State of California—Health and Human Services Agency
California Department of Public Health

SONIA Y. ANGELL, MD, MPH
State Public Health Officer & Director

GAVIN NEWSOM
Governor

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.

Robert J. Thomas

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