California Department of Public Health
All LHD Coronavirus Update Call September 17, 2020
1:00 pm – 2:00pm

Contents

Clinical

Cases of Potential Reinfection

The Clinical Team at CDPH continues to be interested in hearing about and helping to evaluate cases when there is a concern for potential reinfection with SARS-CoV-2. We continue to suspect reinfection is a very rare event, although the frequency of reinfection and the spectrum of disease has yet to be determined.

We are interested in hearing about any cases that meet either of the following criteria:

- A positive RT-PCR result in a patient with recurrence of COVID-19 symptoms 45 days or more after initial illness onset. The patient should have previously met criteria for ending isolation. Additionally, recurrent symptoms should not be explained by an alternate etiology.
- A positive RT-PCR result in a patient with or without symptoms 90 days or more after initial diagnosis

We do not recommend testing within 90 days after initial illness onset if the patient remains asymptomatic after recovery during that period.

If you are concerned for re-infection please make sure to do the following:

- Retain the most recent positive sample, as this will needed for the laboratory evaluation.
- Request, if possible, that the testing lab provide a PCR cycle threshold (Ct) for the recent positive test. This value is to inform us as to whether culture and/or whole genome sequencing are likely to be successful.
- If possible, locate any SARS-CoV-2 positive samples that the patient has had previously and ensure that they are not discarded.

LHDs who believe a patient meets criteria for additional workup for reinfection or who have questions about whether a patient is an appropriate candidate for further investigation, should email the Clinical Team at CoronavirusClinical@cdph.ca.gov.

Multisystem Inflammatory Syndrome in Children (MIS-C) Reporting

We continue to ask LHDs to report cases of MIS-C to CDPH. As of the beginning of this week, there were a total of 80 confirmed cases across California.

To report cases, please enter details under the CalREDIE condition entitled “Multisystem inflammatory syndrome associated with Coronavirus disease”. Please send us an email at CoVmis-c@cdph.ca.gov if our team can be of assistance as you follow-up on these cases.

We are available to discuss if cases might meet the case definition, requirements for diagnostic testing, as well as outreach to local pediatric hospitals and providers. Thank you all for your work in helping to track this rare but severe condition.

Reporting of Pregnant and Pediatric Cases

CDPH is interested in understanding the morbidity and mortality of vulnerable populations such as pediatric and pregnant cases. We continue to ask LHDs to please enter and update information in CalREDIE on pregnancy status as well as whether or not pediatric or pregnant cases have been hospitalized, are admitted to the ICU, or have died.

Reporting guidelines for these vulnerable populations are as follows:

1. For children 5 years old or younger and all pregnant cases requiring an ICU admission, LHDs should call the warmline during business hours.
2. For all pregnant and pediatric (age 18 years or younger) deaths, including stillbirths, LHDs should call the warmline during business hours and the Duty Officer on evenings and weekends.

The clinical team will follow up with you regarding reports. Thank you all again for keeping us informed about these cases.

Assistance in Determining Cause of Deaths

Also, as a reminder, the clinical team at CDPH is available to assist jurisdictions in helping to determine whether mortality in any case is related to COVID-19. Please reach out to us if we can be of assistance.

COVID-19 Warmline

As a reminder, the CDPH warmline operates from 8am to 5pm on Monday through Friday. At all other times, urgent reports and requests for assistance should be directed to the DCDC Duty Officer. The warmline is only for local health departments to use to report on new outbreaks and potential outbreaks; deaths and ICU admissions among vulnerable populations; and requests for consultation. Thank you for not sharing this number with the general public.

	Reporting Requirements	
Type of report	**WARMLINE** **8am-5pm, Monday - Friday**	**DCDC DUTY OFFICER** **5pm-8am,** **Monday-Friday; All weekend days**

Deaths	• <18 years old • Pregnant person • Fetal demise (stillbirth) • Death of special concern (at discretion of LHD)	
Outbreak / cluster in congregate living or community setting	• First report from all outbreaks / clusters • Unit of reporting is by outbreak; no need to report each individual case.	Only if urgent assistance is required
Case with potential for large transmission and/or **Case in vulnerable population**	Report cases in: • <5 years old in ICU • Pregnant in ICU Other cases at LHD's discretion, e.g.: • People experiencing homelessness in a congregate living facility • Long-term care facility residents and staff	

Epidemiology & Surveillance Update

Probable and confirmed cases

CDPH epi team is using death certificate data from the CDPH Center for Health Statistics and Informatics to identify COVID-19 case deaths in alignment with Council for State and Territorial Epidemiologists (CSTE) surveillance case and death classifications. On Monday, August 31, we began sending LHJs weekly line lists of deaths potentially associated with COVID-19. We ask that LHJs review these lists, update variables in CalREDIE to indicate the death, and update or enter probable case deaths identified by death certificates only (i.e., without laboratory information). A protocol is attached in the weekly email with more details about how to review the line lists and make updates in CalREDIE.

