California Department of Public Health
All LHD Coronavirus Update Call August 6, 2020
1:00 pm – 2:00pm

Contents

Lane6

CDPH continues to monitor county data monitoring metrics. The watch list of counties, which is based on these metrics, has been frozen temporarily due to data flow issues related to the Department's IT infrastructure. The list was frozen on August 1.

VRDL

Antigen Assays to detect SARS-CoV-2

There are currently two SARS-CoV-2 Antigen (Ag) Assays available through FDA Emergency Use Authorization (EUA): 1) the Quidel Sofia SARS Antigen FIA assay, and 2) the BD Veritor System for Rapid Detection of SARS-CoV-2. Both assays are approved as CLIA-waived tests (point of care).

These antigen tests are lateral flow assays designed to detect the nucleocapsid of SARS-CoV-2 virus, if present, from a patient's nasal swab and can provide results in about 15 minutes.

The Sofia Ag assay allows for the collection of NP specimen using a nylon flocked NP swab (not supplied)

- Both tests require dry swab collection with NO transport media
- Both tests recommend testing as soon as possible once the specimen is collected

	BD Veritor	**Sofia Ag FIA**
PPA	84% (C.I. 67%–93%)	96.7% (C.I. 83.3% - 99.4%)
NPA	100% (C.I. 98%–100%)	100.0% (C.I. 97.9% - 100.0%)
OPA	98% (C.I. 95%–99%)	99.5% (C.I. not provided)
PPV	100% (C.I. 89% -100%)	100% (C.I. not provided)
NPV	97.5% (C.I. 95% - 99%)	99.4% (C.I. not provided)

PPA: positive percent agreement; **NPA:** negative percent agreement; **OPA:** overall percent agreement; **PPV:** positive predictive value; **NPV:** negative predictive value

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.

Indeed, negative results for the BD Veritor antigen test should be treated as presumptive negative, while negative results for the Sofia Ag test should be treated as presumptive if the specimen is collected beyond five days from symptom onset.

> **NOTE:** this detailed information is contained within the Instructions for Use (IFU) brochure and on the FDA EUA website for each test

If necessary, for clinical management or infection control, negative antigen test results should be confirmed using a PCR-based assay with FDA Emergency Use Authorization (EUA) for SARS-CoV-2 detection.

At this time, antigen tests are NOT recommended for screening of asymptomatic individuals or screening of healthcare workers, first responders and other essential personnel.

CLIA Waived SARS-CoV-2 Point of Care Antigen Tests

As a reminder, CLIA waived tests may be performed at sites that possess a CLIA Certificate of Waiver. These sites are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Facilities performing only waived tests have no routine oversight and no personnel requirements. These sites are only required to obtain a CLIA Certificate of Waiver, pay biennial certificate fees, and follow manufacturers' test instructions.

CLIA waived assays, as defined by CLIA, are simple tests with a low risk for an incorrect result, but they are not error-proof.

Despite being CLIA waived, erroneous results may have serious health consequences. To decrease the risk of erroneous results, the test must be performed correctly according to the IFU, be conducted by personnel who are fully trained to do the test according to the IFA, and must be done in an environment where good laboratory practices are followed to avoid cross-contamination and maintain safety.

Select Guidance Links:

CDC guidance on CLIA Waived tests

BD Veritor SARS-CoV-2 Antigen Instructions for Use

Quidel Sofia SARS Antigen FIA Instructions for Use

The California COVID-19 Testing Task Force (CA TTF)

Epidemiology & Surveillance Update

CDPH continues to report only laboratory-confirmed COVID-19 cases, publicly and to CDC, daily. Per the CSTE case definition, confirmed cases include only patients that have tested positive via PCR or molecular testing. For clinical and public health purposes, **positive** antigen tests **should** be used for case follow-up. However, antigen tests do not yet meet criteria for confirmatory laboratory evidence according to the CSTE surveillance case definition, and patients with positive antigen tests are not being counted as confirmed cases at this time.

CDPH is counting and reporting all incidents with positive PCR laboratory data received by ELR or entered in the Laboratory Tab in CalREDIE. For any positive PCR lab results received directly by your jurisdiction and not by ELR in CalREDIE, please be sure to enter the specimen collection

date and result in the appropriate section on the Laboratory Tab in CalREDIE. Cases in CalREDIE closed with a Resolution Status of "Confirmed" will only be counted if they also include evidence of a positive PCR laboratory result in the incident report.

