

Updated March 24, 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.

### 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 any positive test results for SARS-CoV-2 **within one hour** to the local health officer for the jurisdiction where the patient resides, by telephone and through the 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 [LFSCOVVID@cdph.ca.gov](mailto:LFSCOVVID@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 [LFSCOVVID@cdph.ca.gov](mailto:LFSCOVVID@cdph.ca.gov) if you have questions.



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