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State Public Health Officer & Director

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



GAVIN NEWSOM
Governor

April 8, 2020

Dear Laboratory Directors and Managers,

On March 12, 2020, Governor Gavin Newsom issued Executive Order N-25-20, which states, “The certification and licensure requirements of California Code of Regulations, Title 17, section 1079 and Business and Professions Code section 1206.5 are suspended as to all persons who meet the requirements under the Clinical Laboratory Improvement Amendments of section 353 of the Public Health Service Act for high complexity testing and who are performing analysis of samples to test for SARS-CoV-2, the virus that causes COVID-19, in any certified public health laboratory or licensed clinical laboratory.”

This letter provides guidelines on the qualifications of SARS-CoV-2 virus testing personnel. The emergency order is specific to requirements for testing personnel in BPC section 1206.5 and is not applicable to other personnel requirements. For the duration of the COVID-19 emergency, persons may perform testing for SARS-CoV-2, the virus that causes COVID-19 disease, without holding the California license required to perform such testing if they meet the requirements of 42 CFR section 493.1389 for high-complexity testing personnel. Those requirements are as follows:

42 CFR § 493.1489: Standard; Testing personnel qualifications.

Each individual performing high complexity testing must ...

(b) Meet one of the following requirements:

(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or—

(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—

(1) 24 semester hours of medical laboratory technology courses; or

(2) 24 semester hours of science courses that include—

(i) Six semester hours of chemistry;



- (ii) Six semester hours of biology; and*
- (iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and*

(B) Have laboratory training that includes either of the following:

- (1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)*
- (2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.*

(3) Have previously qualified or could have qualified as a technologist under §493.1491 on or before February 28, 1992;

(4) On or before April 24, 1995 be a high school graduate or equivalent and have either—

- (i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or*
- (ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).*

In addition:

- The laboratory director is responsible for the competency assessment and documentation of all personnel testing for SARS-CoV-2.
- This order is specific to testing personnel. It does not alter the qualifications of a laboratory director, clinical consultant, technical consultant, technical supervisor and general supervisor or the supervision requirements in current California law.
- The laboratory director must provide the list of testing personnel along with documentation of competency upon request by LFS.

If you have any questions about personnel or laboratory testing related to COVID-19, please contact LFS at LFSCOV1D@cdph.ca.gov.

Sincerely,

Dolapo Afolayan, MPH
Section Chief, Personnel Licensing

Cc: Robert J. Thomas, M.S., MT (ASCP), HCLD (ABB)
Branch Chief