CDPH continues to assist LHJs with notification to CDC Division of Global Migration and Quarantine when a confirmed case of COVID-19 has traveled on an airplane while infectious. As a reminder, if an investigation reveals that a case was on any domestic or international flights while infectious **in the last 14 days**, please call the CDPH warmline or email CovTravelEpi@cdph.ca.gov. Flights that have occurred more than 14 days in the past do not need to be reported because the passengers on that flight have passed an incubation period. Also, to avoid duplication of effort, please only notify CDPH if you have not already reported the passenger and flight to the CDC DGMQ. As a reminder, for any reports, CDC will need the patient name, date of birth, symptom onset date, symptoms on last day of travel, lab results, and flight dates and details. This information will also need to be entered into CalREDIE.

Clinical

MIS-C Update

Currently we are aware of 30 confirmed cases of multisystem inflammatory syndrome in children (MIS-C) in the state of California and are working through several suspected cases.

Reporting this condition is extremely important so that we can continue to track this severe condition. Hospitals and health care providers should immediately report cases meeting the MIS-C case definition to their respective local health jurisdictions (LHJs). LHJs should then report cases to CDPH.

Thank you again to all those who have continued to work with us to report cases. Please also send us an email at CoVmis-c@cdph.ca.gov if our team can be of assistance to you as you work on these cases.

Update on the Call for Early Potential COVID-19 Cases to Medical Examiners and Coroners

An update on the call for cases to medical examiners and coroners that was released on April 29, 2020. This call for cases focused on autopsy specimens in cases concerning for COVID-19 in the early phase of the pandemic, with a specific request for cases between December 17, 2019 to March 16, 2020. We received 104 cases to review and 64 were approved for CDC review. While all results will take some time to get back, we have received results back in less than half of the approved cases thus far and none are positive for SARS-CoV-2.

If pathologists or medical examiners in your jurisdiction submitted cases, they should have received an email updating them as to the status of their cases earlier this week. Once results are available from CDC, they will be sent to the submitter. Additionally, I wanted to inform you that CDC's Infectious Diseases Pathology Branch (IDPB) will only assess specimens that are in FFPE tissue blocks. Thank you for your help and partnership in this endeavor.

Reporting of Pregnant Cases and Pediatric Cases

Please note that ICU admission in pregnant patients as well as ICU admissions in children under 5 years of age should be reported to CDPH. To report admission to the ICU in either of these populations, please call the warmline during business hours.

Additionally, COVID-19 deaths in cases under the age of 18, COVID-19 deaths in pregnant cases, and cases of stillbirth or fetal demise related to COVID-19 should be reported. To report these cases, please call the warmline if during business hours or the DCDC Duty Officer if after hours.

Warmline

The CDPH warmline operates from 8am to 5pm on Monday through Friday and is only for local health departments to use. Please use the warmline to request assistance for outbreaks if needed; report deaths and ICU admissions among vulnerable populations; and submit requests for consultation. Outside of the warmline hours urgent reports and requests for assistance should be directed to the DCDC Duty Officer. Please note that new outbreaks do not need to be called into the warmline unless assistance is needed.

<table>
<tr><th>Type of Report ↓</th><th>8am-5pm
Mon-Fri</th><th>8am-5pm
Sat-Sun</th><th>5pm-8am (after hours)
7 days/week</th></tr>
<tr><td>Death
<18 years old
Pregnant person
Fetal demise (stillbirth)
Death of special concern (at discretion of LHD)</td><td rowspan="3">Call Warmline
(510) 255-8922</td><td rowspan="3">Call DOD
(916) 328-3605</td><td>Call DOD</td></tr>
<tr><td>Outbreak/ cluster in congregate living, community, or workplace setting
Requests for assistance</td><td>Call DOD only if urgent assistance is required that cannot wait until the morning</td></tr>
<tr><td>Case in vulnerable population and/or case with potential for large transmission
Report cases in:
<5 years old in ICU</td><td>Call DOD only if urgent assistance is required that cannot wait until the morning</td></tr>
</table>

Type of Report ↓	8am-5pm Mon-Fri	8am-5pm Sat-Sun	5pm-8am (after hours) 7 days/week
• 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			
Cases related to flights	Email flight info to CovTravelEpi@cdph.ca.gov		

NOTE: ALL cases should be reported to CDPH by entry into CalREDIE by the following day, or by LHJ's usual method of reporting.