Efforts made by LHJs to update information in CalREDIE will be used to assess both confirmed and probable COVID-19 associated deaths in California. Currently, CDPH is only reporting confirmed COVID-19 deaths.

We have been getting questions from LHJs on how to determine if a death in a confirmed case is COVID-19 associated. Currently, there is no guidance recommended by CDC. CDPH does not require confirmed cases to have COVID-19 listed on the death certificate to be included as a COVID-19 death. LHJs may consider cases in which 1. The decedent did not experience complete recovery back to baseline state of health, AND 2. Decedent did not otherwise have a fully explanatory alternative cause of death that is determined by clinical judgement to be causally unrelated to SARS-CoV-2 infection (e.g., accident, homicide).

PCR and antigen testing

If a patient has a positive PCR test following a positive antigen test, both tests should be captured in the same incident. We ask LHJs to update the case's specimen collection and result date to the PCR test and change the resolution status from "probable" to "confirmed." CDPH has been requesting LHJs to follow-up on cases with positive antigen tests.

Residency and Jurisdiction

All cases and deaths should be counted by the jurisdiction in which patients were living at the time of illness. To assist with defining residence during this timeframe, CDPH proposes that LHJs consider where the person was residing in the 14 days prior diagnosis. This could apply to cases who live in the LHJ temporarily, including seasonal workers, university students, and people experiencing homelessness. University students who are attending remote courses and are not living at the university should be counted in the LHJ where they are residing.

As reminders:

- Persons who are incarcerated should be reported by the LHJ in which the correctional facility is located.
- Cases among correctional facility staff members should be counted by the LHJ in which they reside.
- A resident of a Skilled Nursing Facility (or SNF) who tests positive while living at the SNF, but whose permanent address in another county, should be counted by the LHJ in which the SNF is located.
- Patients who tested positive while hospitalized will be counted for the jurisdiction of their primary residence prior to hospitalization.

VRDL

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, and 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, when used on asymptomatic individuals, or when used in low prevalence settings. It's important to keep in mind these caveats when interpreting the

manufacturers' stated performance data: The manufacturers' stated performance characteristics are calculated from small sample sizes. And importantly, there is no recognized gold standard or reference comparator assay, and the comparator molecular tests differed across the manufacturers. Thus, comparing the manufacturers' stated positive percent agreement and negative percent agreements is not really possible. It is also important to keep in mind is that while the PPA and NPA are calculated the same as sensitivity and specificity, respectively, these values should not be construed to be identical to clinical sensitivity and specificity.

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.

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 their ability to test saliva with an EUA assay that was not FDA-approved for testing saliva. Under this guidance, the testing laboratory does not have to submit their saliva validation to the FDA for approval; however, if asked during a CLIA/CMS inspection, the laboratory would need to provide their validation documentation to CMS inspectors. We recommend confirming with the laboratory that they are using an EUA for which saliva was approved, or, that the laboratory validated saliva themselves, if 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%.

Comparative LOD Data

On Tuesday, the FDA published comparative Limit of Detection (LOD) data for 55 of the more than 160 authorized COVID-19 molecular diagnostic tests. The data were generated using a

standardized sample panel provided by the FDA. The analytic sensitivities provided ranges from 180 to 180,000 NAAT detectable units per ml.

Select Guidance Links:

CDPH Antigen Testing Guidance

APHL Antigen Testing Guidance

Considerations for Interpreting Antigen testing at SNFs

HHS COVID-19 Testing in Nursing Homes Video

BD Veritor SARS-CoV-2 Antigen Instructions for Use

Quidel Sofia SARS Antigen FIA Instructions for Use

LumiraDx SARS-CoV-2 Antigen Test Instructions for Use

Abbott BinaxNOW COVID-19 Ag CARD Instructions for Use

CalREDIE & ELR

Please continue to contact CalREDIE Help (calrediehelp@cdph.ca.gov) if your local health department needs assistance with importing records from the DISA.

