

Updated May 5, 2020

Dear Laboratory Directors and Managers,

The California Department of Public Health (CDPH) expects that many CLIA-certified laboratories qualified to perform high complexity testing are eligible to test for SARS-CoV-2, the virus that causes COVID-19, or novel coronavirus infection, and is providing the following information to address laboratory concerns.

Emergency Use Authorization and COVID-19 Tests

- On February 29, 2020, the Food and Drug Administration (FDA) issued an immediately in effect guidance with policy for diagnostic testing specific to the COVID-19 public health emergency, along with a template for Emergency Use Authorization (EUA) submissions, and followed it with a new guidance on March 16, 2020. The guidelines and template are available on the FDA website:
 - Guidance for obtaining approval: <https://www.fda.gov/media/135659/download>.
 - Template for EUA submissions: <https://www.fda.gov/media/135658/download>.
- Please note: The State of California is not authorizing California laboratories to develop and perform tests for COVID-19 at this time and currently has not established a process for authorizing such tests. Laboratories seeking authorization for their own tests for COVID-19 should refer to the FDA Guidance linked above and submit an EUA submission to the FDA as directed in that guidance.
- CDPH requests that any laboratory applying for an EUA please copy Laboratory Field Services (LFSCOVID@cdph.ca.gov) on the email submitting the completed EUA request to the FDA.
- On May 4, 2020, the FDA revised its policy on serological/antibody tests to require commercial manufacturers of serological tests to submit EUA requests, with their validation data, within 10 business days from the date they notified the FDA of their validation testing OR from the date of the revised policy, whichever is later. The FDA also provided specific performance threshold recommendations for specificity and sensitivity for all serology test developers.
 - Information about revised policy for serological tests: <https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy>

Disease Reporting

- On March 9, 2020, the list of reportable diseases in [Title 17, California Code of Regulations \(17 CCR\) section 2500](#) was amended to include COVID-19 and Novel coronavirus infections, and [17 CCR section 2505](#) was amended to include SARS-CoV-2 and Coronavirus, novel strains, effective immediately.
 - Any laboratories approved to test for SARS-CoV-2 must report **all positive and non-positive (negative, indeterminate, and specimen unsatisfactory) test results** from both antigen/molecular and antibody/serology tests for SARS-CoV-2 **at least daily** through the CalREDIE Electronic Laboratory Reporting system (ELR).
 - For more information about the ELR, please visit the CDPH website at <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-ELR.aspx>.

- Please use the encoding guidelines for ELR messages for SARS-CoV-2. The LOINC codes are pre-release codes, developed for special use. You can find them, and check for future updates, at <https://loinc.org/prerelease/>.
- In addition, please use the following SNOMED codes:

• 260373001	Detected		• 260415000	Not detected
• 419984006	Inconclusive		• 125154007	Specimen unsatisfactory

Laboratory and Personnel Requirements

- Please note that any California laboratory performing testing under the provisions of the EUA must hold a valid California clinical laboratory license pursuant to [Business and Professions Code \(BPC\) section 1265](#).
- If a California laboratory sends biological specimens originating in California for SARS-CoV-2 testing to a laboratory outside the state that does not hold California licensure, the California laboratory can apply for approval to add the out-of-state laboratory as a temporary testing site to test for SARS-CoV-2 for the duration of the emergency.
 - For more information on this process or to request an application, please contact LFS at LFSCOVID@cdph.ca.gov. LFS will process the application within 10 days of receipt of a complete application, which should be sent to the same email address.
 - Both the California and the out-of-state laboratory must have a CLIA certificate of compliance.
- On March 12, 2020, Governor Newsom issued Executive Order N-25-20, which suspends the certification and licensure requirements of California Code of Regulations, Title 17, section 1079 and Business and Professions Code section 1206.5 for the duration of the COVID-19 emergency. This order allows all persons who meet the requirements for personnel performing high-complexity testing specified in [Title 42, Code of Federal Regulations, Section 493.1489](#) to test for SARS-CoV-2, the virus that causes COVID-19, in any certified public health laboratory or licensed clinical laboratory for the duration of the emergency.
 - The laboratory director is responsible for the competency assessment and documentation of all personnel testing for SARS-CoV-2.
 - This order applies to high-complexity testing personnel. It does not alter the qualifications required of a laboratory director, clinical consultant, technical consultant, technical supervisor, and general supervisor or the supervision requirements in current California law.
 - The laboratory director must provide the list of testing personnel along with documentation of competency upon request by LFS.

Please contact Laboratory Field Services at LFSCOVID@cdph.ca.gov if you have questions.



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