# California Department of Public Health
# All LHD Coronavirus Update Call September 03, 2020
# 1:00 pm – 2:00pm

**Contents**

# Clinical

## Guidance for Reinfection

CDPH is preparing a guidance document on evaluation of cases when there is concern for potential reinfection with SARS-CoV-2.

While this seems like a very rare event, recently there have been two reported cases of suspected reinfection. These include an asymptomatic patient in Hong Kong with suspected reinfection occurring four and a half months after initial infection, and a patient in Nevada who developed new symptoms 48 days after initial infection. In both cases, RT-PCR testing was positive and genomic sequencing revealed a significant difference between samples from the initial illness and the supposed reinfection. The frequency of reinfection and the spectrum of disease has yet to be determined. For this reason, the CDPH Clinical Team is interested in collecting data from local health departments (LHDs) on any potential cases of reinfection.

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 30 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

As we have discussed previously, 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.
- If possible, locate any SARS-CoV-2 positive samples that the patient has had previously and ensure that they are not discarded.

In addition, it is helpful to have a PCR cycle threshold (Ct) available, this value is to inform us as to whether culture and/or whole genome sequencing are likely to be successful

Please note that samples for viral culture sent to CDPH are not diagnostic and results should not be used for clinical management.

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. 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.

In cases where patients have died, we are available to assist you in determining whether mortality in these cases is related to COVID-19.

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.

## 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.

| Type of report | Reporting Requirements<br>WARMLINE<br>8am-5pm, Monday - Friday | DCDC DUTY OFFICER<br>5pm-8am,<br>Monday-Friday; All weekend days |
|---|---|---|
| **Deaths** | • <18 years old<br>• Pregnant person<br>• Fetal demise (stillbirth)<br>• Death of special concern (at discretion of LHD) | |
| **Outbreak / cluster in congregate living or community setting** | • First report from all outbreaks / clusters<br>• 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**<br>**Case in vulnerable population** | Report cases in:<br>• <5 years old in ICU<br>• Pregnant in ICU<br>Other cases at LHD's discretion, e.g.:<br>• People experiencing homelessness in a congregate living facility<br>• Long-term care facility residents and staff | |

## Epidemiology & Surveillance Update

The Epi Team at CDPH is working hard to identify and remedy situations where CDPH and LHJ case counting are not aligned. To this end, we are working to increase the transparency of our methods and have developed FAQs on case and testing calculations and definitions which is in the final phase of approval process and will be distributed as soon as possible. Additionally, we are offering SAS code that can replicate our case counting methods and ELR processing methods. Additionally, CDPH has started to distribute weekly line lists of counted and not counted cases to requesting LHJs. To receive this line list for your LHJ or the code, please email COVDATA@CDPH.CA.GOV.

A reminder that for a case to be counted, confirmatory molecular laboratory evidence (i.e. PCR) must be entered on the laboratory tab, either manually, or via ELR. Attachments in the electronic filing cabinet (EFC) cannot be used towards case counting and therefore this

information should be manually entered on the laboratory tab. However, for testing positivity metrics, tests are drawn from ELR records only.

We have an update for case counting methodology in that we have begun to exclude incidents with a confirmatory laboratory evidence and a resolution status of “Not A Case” to better align CDPH case counts with jurisdictional usage of resolution status. Thank you for your patience as we continue to work towards better alignment of our methods with LHJs.

This week CDPH has begun implementing code to examine vital statistics data to identify deaths among confirmed cases that have not already been reported as well as deaths among cases which fulfill the probable CSTE case definition. We sent initial email notifications with line lists of these individuals this past Monday and will continue to update LHJs weekly with newly identified deaths. CDPH requests that LHDs verify that these incidents meet the criteria to be counted as confirmed COVID-19 deaths, and enter or update these incidents into CalREDIE as needed.

With the recent update of the CSTE case definition, CDPH is finalizing the methodology for reporting probable cases in our surveillance system, and will share the details with LHJs before the process goes live. Neither probable cases nor deaths in probable cases are being enumerated or reported by CDPH at this time.

A last reminder to please enter outbreaks as they occur in your jurisdictions into the outbreak module in CalREDIE so that the dynamics of the pandemic can be adequately tracked and addressed.

We thank you for your continued efforts, and greatly appreciate your commitment to providing the data that help drive this response.

## VRDL

### 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 from a nasal swab and can provide results in about 15 minutes.

- The Sofia Ag assay also 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 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.

Guidance Links:

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

Considerations for Interpreting Antigen testing at SNFs

## HAI

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 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.

Also last week, the Centers for Medicare and Medicaid Services (CMS) released QSO 20-38-NH, which includes updated testing requirements for skilled nursing facilities. Of note, the testing frequency for routine (surveillance or screening) testing of SNF healthcare personnel is determined based on the extent of transmission in the community, therefore facilities are instructed to use their county percentage test positivity in the prior week as the trigger for staff testing frequency.

