

The Commonwealth of Massachusetts

Executive Office of Health and Human Services Department of Public Health Bureau of Health Care Safety and Quality

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CLINICAL LABORIATORY PROGRAM NOTIFICATION OF CHANGES

TO: Clinical Laboratories

FROM: Teryl Smith, RN, MPH, Director, Bureau of Health Care Safety and Quality

DATE: November 17, 2025

RE: Massachusetts Clinical Laboratory Program—Changes to Requirements for

Clinical Laboratory Directors

The purpose of this notice is to inform all clinical laboratories of important changes to the requirements for clinical laboratory directors under M.G.L. c. 111D, § 7.

Effective April 8, 2025, clinical laboratory directors may accept simultaneous employment at **no more than five** clinical labs. St. 2024, c. 343, § 70. Previously, clinical laboratory directors were limited to accepting simultaneous employment at no more than three clinical labs. This statutory change puts the Commonwealth of Massachusetts in line with the current Clinical Laboratory Improvement Amendments (CLIA) requirements. 42 CFR 493.1359(a) and 493.1445(d).

As a reminder, for a lab with a valid CLIA certificate of waiver, there is no limit to the number of such labs a clinical director may simultaneously be employed with. 42 CFR 493.35.

If you have any questions about this notification, please review the <u>Frequently Asked Questions About Clinical Laboratory State Licensure</u> or call the Clinical Laboratory Program at CLIALab@mass.gov.