.S. Food and Drug Administration (FDA) is alerting clinical laboratory staff and health care providers that false positive results can occur with antigen tests, including when users do not follow the instructions for use of antigen tests for the rapid detection of SARS-CoV-2. The FDA is aware of reports of false positive results associated with antigen tests used in nursing homes and other settings. The FDA continues to monitor and evaluate these reports and other available information about device safety and performance.

The FDA reminds clinical laboratory staff and health care providers about the risk of false positive results with all laboratory tests. These are expected, especially when tests are used for screening in large populations with a low prevalence of infection. Clinical laboratory staff and health care providers can help ensure the accuracy of test results by closely following the authorized instructions for use of a test as well as key steps in the testing process as recommended by the Centers for Disease Control and Prevention (CDC).

Read More

The Letter to Clinical Laboratory Staff and Health Care Providers includes important information about potential false positive results with antigen tests for rapid detection of SARS-CoV-2, including:

1. Details on false positive results with antigen tests
2. Recommendations for health care providers and clinical laboratory staff
3. Actions the FDA is taking
4. Instructions for reporting problems with a device.

Questions?

If you have questions about this Letter to Clinical Laboratory Staff and Health Care Providers, email COVID19DX@fda.hhs.gov.

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

Last week, CDC posted new Investigative Criteria for Suspected Cases of SARS-CoV-2 Reinfection. Confirmed and suspected cases of reinfection of the virus that causes COVID-19 have been reported but remain rare. SARS-CoV-2 reinfection is a rapidly evolving area of research, and there is currently no widely accepted definition of what constitutes SARS-CoV-2 reinfection. To help better understand the potential for reinfection and to create a standardized case definition of SARS-CoV-2 reinfection, CDC developed proposed criteria for further investigation. These criteria are relevant to healthcare facilities, particularly skilled nursing facilities, that are resuming routine screening testing of previously positive asymptomatic healthcare personnel as well as including previously positive residents and healthcare personnel in response testing starting at ≥90 days from their prior positive test.

CDC recommends further investigation for:

- Persons with detection of SARS-CoV-2 RNA* ≥90 days after the first detection of SARS-CoV-2 RNA, whether or not symptoms were present **AND**
- Paired respiratory specimens (one from each infection episode) are available
  *If detected by RT-PCR, only include if Ct value <33 or if Ct value unavailable

In these situations, further investigation including genomic sequencing of paired specimens may be pursued. Recognizing that it is uncommon for most laboratories to retain positive specimens for long enough, it is likely that there will be few scenarios where further investigation for reinfection can be carried out. In addition, many positive test results in asymptomatic, previously positive individuals ≥90 days from their prior positive test likely represent persistent shedding of non-viable virus.

CDPH is developing guidance and the HAI program is available for consultation to help facilities and local health departments to make infection control management decisions for individuals that have a positive SARS-CoV-2 test ≥90 days after their previous positive test that don't meet criteria for a formal reinfection evaluation, taking into account a combination of factors such as whether the individual was symptomatic or not, whether there was a known exposure or facility outbreak, and the cycle threshold value of the repeatedly positive test.

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

General Therapeutic Update for all Healthcare Facility Call

As stated previously, two companies, Regeneron and Eli Lilly, have submitted emergency use authorization (or EUA) requests to the FDA for their monoclonal antibody products for the treated of mild to moderate COVID-19 in the outpatient setting. We don't have any updates at this time whether these EUAs will be approved or not but are trying to make some preliminary plans for distribution in case these products are approved.
As a reminder that the California Medical Association in collaboration with CDPH will be hosting another virtual grand rounds on November 10th at noon. The topic will be a COVID-19 Vaccine Update and will feature four excellent speakers who will discuss the latest updates on the vaccine's progress, status of clinical trials and California's distribution plans. Grand rounds attendees will also hear from the lead of a statewide National Institutes of Health (NIH) grant focused on vaccine trials among

vulnerable and underserved populations. 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_1110_GRCOVID

VI. **COVID-19 Vaccine Task Force Update** **Louise McNitt**

COVID-19 Vaccine Planning

COVID-19 vaccine candidates are currently only available through clinical trials. Two manufacturers, Pfizer and Moderna, might in November or December submit data from their trials to the FDA for consideration of an Emergency Use Authorization (EUA). If FDA agrees that the candidate vaccine is safe and effective, there might be doses available by the end of the year, with more to follow in 2021.

Once FDA authorizes use of a vaccine, the federal Advisory Committee on Immunization Practices (ACIP) is expected to issue prioritized recommendations for initial supplies, which are expected to be limited. Based on efforts to date by ACIP and the National Academy of Medicine to support equitable national allocation, workers in health care settings at risk for SARS-CoV-2 exposure could be the early recipients of COVID-19 vaccines, followed by other groups that include essential workers and people at higher risk for severe COVID-19 illness, including those over age 65.

California's plan for the distribution and administration of COVID-19 vaccine is being developed to ensure that the vaccine meets safety standards and is distributed equitably. FDA and ACIP efforts will be monitored closely by the state's new COVID-19 Scientific Safety Review Workgroup to assure Californians of the safety and efficacy of COVID-19 vaccines. In addition, the state's Community Advisory Vaccine Committee will provide input and feedback to the planning, while another Drafting Guidelines Workgroup is developing guidance for the local prioritization and allocation of vaccine when supplies are limited.

To assist California's local health departments with their vaccine planning efforts, CDPH has been compiling information on vaccine target populations in the state, including workers at health care facilities such as those that are represented by you on today's call. This is the third and final week for LTCFs and ALFs to register for a CDC-sponsored program to have teams from large chain pharmacies visit facilities in 2021 to immunize residents. The deadline for preliminary registration is this Friday, November 6. We encourage you to consider this offer if eligible; the decision to enroll is non-binding. Your local health department will have additional information later this year about enrolling to directly receive doses of vaccine as an alternative or supplement to this program.

