

Dear Laboratory Directors and Managers,

The California Department of Public Health (CDPH) expects that CLIA-certified laboratories qualified to perform high complexity testing will soon become eligible to test for SARS-CoV-2, the virus that causes COVID-19, or novel coronavirus infection.

- 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. 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>.
- 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 |
- 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](#), and testing personnel must be authorized to perform testing classified as high complexity under CLIA, as specified in [BPC section 1206.5 \(c\)](#).
 - If a California laboratory sends biological specimens originating in California to a laboratory outside the state for testing, [BPC section 1241](#) requires the out-of-state laboratory to hold a valid California clinical laboratory license.
- 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.

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



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