SENATE DOCKET, NO. 1332 FILED ON: 1/16/2025

SENATE . . . . . No. 1490

The Commonwealth of Massachusetts

PRESENTED BY:

Brendan P. Crighton

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to modernizing the regulation of clinical laboratories.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Brendan P. Crighton	*Third Essex*

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SENATE . . . . . No. 1490

By Mr. Crighton, a petition (accompanied by bill, Senate, No. 1490) of Brendan P. Crighton for legislation to modernize the regulation of clinical laboratories. Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. *1343* OF 2023-2024.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Fourth General Court
(2025-2026)

An Act relative to modernizing the regulation of clinical laboratories.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Section 1. Chapter 111D of the General Laws is hereby amended by striking out section 1 and inserting in place thereof the following section:-

Section 1. As used in this chapter, the following words shall, unless the context requires otherwise, have the following meaning:-

"CLIA-waived test", 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 (CLIA).

"Clinical Laboratory", a facility or place, however named, the purpose of which is to make biological, serological, chemical, immuno-hematological, cytological, pathological, or other examinations of materials derived from a human body.

"Commissioner", the commissioner of public health.

"Company", a corporation, partnership, limited liability company, limited liability partnership, an association, a trust or and organized group of persons, whether incorporated or not.

"Department", the department of public health in the executive office of human services.

"Exempt test", a test designated by the department as a simple laboratory examination or a procedure that has an insignificant risk of error, including but not limited to, CLIA-waived tests. Exempt test also may include tests designated by the department that the federal Centers for Medicare and Medicaid Services has determined qualify for a Certificate of Provider Performed Microscopy under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA).

"Ownership interest", interests including, but not limited to, any membership, proprietary interest, shares of stock in a corporation, units or other interest in a partnership, bonds, debentures, notes or other equity interest or debt instrument or co-ownership in any form.

"Person", corporations, societies, associations, partnerships, limited liability companies, limited liability partnerships, trusts, organized group of persons, whether incorporated or not, an individual or the individual's estate upon death, any other entity including, but not limited to, medical practice, medical office, clinic, counseling center, substance use disorder treatment program or sober house or a political subdivision of the commonwealth.

SECTION 2. Section 2 of said chapter 111D of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by striking out clause (9) and inserting in place thereof the following clause:-

"(9) to classify, with the advice of the advisory committee on clinical laboratories, laboratory tests as exempt for purposes of licensing physician clinical laboratories;" and

SECTION 4. Section 8 of said chapter 111D of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by striking out clause (7) and inserting in place thereof the following clause:-

"(7) examine any specimen derived from a human body except upon the written request of a licensed physician or other licensed health care practitioner authorized under chapter 112 to make such a written request or, for the sole purpose of requesting urine drug screening, department-licensed substance abuse programs, state agencies or those vendors that contract with state agencies and are designated by the contracting agency to request such screenings, or other person authorized to use the report of such examination by provision of chapter 112, unless such examination is for the sole purpose of testing the accuracy or sufficiency of the procedures or equipment of a clinical laboratory and is by instruction of the director of such laboratory, or unless such examination is for the purpose of providing a health promotion screening program and is not used for diagnosis or treatment of patients;"

SECTION 5. Said section 8 of said chapter 111D, as so appearing, is hereby further amended by striking out clause (11) and inserting in place thereof the following clause:-

"(11) employ a person as a director of a clinical laboratory, or to serve as a director of a clinical laboratory, except as authorized by department regulation, rule or order pursuant to section 2 of this chapter;"