HAI

Last week, CDPH disseminated an updated AFL 20-53.2 COVID-19 Mitigation Plan Recommendations for Testing of Health Care Personnel (HCP) and Residents at Skilled Nursing Facilities (SNF). This AFL updates testing and isolation guidelines, and HCP return to work criteria to reflect recent changes to the Centers for Disease Control and Prevention (CDC) guidance. The AFL also highlights the Department of Health and Human Services recent announcement of the dissemination of point-of-care antigen test instruments and tests to nursing homes in COVID-19 geographic hotspots.

The updates include additional clarification about admission testing and quarantine. The purpose of testing and quarantining new admissions to SNF is to monitor the resident for the 14 days since the date of their last likely potential exposure outside the SNF, which could be in the community or in the transferring healthcare facility if that facility is having an outbreak. In general, we would not consider an acute care hospital stay to constitute an exposure unless that hospital is having a suspected or confirmed outbreak. The AFL includes recommended criteria for assessing whether or not a transferring acute care hospital should be considered a site of potential exposure, for the purpose of determining whether to count acute care hospital days as part of the quarantine observation period from the date of last potential exposure for new admissions.

Residents that are being re-admitted to the same SNF after a hospital stay, ED or clinic visit where there is no suspected transmission would not be considered to have an exposure at that outside facility and so do not necessarily require testing and quarantine upon readmission to

the same SNF. From a practical standpoint, the practice of quarantine in a separate observation area with use of full personal protective equipment for COVID following a hospital stay or outpatient visit for readmitted residents can lead to SNF residents remaining in the acute care hospital for longer than medically necessary because the SNF is unable to accommodate them in their observation/quarantine area. Rather than quarantine, SNF can consider periodically testing individuals who frequently leave the facility (for example, for dialysis).

I'd also like to clarify regarding the recommendation for response testing every 7 days until no new cases are identified among residents in two sequential rounds of testing. The rationale for this recommendation is that we consider two sequentially negative rounds of testing in residents to be evidence that transmission is no longer ongoing within the facility, because cases in residents are generally a result of transmission within the facility whereas HCP often acquire their infections in the community. So a facility that identifies new cases in HCP while there are no new cases among residents during response testing may still have contained transmission within the facility; new cases identified in HCP in this scenario with control measures in place would trigger additional response testing, but this could be done with contact tracing and a more targeted response testing of residents and HCP, for example, on the same unit where the new positive HCP was identified –will try to clarify this in the next update to the AFL.

Many local health departments require SNF to close to new admissions until transmission is contained, often as evidenced by two sequentially negative rounds of response testing among residents. There have been concerns from some hospitals as well as LHD that SNF residents were backing up in surging hospitals that were unable to discharge to SNF with lengthy closures to new admissions, and a desire for some flexibility around the criteria for resuming admissions. As such we recommend that the two sequentially negative rounds of testing in residents not be the sole basis of determinations to resume new admissions; a facility carrying out a diligent outbreak response, with no staffing or operational issues, and a well-separated observation area could likely safely take new admissions.

OHB

Our Occupational Health Branch has been providing consultations to local health departments dealing with workplace outbreaks, and as most of you know, we have developed workplace outbreak guidance for both health departments and employers, which are available on the CDPH website. We also wanted to make you aware of the Employer Playbook for Safe Reopening, which is an additional resource that can be shared with employers.

We also wanted to let you know that, because of the high number of COVID cases occurring among workers and at workplaces, we are updating our guidance to **require** that employers report COVID outbreaks at their workplaces to their local health departments. Outbreaks are

defined as three or more lab-confirmed cases among workers who do not live in the same household over a two-week period. When these outbreaks are reported to you, we request that your health departments continue to report these outbreaks in the outbreak module in CalREDIE; please make sure to specify the type of workplace using the outbreak setting field in CalREDIE. This will help us track where workplace outbreaks are occurring and help us target our prevention efforts.

Contact Tracing

Updates from the CA COVID-19 Contact Tracing workgroup.