The Pfizer and Moderna vaccine candidates that are currently furthest along in their trials both require a two-doses series over 3-4 weeks. Both also require storage at freezing temperatures The Pfizer vaccine, which could arrive first:

- Must be stored for longer periods at minus 70 degrees C, using an ultra-low temperature freezer or dry ice replenished every 5 days
- For the short term, the vaccine can be maintained at -200C for 5 days and at room temp for 6 hours

- Is shipped in a minimum order of 975 doses

These characteristics make the Pfizer vaccine more suitable for storage at larger facilities.

In closing, we welcome your questions on the call and urge you to work closely with your local health department over the next months. For more information please refer to CDPH's vaccine planning website
https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID-19Vaccine.aspx

VII. Educational Opportunity

Alzheimer's Association has a longstanding relationship with Project ECHO and we're one of the approved CMS vendors. If you or your evaluators identify facilities that need this training, please send them our way.

First scheduled training is next Friday:

- Group 1 runs weekly on Fridays, from 12-1:30 PST, beginning November 6th. The registration form can be accessed via Google Docs.
- Group 2 runs weekly on Wednesday, from 10:00-11:30 PST, beginning November 11th. The registration form can be accessed via Google Docs.
- Group 3 runs weekly on Mondays from 12-1:30 PST, beginning November 9th.

The registration form can be accessed via Google Docs.

VIII. Questions and Answers

Q: With the weekly reporting of testing that LTC facilities have to do, if we are retesting an individual that tested positive the first time and has been included in our previously positive count and they test positive, do we count them as a new positive and remove them from the previously positive or do we just leave them in the previously positive?
A: Are you referring to repeat positives, 90 or more days after their previous positive?
Q: That is correct.
A: I would leave them in the previously positive and not count them in the new positive categories. We are looking for new cases, meaning someone who was not previously positive at all.

Q: For patients that have not taken the flu vaccine this year, should we be using gloves and gowns for all those patients for drugs care?
A: We are not considering an individual who weren't vaccinated for influenza as high risk from that standpoint. To answer your question, no, that would not be recommended to use gloves and gowns for those residents.
Q: Sometimes we get residents that are not able to verbalize any person to act on their behalf and if there's no family involved once we receive them from the hospital, how long of a process are we allowed to have before we write as an IDP to get consent?
A: We will be partnering with the Department of Aging. They will be carrying out these functions and duties along with their ombudsman as indicated in the AFL.

Q: In regards to the CLIA waiver, one of the requirements require a medical director for such a case and ICFs aren't required by regulatory guidelines to have a medical director or a lab director. The other thing is it specifically asks you to name the kits and the manufacturer's information. These communities have not seen the case because they don't have CLIA waivers.
A: I know there is a group of individuals working on this at the state. If you want to summarize your concerns, we can make sure that that's part of what's being worked on. Send that in through the proper channels for this call.

Q: The N95 supply is still pretty bad. I just wanted to know if there was any thought about either changing the guidelines on how we use N95s or increasing supplies for these masks in the future?
A: Cal OSHA is the entity that has made guidelines around N95s specifically. I encourage you to reach out to Cal OSHA points of contact. I believe we distributed them through an email.
Q: Are there any efforts being done for the supply chain issues in the next couple of months?
A: Regarding the supply chain, I know thar our Medical Health Coordination Center has been working, contracting, stockpiling and trying make sure that we have adequate supply of N95s. I know concern for the last few months has been getting the right model number that everyone wants for proper fit testing. Will be continuing to provide some documentation and guidance. We will also continue to work with Cal OSHA regarding any policies and things that may shift or change during the pandemic.

Q: Is there a website to get more detailed information on the Pfizer and Maternal vaccine. Also you mentioned that there were outbreaks where people weren't properly fit tested. Can you mention where the data resides. I would love to read about that.
A: About the fit tests, we do track root causes and look at what the reason for some of the most recent outbreaks we do have. We do post all of our data online on our web page on the COVID website. However, we do not always have all of the root causes of every single outbreak on there. We do track and look at information on why we believe different outbreaks occurred.
A: About your vaccine question, we encourage you to be in touch with your local health department about your vaccine plans as they will be the ultimate keeper of the knowledge. We don't really have much written information about this because a lot of it is still very early. Once the vaccine is in the process of being approved for distribution and administration, there will be lots of information available. It's a little early for those kinds of material to be available.

Q: The All Facilities Letter regarding visitation, I was just hoping for some clarification regarding the wording in the summary box at the beginning of the letter. It talks about CDPH permitting facilities with medium or low coronavirus disease 2019 county positivity rate, to allow one visitor per patient at a time. That is not necessarily what you would find in a later section of the letter where it talks about in counties with substantial or lower risks of community transmission per the CDPH blueprint for a safer economy, you should permit any patient to have one visitor at a time. Which benchmark should we be using? How do you interoperate those two statements?
A: When we put in the summary box in the top, it's usually generic terms that we are using to describe the overall piece of the AFL. I see where your concern is. We do go by the tiered process for our AFLs. That's helpful feedback to hear that that was confusing. We can take that back to work on clearing that up.
Q: My infection preventionist was concerned about a line in there that says, "should permit any patient to have one visitor at a time". Does that apply to PUIs and COVID positives or any patients?

A: We had left that open for hospitals to have the ability to have policies and procedures that are more specific. We just lay out the overall framework.

Wednesday Webinar, 3–4 p.m., October 21, Attendee Information:
Register at: https://www.hsag.com/cdph-ip-webinars
Call-In Number: 415.655.0003 Access Code: 133 788 3426