

SENATE No. 1231

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:

Brendan P. Crighton

DISTRICT/ADDRESS:

Third Essex

SENATE No. 1231

By Mr. Crighton, a petition (accompanied by bill, Senate, No. 1231) of Brendan P. Crighton for legislation relative to modernizing the regulation of clinical laboratories. Public Health.

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-First General Court
(2019-2020)**

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:

1 SECTION 1. Section 1 of chapter 111D of the General Laws, as appearing in the 2016
2 Official Edition, is hereby amended by inserting the following definition:-

3 “CLIA-Waived Test”, a test system, assay, or examination that the federal department of
4 health and human services has determined meets the statutory criteria as specified for waiver
5 under section 353(d)(3) of the Public Health Service Act.

6 SECTION 2. Said section 1 of said chapter 111D, as so appearing, is hereby further
7 amended by striking the definitions for “Complex Laboratory Test” and “Simple Laboratory
8 Test”.

9 SECTION 3. Said section 1 of said chapter 111D, as so appearing, is hereby further
10 amended by striking the definition for “Exempt Test” and replacing it with the following
11 definition:-

12 "Exempt test", a test designated by the department as having a low risk of error,
13 including, but not limited to, CLIA-waived tests and provider-performed microscopy.

14 SECTION 4. Subsection (9) of section 2 of said chapter 111D, as so appearing, is hereby
15 amended by striking the following words:- "simple or complex,"

16 SECTION 5. Said section 2 of said chapter 111D, as so appearing, is hereby further
17 amended by inserting at the end thereof the following subsection:-

18 (10) to establish minimum qualifications of clinical laboratory directors.

19 SECTION 6. Said chapter 111D, as so appearing, is hereby further amended by striking
20 section 7 in its entirety.

21 SECTION 7. Section 8 of said Chapter 111D, as so appearing, is hereby amended by
22 striking subsections (7) and (8).

23 SECTION 8. Subsection (11) of said section 8 of said chapter 111D is hereby amended
24 by striking out the words "except as provided in section seven;" and inserting in place thereof
25 the following:- who does not meet the department's minimum qualifications for a laboratory
26 director;