The Commonwealth of Massachusetts
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

Tel: 617-624-6000

ORDER OF THE COMMISSIONER OF PUBLIC HEALTH REGARDING TEMPORARY LABORATORY LICENSES FOR COVID-19 TESTING

On March 10, 2020, Governor Charles D. Baker declared a State of Emergency in the Commonwealth to respond to the spread of COVID-19. The Public Health Council has approved and authorized me to take such actions, incur such liabilities, and establish such rules, requirements, and procedures which are necessary to prepare for, respond to, and mitigate the spread of COVID-19 in order to protect the health and welfare of the people of the Commonwealth, consistent with the Governor's declaration.

As of January 11, 2021, the Department reported 417,568 confirmed cases of COVID-19 and 12,929 deaths among confirmed cases in the Commonwealth.

Sufficient access to COVID-19 testing for all Massachusetts residents is a necessary component of the Commonwealth's comprehensive strategy to mitigate and slow the spread of COVID-19. Swift intervention is needed to expedite the process for applying for and being approved for a state clinical laboratory license, which entities must often receive before conductingCOVID-19 testing. Expediting the process for applying for and approval of a state clinical laboratory license for the limited purpose of conducting COVID-19 testing will increase critical access to COVID-19 testing for all Massachusetts residents.

Accordingly, pursuant to the authority granted by G.L. c. 17, § 2A and with the approval of the Governor and the Public Health Council, and in order to assure the maintenance of the public health during the continuing public health emergency, I issue the following Order:

To increase access to COVID-19 testing, notwithstanding G.L. c. 111D, §§ 4 and 5, facilities may apply for a temporary COVID-19 laboratory license, for purposes of conducting CLIA-waived COVID-19 tests.

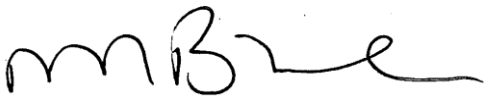
Notwithstanding G.L. c. 111D, § 7, the clinical laboratory director for such temporary COVID-19 laboratory license may be a physician, nurse practitioner, or physician assistant, or an individual who otherwise qualifies under M.G.L. c. 111D, Section 7.

Such temporary COVID-19 laboratory shall comply with guidance issued by the Department pursuant to the Order, and all other applicable statutes, regulations and guidance not inconsistent with this Order remain in effect.

A temporary COVID-19 laboratory license shall remain in effect for the duration of the declared state of emergency. At the end of the state of emergency, facilities granted a temporary COVID-19 laboratory license shall apply within 60 days after state of emergency for a clinical laboratory license or must cease operations.

This Order shall remain in effect from January 12, 2021, until the State of Emergency is terminated by the Governor, or until rescinded by me, whichever shall happen first.

IT IS SO ORDERED.



Monica Bharel, MD, MPH
Commissioner, Massachusetts Department of Public Health

January 12, 2021