



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Office of Emergency Medical Services
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MEMORANDUM

TO: MA Licensed Ambulance Services
FROM: Elizabeth Kelley, Bureau Director, Bureau of Health Care Safety and Quality
DATE: February 27, 2024
RE: CLIA Laboratory Testing Requirements for Ambulance Services

The Department of Public Health's (Department) Office of Emergency Services and Clinical Laboratory Program is providing information to licensed ambulance services of the federal and state requirements relative to performing laboratory testing.

The federal Clinical Laboratory Improvement Amendments (CLIA) establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results, regardless of where the test is performed, including while providing emergency medical care. The CLIA standards require certification to perform these tests.

Ambulance services that are performing only CLIA-waived tests are federally required to apply for and obtain a federal CLIA Certificate of Waiver. CLIA-waived tests are those tests that are determined by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) to be so simple that there is little risk of error. Many testing methods for glucose and cholesterol are CLIA-waived. The current list of CLIA-waived tests can be found [here](#). If an ambulance service performs any of the laboratory tests on the CLIA-waived list, it must apply for and obtain a CLIA Certificate of Waiver through the Department's Clinical Laboratory Program. Information on how to apply for and obtain a CLIA Certificate of Waiver, including the application form, can be found [here](#).

If an ambulance service performs applicable testing that does not appear on the list of CLIA-waived tests, the ambulance service is federally required to apply for and obtain a federal CLIA Certificate of Compliance or CLIA Certificate of Accreditation. Information on how to apply for and obtain a CLIA Certificate of Compliance or CLIA Certificate of Accreditation, including the application form, can be found [here](#). When an ambulance service performs more complex testing, in addition to the federal CLIA Certificate requirements, the ambulance service must obtain a clinical laboratory license from DPH. Information on how to apply for a state clinical laboratory license can be found [here](#), including all relevant application forms.

If you have any questions, please contact the OEMS Ambulance Regulation Program at OEMS.Ambulance@mass.gov.