Updated April 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](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).
- 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 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 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/).
  - Please use the following SNOMED codes:
    - 260373001 Detected
    - 419984006 Inconclusive
    - 260415000 Not detected
    - 125154007 Specimen unsatisfactory
  - Please ensure that OBX-8 is populated with “Abnormal” for positive results and “N” for non-positive results.
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.
  
  o 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.
  
  o 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, Title17, 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.
  
  o The laboratory director is responsible for the competency assessment and documentation of all personnel testing for SARS-CoV-2.
  
  o 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.
  
  o 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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