CDPH is requesting that entities performing antigen or other point-of-care (POC) tests report them via the CalREDIE Manual Laboratory Reporting Module (MLRM), if reporting via electronic laboratory reporting is not possible.

CalREDIE Help distributed 3 documents to local health departments yesterday, including:

- One-pager on the Manual Laboratory Reporting Module, which can be shared with any entity performing these tests
- Manual Lab Reporting Quick Start Guide, which walks users through the module
- Manual Lab Reporting Account Request Form, to be used to request an account for the Manual Lab Reporting Module

I would also like to spend a few minutes discussing the various ways labs can report results to CDPH. There are 3 ways that labs can report their test results:

1. ELR – Electronic Laboratory Reporting (ELR)
2. .CSV files that meet CDPH-issued standard, for consumption as ELR into CalREDIE
3. Manual Lab Reporting – manual data entry by the laboratory data, which is treated by CalREDIE as an ELR

The CalREDIE Team is working very hard to onboard laboratories as quickly as possible, and provide them feedback on the content and structure of their ELR and/or .CSV submissions, but we need the lab to do their part. Laboratories submitting either via ELR or .CSV are directed to report to the LHJ directly until they are approved for CalREDIE Production.

We are working on developing a process for following up with labs that are not meeting their reporting requirements.

HAI

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 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.

OHB

We mentioned on a call last month that we were planning to update our workplace outbreak guidance to say that employers must report to LHDs when they meet the reporting threshold of three cases at a worksite in a two-week period (remains up to LHDs to determine which to investigate and what constitutes an outbreak). Of note, CDC recently released recommendations on how LHDs could prioritize performing outbreak assessments in non-healthcare workplace settings.

We are in the process of planning outreach to employers to communicate this change, which we hope to do in partnership with LHDs. Please continue to report any outbreaks you identify in your county in the CalREDIE outbreak module. OHB remains available for consultation on workplace outbreaks.

Contact Tracing

Guidance Documents

On September 16, CDPH released new patient education materials providing detailed instructions for how cases and contacts can self-isolate and quarantine. These can be found on COVID-19 CDPH Guidance webpage and are currently available in English, with plans to translate them to other languages.

ELC Metrics

In addition to the 6 performance measures and metrics required by CDC for ELC funding, the State is requiring the reporting of additional metrics regarding case interviews and isolation, contact elicitation, and contact notification and quarantine by each local health department (LHD) as part of their ELC Enhancing Detection funding for Strategy 5 (Contact Tracing, Isolation & Quarantine support). CDPH has provided LHDs with a reporting tool and data definition guide to facilitate this reporting. For LHDs using CalCONNECT for at least 85% of their cases, CDPH will run and report their data metrics; all other LHDs will report their own metrics using the reporting tool. Data are due to CDPH by the 5th day of the month, with the first report due October 5th. State-level ELC metrics will be reported to CDC; LHD-level metrics will be posted on the CA COVID-19 public dashboard.

Program Readiness Survey

A survey link to assess LHD contact tracing program readiness was sent out last week. To date, 57 LHDs have submitted their survey results. Results aggregated at the state level have been included in an executive summary report and shared with CCLHO and CHEAC and CDPH and HHS leadership on Wednesday, September 16. Tables with results by LHD were also shared with CDPH and HHS leadership.

Training

In partnership with UCSF and UCLA, we continue to provide case investigator and contact tracer training to LHD staff and their external partners through the Virtual Training Academy (VTA). The VTA team is currently in the process of modifying the VTA registration page and the VTA curriculum for a community based organization (CBO) audience. If you are aware of a CBO in your jurisdiction that has sent staff to the VTA and would be able to participate in a brief key informant interview to assist with VTA content modification, please email vta.uc.info@gmail.com with suggested CBO contacts. In addition, a VTA outbreak management course is being developed and piloted. Details regarding future outbreak training courses will be provided in the near future.

Data Management Platform (CalCONNECT)

The state's contact tracing data management platform, CalCONNECT, continues to implement

significant enhancements and new functionality through new releases that are rolled out every two weeks. We have developed a brief electronic survey using a virtual agent that now can be sent via text message to both cases and contacts in CalCONNECT. The survey for contacts was released today. It is designed to expand LHD outreach capacity by providing isolation and quarantine instructions and collecting key information to prioritize additional outreach for further investigation based on survey responses. We hope this can help increase efficiencies and allow for prioritization of case investigation and contact tracing for LHDs.

