



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

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



GAVIN NEWSOM
Governor

March 26, 2020

Dear Laboratory Directors and Managers,

On February 29, 2020, the Food and Drug Administration (FDA) issued guidance authorizing diagnostic testing for SARS-CoV-2, the virus that causes COVID-19, pursuant to the Emergency Use Authorization (EUA) process. On March 16, 2020, the FDA provided updated guidance that presented a policy granting states flexibility in authorizing laboratories with the state to develop and perform tests used to test for COVID-19. The FDA memorandum stated that a state "choosing to authorize laboratories within that State . . . to develop and perform a test for COVID-19 would do so under the authority of its own State law"

The California Department of Public Health (CDPH) acknowledges that many CLIA-certified laboratories qualified to perform SARS-CoV-2 testing seek an alternative testing pathway in light of the short supply of specific reagents required for FDA-approved EUAs. To clarify, the State is not establishing a process to independently authorize the manufacturing, use, and distribution of COVID-19 tests. However, in recognition of the need to immediately expand testing for the SARS-CoV-2 virus and the FDA's memorandum granting states regulatory flexibility, CDPH is providing the following guidance and information specific to Laboratory Developed Tests (LDTs) for SARS-CoV-2. In this guidance letter, CDPH proposes that clinical laboratories utilize an alternative pathway that is set forth in existing law.

Under existing California law, a licensed clinical laboratory that tests for SARS CoV-2 using a test kit that is not FDA-approved through the EUA request process may do so if:

- The test is a LDT that is manufactured by and used within that laboratory.
 - For example, the LDT may consist of a test that constitutes a modified FDA-approved EUA test for SARS-CoV-2 with substantially similar performance data and specifications. This would permit clinical laboratories to use additional standard instruments and methods, including high throughput testing, that are widely used for other FDA-approved high complexity testing without applying for additional FDA authorization.
 - The LDT may also consist of an entirely new test that is developed by the laboratory in-house using its own methods and materials that may be manufactured with components not legally marketed for clinical use.



- Pursuant to Business and Professions Code (BPC) section 1220(d)(2)(B), the laboratory complies with the quality control program requirements specific to test systems that are not subject to FDA clearance or approval.
- Pursuant to BPC section 1209(d)(1), the laboratory director maintains responsibility for the selection and supervision of SARS-CoV-2 testing procedures, the competency assessment and documentation of all testing personnel, the reporting of test results, and continued compliance with the state and federal clinical laboratory laws.

CDPH requests that any clinical laboratory that develops and uses an LDT for SARS-CoV-2 independently of the FDA's EUA process notify Laboratory Field Services at LFSCovid@cdph.ca.gov.

A laboratory that has chosen to be under the oversight of a California-approved accrediting organization may have questions regarding how the LDT process applies to them. In this instance, the laboratory should contact its respective accrediting organization and copy Laboratory Field Services at LFSCovid@cdph.ca.gov.

Sincerely,

A handwritten signature in blue ink that reads "Robert J. Thomas". The signature is written in a cursive style.

Robert J. Thomas
Branch Chief

March 26, 2020