CMS is posting COVID-19 county-level positivity data on the following website (see section titled, "COVID-19 Testing"). We are aware that some SNF have reported the CMS reported percentage test positivity differs from that reported by their county and on the California blueprint website; we are working on understanding the discrepancy. Additionally, the CMS memo indicates that facilities conducting tests under a CLIA certificate of waiver are subject to regulations that require laboratories to report data for all testing completed, for each individual tested; this reporting includes their requirement to report test results to their local health department and CDPH as required under Title 17. CalREDIE staff will be providing information and a presentation on the CalREDIE Manual Lab Reporting Module (MLRM) to SNF participants during next week's regular CDPH webinar and call for SNF. Additionally, CDPH is updating AFL 20-53 to incorporate the CMS memo.

## 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.

Please do NOT send protected health information (PHI) when emailing CalREDIEHelp. Use the Incident ID# or Patient ID# instead.

The CalREDIE Team plans to hold our CalREDIE COVID Local Users' Call (LUC) next Wednesday, September 9th. We are continuing to update our agenda, but plan to provide a general overview of COVID in CalREDIE for our newer users; an update on CalCONNECT/CalREDIE integration efforts; and updates on the COVID Reporting System.

## Contact Tracing

### Workforce

Our workforce team is continuing to deploy redirected state staff to local health departments (LHDs) throughout the State. We continue to deploy contact tracers and case investigators. If you have not placed a formal MHOAC request for case investigators or contact tracers, please do so while we have state staff available. We ask that for case investigators, LHDs provide some mentorship for these case investigators as written in the MOU signed by your LHD and the State, however for jurisdictions that do not have this capacity internally, the State has mentorship support available. LHDs may also choose to train redirected state staff contact tracers to become case investigators but it is required that this is done in consultation with CDPH prior to training.

In addition, our program has a new Disease Investigations Unit composed of 37 communicable disease investigators (CDIs) and team leads hired recently through the CDC Foundation. After their initial 4-6 week training deployments, these CDI "strike teams" will be available to provide short-term assistance to LHDs to increase surge capacity, mentor local communicable disease investigators, and assist with outbreak management. The first set of these CDIs were virtually deployed to a host county for training and mentorship beginning August 17, and additional teams will be deployed to other training counties over the next few weeks. We will communicate how requests for outbreak management assistance should be made over the next couple of weeks, but determinations for deployments will be made in collaboration with the Science Branch.

### Training

In partnership with UCSF and UCLA, we continue to provide subject-matter training courses, which include both formal presentations and interactive skills labs, for case investigators and contact tracers. This training, called the Virtual Training Academy, or VTA, runs weekly. LHD staff can register for the VTA by visiting the training registration portal. **The weekly VTA sessions are also open to staff from agencies in your community that you are partnering with**. These external partners would simply need to indicate on their registration form that they are linked to a LHD COVID-19 contact tracing effort. This can be done by providing a name and email for an LHD contact as the "supervisor". This allows the VTA registration team to know that the external partner is working on your behalf and/or with your consent. Many of you participated in the VTA informational session last week - your input was very helpful and will help guide the development of future VTA courses such as the outbreak module and a community based organization focused training track. If you were unable to attend that session and would like to provide input, please send your suggestions/comments to vta.uc.info@gmail.com.

## 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. Recently launched functions include integrated Spanish scripts for case investigators and contact tracers. In addition, we have developed a brief electronic survey using a virtual agent that can be sent via text message to cases in CalCONNECT. The survey is available in both English and Spanish. It is designed to expand LHD outreach capacity by providing self-isolation instructions and collecting key information to prioritize additional outreach for further investigation based on survey responses. We recently added the ability for cases to enter information on their close contacts into the survey. We soon will be launching an electronic survey for notification and outreach to contacts via text as well. We hope this can help increase efficiencies and allow for prioritization of case investigation and contact tracing for LHDs.

## Testing of asymptomatic contacts

Last week, testing guidance on the CDC website was changed to say if an individual has been in close contact of a person with a COVID-19 infection but does not have symptoms, they do not necessarily need a test unless they are a vulnerable individual or their health care provider or State or local public health officials recommend they take the test. CDPH recognizes that this statement could be misleading as it seems to suggest that testing of asymptomatic contacts is not critical. Given current evidence indicating the significant role that asymptomatic individuals play in transmission, CDPH believes that testing all contacts, including those who are asymptomatic, will be needed in order to control the COVID-19 epidemic in CA. However, when testing capacity is limited, CDPH recommends that symptomatic contacts be prioritized for testing over asymptomatic contacts. We continue to work on expanding testing capacity across the state to allow for testing of all recommended individuals, including asymptomatic people who have been exposed.

## Close Contact definition

Finally, we wanted to revisit the definition of close contact we provided two weeks ago. Both CDC and CDPH have stated that anyone who has been within 6 feet of someone infected with COVID-19 for at least 15 minutes should be considered a close contact and "exposed." The question of whether the 15 minutes should be considered consecutive versus cumulative is dependent on many factors, including the duration and circumstances of each encounter, and may be made on a case-by-case basis. For instance, someone with multiple, very brief encounters (e.g, <1 minute each) that may add up to 15 minutes, is of less concern than someone who carpooled with someone to and from work for 12 minutes each way for multiple days with the windows closed. Given this variability, how to operationalize the definition of a close contact should be decided by each LHD within their jurisdiction.

