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](https://www.fda.gov/media/135659/download).
  - Template for EUA submissions: [https://www.fda.gov/media/135658/download](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](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-ELR.aspx) was amended to include COVID-19 and Novel coronavirus infections, and [17 CCR section 2505](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-ELR.aspx) 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](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/](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](https://leginfo.legislature.ca.gov/faces/billText.xhtml?bill_id=2018_2019%2Fabv%2F01200%2F01265.0.html), and testing personnel must be authorized to perform testing classified as high complexity under CLIA, as specified in [BPC section 1206.5 (c)](https://leginfo.legislature.ca.gov/faces/billText.xhtml?bill_id=2018_2019%2Fabv%2F01200%2F01206.5.0.html).
  - If a California laboratory sends biological specimens originating in California to a laboratory outside the state for testing, [BPC section 1241](https://leginfo.legislature.ca.gov/faces/billText.xhtml?bill_id=2018_2019%2Fabv%2F01200%2F01241.0.html) 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, Branch Chief