Workforce

Our workforce team is continuing to deploy redirected staff to local health departments (LHDs) throughout the State. In the past, we were only training and deploying redirected state staff as contact tracers. However, we understand the urgent need for case investigators and have developed a plan to deploy redirected staff who are qualified and committed to serve as case investigators for LHDs. We have identified about 100 state staff to become case investigators, who have completed the required trainings and will be assigned to various LHDs throughout the State. If you have submitted a formal MHOAC request for case investigators, you have probably been contacted by our LHD liaison team to determine specifics of your request. Our plan is to deploy a first wave of case investigators on Monday, August 10. We are asking local health departments to provide some mentorship for these case investigators as written in the MOU signed by your LHD and the State. 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. If you have not placed a formal MHOAC request for case investigators or contact tracers, please do so while we have state staff available.

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. In response to the need for additional case investigators around the state, the VTA launched a new track for previously trained contact tracers who will be promoted to become case investigators and need specific, additional training. This track includes approximately 1.5 hours of webinar and two 90-minute skills labs. The first session began this week and will continue through the end of the month. LHD staff can register for the VTA by visiting the training registration portal. Additionally, UCSF is developing a new Outbreak Investigation & Management course that they hope to offer as part of the VTA course options by the end of this month. A survey has been sent to LHDs to ask about the need for this type of training

opportunity and to solicit feedback on the draft course outline. Please complete this survey to help the UCSF training team develop a course that best meets your needs.

Data Management Platform (CalCONNECT)

The state's contact tracing data management platform, CalCONNECT (California CONfidential NEtwork for Contact Tracing), continues to implement significant enhancements and new functionality through new releases that are rolled out every two weeks. Given the increase in COVID-19 case numbers, we have developed a brief electronic survey using a virtual agent that can be sent via text message to unassigned cases in CalCONNECT. The survey 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. Current data collected in the survey include basic demographic information as well as if the case has symptoms (and if so, symptom onset date), if they are able to safely self-isolate, and if during their infectious period have been in a place in which they could have potentially spread the virus to a large number of people, such as congregate settings, workplaces, schools, and others. LHDs will be able to sort and filter responses to prioritize additional telephone outreach. The next release of this survey will also collect information on close contacts, and we are creating a similar outreach survey for exposed contacts, which is planned to be released in early September. The case outreach survey went live today in English, and will be available in Spanish in approximately two weeks. We hope this can help increase efficiencies and allow for prioritization of case investigation and contact tracing for LHDs.

CDC-CMS Announcement

Finally, we wanted to share that last week the Centers for Medicare and Medicaid Services (CMS) and CDC announced that payment is now available to physicians and health care providers to counsel patients at the time of COVID-19 testing about the importance of self-isolation after they are tested and prior to the onset of symptoms. Information about this new policy can be found here

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.

CalREDIE & ELR

Update on CalREDIE and ELR:

We want to personally acknowledge the frustrations and challenges each of you are encountering in doing your work to protect your communities, due to the issues with ELR, on top of the already exhausting work related to this pandemic.

We want to assure you that the CalREDIE Team and our partners in the Information Technology Services Division (ITSD), California Department of Technology (CDT), and various vendors are working around the clock to investigate and resolve the issues with transmitting ELR to CalREDIE. Additionally, the teams are working to stand-up a back-up system to ensure redundancy in the lab data feeds, going forward.

We did identify and resolve an issue with Quest, where one of the Quest feeds went offline late last week. Due to the low volumes of data seen by other laboratories, this was not readily apparent as one problem. A certificate was reissued on Wednesday, and Quest resumed their transmission for ELR data received through the AIMS hub.

A few other items of note:

- The CalREDIE team in collaboration with the statewide Testing & Tracing Integration Team, will be hosting a pair of "Super Users" training webinars on Friday, August 7th and Wednesday, August 12th. A key focus area of these webinars will be to improve the time it takes a positive COVID-19 result to be released into CalREDIE to initiate contact tracing in a timely manner. Several local health jurisdictions (LHJ) have expressed the need for additional CalREDIE training to help improve current COVID-19 processing times. As such, the CalREDIE team has developed and will be hosting two live 90-minute webinar sessions focused on common COVID-19 processing scenarios. Please contact CalREDIEHelp for the WebEx information, if you have not already received it.
- Additionally, the CalREDIE team will be hosting a Local Users' Call on Wednesday, August 12th.

