



To: CAHAN San Diego Participants
Date: October 16, 2020
From: Public Health Services

Health Advisory Update #19: Updated Coronavirus Disease 2019 (COVID-19) Test Result Reporting Guidance

Key Messages

- All laboratories testing California specimens for SARS-CoV-2 are required to report SARS-CoV-2 test results to the California Department of Public Health (CDPH) or the County of San Diego Public Health Services. This requirement applies to entities that conduct Clinical Laboratory Improvement Amendments (CLIA)-waived point-of-care (POC) tests for SARS-CoV-2, including those operating at drive-through sites, physician offices, and pharmacies.
- Labs must ensure all SARS-CoV-2 test results (positive, negative, indeterminate, and specimen unsatisfactory) from molecular, antigen, and antibody/serology tests are reported within 8 hours from the time the laboratory notifies the health provider or other person authorized to receive the report.

Situation

- On September 23, 2020, [California Department of Public Health \(CDPH\) Laboratory Field Services \(LFS\)](#) issued updated guidance regarding mandated laboratory reporting of SARS-CoV-2 test results.
- While LFS noted that the need to provide testing for SARS-CoV-2 during the Coronavirus Disease 2019 (COVID-19) emergency has imposed unique demands upon testing laboratories that have affected the ability of laboratories to report results within the required time frame, it is critical that laboratories report test results and patient information within the regulatory time frames.
- These data are a prerequisite to timely case investigation and contact tracing to slow the spread of SARS-CoV-2.
- On July 28, 2020, the reporting regulations in [Title 17 of the California Code of Regulations \(CCR\) section 2500](#) and [2505](#) were amended to change laboratory reporting times and require additional patient information.
- Failure to comply with these disease reporting requirements may be a basis for the denial, suspension, or revocation of any clinical laboratory license or registration. In addition, CDPH may also impose on a clinical laboratory alternative sanctions in lieu of, or in addition to, a denial, suspension, or revocation.

Actions Requested

- Laboratories that test San Diego County residents, regardless of the location of where the laboratory is based, are required to [report](#) as per the [Health Officer Order](#). This includes testing performed **at drive-through sites, physician office laboratories, and laboratories located outside California, as well as pharmacies performing waived POC testing.**

- Laboratories are required by state law (Title 17 CCR [Sections 2500](#) and [2505](#)) to report SARS-CoV-2 test results to the California Department of Public Health (CDPH) or the County of San Diego Public Health Services.
- Laboratories must report results electronically to the [CalREDIE Electronic Lab Reporting \(ELR\) system](#) or directly to the County of San Diego.
 - Laboratories shall establish electronic lab reporting interfaces with the CalREDIE ELR system or directly to the County of San Diego through the San Diego Health Connect Health Information Exchange (HIE).
 - Laboratories and pharmacies not yet registered or otherwise unable to report via ELR should [contact CalREDIE](#) to arrange for reporting through alternative methods, such as a .CSV file reporting mechanism.
 - For those labs who will be submitting .CSV files, the County of San Diego requests a copy of the .CSV file to be sent to the County, as well.
 - To inquire about reporting SARS-CoV-2 test results to the County of San Diego, send an email to Epi-CDReporting.HHSA@sdcounty.ca.gov.
 - CalREDIE has established a special team to assist labs with questions about reporting SARS-CoV-2 results to CDPH, which may be contacted at CalREDIEHelp@cdph.ca.gov.
- Laboratories must report all **positive** and **non-positive (i.e., negative, indeterminate, and specimen unsatisfactory)** test results from molecular and antigen diagnostic tests and antibody/serology tests for SARS-CoV-2.
- Laboratories must report **within 8 hours** from the time the laboratory notifies the health care provider or other person authorized to receive the report.
 - Please note that laboratories no longer need to report SARS-CoV-2 results by telephone within one hour.
 - The lab results must include [key reporting data elements](#) which are outlined in the California Code of Regulations, Title 17, [Section 2505](#), plus race/ethnicity. Lab requisition forms should be revised to include this information, and healthcare providers should ensure that demographic information is collected during patient intake and is available to the laboratory to include when reporting results.

Please visit the County [Reporting Guidelines for COVID-19](#) webpage for further laboratory reporting information.

General public inquiries about COVID-19 should be directed to [2-1-1 San Diego](#) or to the [County COVID-19 website](#). Thank you for your participation.

CAHAN San Diego

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