For additional questions, please email our team at CALHJ_COVIDCT@cdph.ca.gov. Note, this e-mail address is for LHD use only -- please do not share it outside of LHD staff.

## Investigations

As you know, some institutions of higher education are reopening, at least for some students, in California. CDPH is now getting queries about COVID-19 case management and other issues in these settings. CDPH has general guidance about reopening strategies, including safety measures to be implemented. CDC also has general COVID-19 guidance as well as testing guidance for institutions of higher education and does not recommend testing of asymptomatic people without a known exposure. At this time, CDPH does not have specific guidance about case and outbreak management in these settings, but the investigations team is happy to work with local health departments as these situations arise.

## Questions & Answers

*Several of the questions and answers were difficult to hear. Not all of the questions or answers may have been captured in their entirety.

Q: Question about additional guidance on antigen testing reporting

A: We are reminding folks of the lab reporting manual, there are efforts at the federal level and we are working with several LHJs on this situation. Currently, LHJs have to hand enter antigen testing information into CalREDIE. A positive antigen test would qualify a case as probable. CDPH is not yet enumerating or reporting probable cases.

Q: We have encountered providers entering information into PCR without lab results and it's difficult to know if it's a PCR or Antigen, how can this be fixed?

A: CalREDIE are aware of the provider issue and we are working on that

Q: Do you recommend testing of asymptomatic close contacts using serial antigen testing?

A: Antigen testing is less sensitive than PCR testing; however, antigen testing may be sensitive enough to detect people with COVID-19 when they are infectious (when they have a high viral load). Serial testing would also increase sensitivity. When and how to test asymptomatic contacts depends on testing capacity, and which tests are available (including those with a reasonable turn-around time). Many antigen tests were purchased by the federal government and could be challenging to obtain.

Q: Regarding Antigen test, the specificity is generally accurate but not being counted as confirmed cases, what are preforming characteristics?

A: The challenge about sensitivity is based on analysis of the manufacture and it's based on synthetic spiking samples, antigen test will be counted as probable and entered into CalREDIE

Q: We have encountered cases where SNF residents tested positive and a couple days later ended up in the hospital and the hospital retests and get a negative result, the resident is then asked to return to the SNF, will these cases be reported?

A: In general residents or personnel in high risk setting for transmission, deaths, we would practice caution and isolation for those individuals, we have to factor in why the person went to the hospital, did they have COVID like symptoms, etc.

Q: While CDC/CDPH recommend that the definition of close contact is being within 6 feet of an infected person for at least 15 minutes, LHJs have the discretion to operationalize this definition?

A: It's up to each LHJ to operationalize the definition of close contact – see the notes from the contact tracing section for more details.

Q: We have been encountering cases of SNF residents who are positive being relocated to other counties then pass away, the death is then being counted in another county and not the county which the outbreak/transmission occurred, how can this be fixed?

A: The death count should be related to exposure, we will follow up with you.

| Mentioned URLS | |
|---|---|
| **Title of Articles** | **Article URLs** |
| COVID-19 re-infection by a phylogenetically distinct SARS-coronavirus-2 strain confirmed by whole genome sequencing | https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1275/5897019 |
| | https://ncrc.jhsph.edu/research/genomic-evidence-for-a-case-of-reinfection-with-sars-cov-2/ |
| BD Veritor SARS-CoV-2 Antigen Instructions | https://www.fda.gov/media/139755/download |
| Quidel Sofia SARS Antigen FIA Instructions | https://www.fda.gov/media/137885/download |
| LumiraDx SARS-CoV-2 Antigen Test Instructions | https://www.fda.gov/media/141304/download |
| Abbott BinaxNOW COVID-19 Ag CARD Instructions | 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 |
| FAQs on Testing for SARS-CoV-2 | https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2?deliveryName=USCDC_425-DM36794#general-screeningasymptomatic |
| Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes | https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html |
| QSO 20-38-NH | https://www.cms.gov/files/document/qso-20-38-nh.pdf |
| COVID-19 Nursing Home Data | https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg |
| VTA Training Registration Portal | http://www.uclaextension.edu/ca-vta |

| | |
|---|---|
| COVID-19 Industry Guidance: Institutions of Higher Education | https://files.covid19.ca.gov/pdf/guidance-higher-education--en.pdf |
| Colleges, Universities, and Higher Learning | https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/index.html |
| Interim Considerations for Institutions of Higher Education Administrators for SARS-CoV-2 Testing | https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/ihe-testing.html |

| **Team Contacts** | |
|---|---|
| **Team** | **Email** |
| **Clinical Team** | CoronavirusClinical@cdph.ca.gov |
| **Cov MIS-C** | CoVmis-c@cdph.ca.gov |
| receive this line list for your LHJ or the code | COVDATA@CDPH.CA.GOV |
| **CalREDIE Help Desk** | calrediehelp@cdph.ca.gov |
| **Contact Tracing (**for LHD use only) | CALHJ_COVIDCT@cdph.ca.gov |