Google Apple Exposure Notification (GAEN) Express App

The California Department of Technology and CDPH announced a partnership with the University of California San Diego and the University of California San Francisco to launch a pilot project to test a bluetooth-based exposure notification mobile application. The app notifies users who may have been in close contact with a COVID-19 test positive case and the pilot version is set to provide links to UCSF and UCSD resources for instructions on monitoring symptoms, getting tested, and self-quarantining. Use of this free smartphone technology is voluntary, and confidential notifications do not reveal a user's identity or location. The goal is to mitigate the spread of COVID-19 by rapidly notifying potentially exposed contacts as well as identifying unknown contacts who might not be identified through traditional contact tracing. Results of the university pilot programs will help to assess a state-wide launch.

Questions & Answers

Q: received a CSTE draft proposed investigation for acute hospitals, has there be any information for reporting and what constitutes an outbreak

A: An AFL similar to that document discussing investigation reporting and outbreak definition is in the works

Q: We have three facilities in our county and one has an outbreak and the other two have staff who have tested positive. Due to the guidance they are not accepting return resident and the hospitals are becoming backed up, is there any state level guidance?

A: Generally we encourage some flexibility in the determination of a new admission due to the reasons you mentioned, backed up hospital. SNFs should be cohorting, testing and achieving some measures of satisfaction before taking new admissions as well as having a designated area for those new admissions with possible healthcare personnel. These are all reasonable strategies to enable new admission to facilities. The fact that they're refusing admission to their own residents is not appropriate especially if the residents' primary location of exposure was at the SNF.

Q: Regarding the reinfection 90 or greater mark is that considered from the onset day, symptoms or the resolution of the infection?

A: We are specifically interested in possible reinfection 90 days after first positive test

Q: Regarding CDPH guidance posted on 9/12 on reporting negatives, if the facility is using Antigen testing as a surveillance tool, are those negatives reported to the LHJ. If the test is positive, should it be entered into CalREDIE as a case, presumably Probable?

A: If you are using the test diagnostically and you are reporting to the patient you will need to enter into CalREDIE. Any healthcare personnel testing as screening testing should be reported to the individual and also reported to CalREDIE by default.

Q: Is saliva testing an appropriate test to be used within a SNF?

A: As long as it's a EUA there shouldn't be any prohibition to using that test since any other HCP can use it, caution the use of saliva for antigen test otherwise there hasn't been any language on limitation of who can use it another thing to remember not all labs are accepting saliva for testing

Q: We are hearing more people refusing to test because they don't want to have to isolate is there any future for the state to look into ICU and hospitalization visits.

A: we will get back to you on that but from an Epi perspective, information is not complete enough for us to do that and that is for hospitalization, estimate around incidents for hospitalization that will come to national level, CA EIP, and at the state and county level it is a complicated analysis

Q: If a SNF staff is positive on an antigen screening point-of-care test, is confirmatory testing required prior to reporting? Reported as Confirmed? Probable?

A: when considering a positive antigen result as a positive and not needing a confirmatory test, that is based on the control measures at the facility, if the environment is of rapid transmission we would suggest follow up testing, that is different from the resolution these would be probable by case definition.

Q: Will there be guidance to our boarding schools in the county, 6 boarding school in the county, can they open?

A: there is a group that drafts those school openings, send Seema.Jain@CDPH an email and she will connect with the right people

Mentioned URLS	
Title of Articles	**Article URLs**
CDPH Guidance on the Use of antigen Tests for Dx of Acute COVID-19	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 Test results in Nursing homes	https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf
Video: COVID-19 Testing in Nursing Homes	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
AFL 20-53.3	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-53.aspx
Centers for Medicare and Medicaid Services (CMS) interim final rule on facility and resident COVID-19 testing	https://www.cms.gov/files/document/qso-20-38-nh.pdf

new Centers for Disease Control and Prevention (CDC) testing guidance	https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
Point of Care (POC) antigen testing	https://www.hhs.gov/about/news/2020/07/14/trump-administration-announces-initiative-more-faster-covid-19-testing-nursing-homes.html
Prioritizing non-healthcare worksite assessments for Coronavirus Disease 2019	https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/prioritizing-non-healthcare-assessments.html?deliveryName=USCDC_425-DM37554
Guidance Documents: COVID-19	https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Guidance.aspx

Team Contacts	
Team	**Email**
Clinical Team	CoronavirusClinical@cdph.ca.gov
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VTA Team	vta.uc.info@gmail.com