Questions & Answers

Question: The CDPH SNF guidance for facilities related to an emergency room and acute visits, our LHD has been receiving various calls, is there written guidance that can be referenced?

Answer: Yes, there is an AFL 20-53.2 which includes recommendations for new admissions and readmission after a hospital ED hospital visit.

Question: If a hospital stay is longer than 24 hours the patient needs to quarantine, yet if the facility doesn't have an outbreak they don't have to quarantine?

Answer: This was the previous recommendations from original AFL, this practice has led to unintended consequences to SNFs not being able to admit residents due to the need to implement full PPE, this clarification around observation around new vs re admissions is intended to address those challenges and unintended consequences and align logically the purpose of quarantine

Questions: The new approach of having employers required to inform LHDs about an outbreak, what resources can be offered?

Answer: we are updating guidance, they are in the final stages, and the language will change that employers MUST report to LHD

Question: Is the ELR system having problems with only COVID19 or with other diseases and lab work?

Answer: Laboratory results on other infectious diseases also go through this system and may be affected.

Question: APHL aren't recommended for symptomatic persons, CMS has implied to test asymptotic persons if appropriate, will guidance be sent to SNFs on how to use antigen testing?

Answer: We are working with the conflict APHL and will be updating guidance on that, CDC is also updating guidance, at the moment but no official guidance. BD Veritor does stipulate there is no assessment to symptomatic testing with that kit, Sofia doesn't mention it

Answer: we are looking for those updated guidance we can recommend the use of these test to be used in symptomatic individuals and does have value in SNFs

Question: CLIA, when a facility is using a waived test only and no personnel requirements, does the lab director have to be an MD or certified PhD, is there clarification since business are asking on waive test?

Answer: Facilities performing waive testing can reach LFScovid@cdph.ca.gov who can help

Question: When will LHJs receive excel spread sheets from the labs directly, this is in regards to the notification that came from CalREDIE update?

Answer: We don't have anyone on this call who can answer that.

Question: How do we know in the LHD who those excel will be sent to?

Answer: We don't have anyone on this call who can respond to that.

Question: Positive antigen test for a person with symptoms are actionable for public health. Are there thoughts that CDPH will push to change definition to have those as confirmed test results and count them since we are told to act as they are cases?

Answer: There have been conversations about case definitions, we do expect to have this updated but don't have a timeline

Comment, can CDPH help with advocacy about the CDCR releasing inmates to LHD who are pending test who are in actuality infectious. We in San Diego had 2 recent instances where inmates were released, then when test results came back positive, they could not be found.

Question: Suggestion to have labs send results to CDPH and CDPH can be clearinghouse and send out results to LHDs, like the earlier Traveler Monitoring System.

Answer: These options are being considered but we are hoping to resolve the issue soon without starting something new.

Mentioned URLS	
Title of Articles	**Article URLs**
CA Coronavirus Testing Task Force	https://testing.covid19.ca.gov/ click *Labs with Testing Capacity* for latest list
CDC guidance on CLIA Waived tests	https://www.cdc.gov/labquality/waived-tests.html
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
AFL 20-53.2	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-53.aspx
VTA registration portal	https://portal.uclaextension.edu/corporate/landingPage.do?method=load&corporateGroupId=741838927
CMS and CDC announce provider reimbursement available for counseling patients to self-isolate at time of COVID-19 testing	https://www.cms.gov/newsroom/press-releases/cms-and-cdc-announce-provider-reimbursement-available-counseling-patients-self-isolate-time-covid-19
COVID-19 Employer Playbook	https://files.covid19.ca.gov/pdf/employer-playbook-for-safe-reopening--en.pdf
Collection and Submission of Postmortem Specimens from Deceased Persons with Known or Suspected COVID-19	https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html

Team Contacts	
Team	**Email**
CoV MIS-C	CoVmis-c@cdph.ca.gov
CoV Travel	CovTravelEpi@cdph.ca.gov
CoV Contact Tracing (LHD use only)	CALHJ_COVIDCT@cdph.ca.gov
CalREDIE Help	CalREDIEHelp@cdph.ca.gov