

The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
67 Forest Street, Marlborough, MA 01752

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TO: Clinical Laboratories

FROM: Elizabeth Kelley, MBA MPH
Bureau Director, Bureau of Health Care Safety and Quality

DATE: October 24, 2022

RE: Notice of Changes for Clinical Laboratory Licensure

The purpose of this memorandum is to provide clinical laboratories with information and implementation guidance on recent statutory changes made to Massachusetts General Law (MGL) chapter 111D, which governs clinical laboratories in Massachusetts.

Effective immediately, clinical laboratories performing only Clinical Laboratory Improvement Amendments (CLIA) waived tests no longer require state clinical laboratory licensure. A CLIA-waived test is defined by statute as “a test that the federal Centers for Medicare and Medicaid Services has determined qualifies for a Certificate of Waiver under the federal Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a”. The current list of CLIA-waived tests can be found [here](#).

Clinical laboratories seeking to perform only CLIA-waived tests must apply for and receive a CLIA Certificate of Waiver prior to conducting CLIA-waived testing. Information on how to apply for a CLIA Certificate of Waiver can be found [here](#).

Clinical laboratories performing only CLIA-waived tests must:

- Comply with all applicable CLIA regulations.
- Report to the Department of Public Health any specimen results that yields evidence significant from a public health standpoint of the presence or for the prevention, diagnosis or control of infectious diseases. Information on reporting infectious diseases can be found [here](#).
- Adhere to all requirements set forth in MGL chapter 111D, section 8.

Unless otherwise exempt¹, a clinical laboratory performing non-CLIA waived tests in addition to CLIA-waived tests is still required to obtain state clinical laboratory licensure and follow all

¹ In addition to clinical laboratories performing only CLIA-waived tests, other laboratories exempt from state licensure include: 1) clinical laboratories maintained by not more than two licensed physicians exclusively in

statutory and regulatory requirements set forth in MGL chapter 111D and 105 CMR 180.000, *The Operation, Approval and Licensing of Clinical Laboratories*.

If you have any questions about the information in this notification, please contact the Clinical Laboratory Program at CLIALab@mass.gov.

connection with the diagnosis and treatment of his own patients, 2) clinical laboratories maintained by three or more licensed physicians exclusively in connection with the diagnosis and treatment of his own patients, provided, however, that (i) the physician or his assistant under the direct supervision of such physician performs all testing; and (ii) the clinical laboratory performs only laboratory tests which the commissioner has determined to be exempt, 3) clinical laboratories maintained exclusively for research and teaching purposes, 4) laboratories with respect to tests or procedures made by it for any person engaged in the business of insurance for the purpose of determining an insurance contract or determining eligibility, or for the examination of its employees, and 5) laboratories maintained exclusively for a health promotion screening program.