

Requirements for Lead Testing*

Massachusetts

* This information is subject to change

Licensure

Facility must: Hold a CLIA Certificate of Waiver or higher.

1. Complete the application for a CLIA Certificate of Waiver (<http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf>)
2. Mail completed applications to:
Clinical Laboratory Program
Department of Public Health
67 Forest Street
Marlborough, MA 01752

For questions or more information, please contact the CLIA department at (617) 753-8438 or 8439.

Patient Testing

Facility must: Confirm capillary blood lead test results greater than or equal to 5 µg/dL with a venous (confirmation testing is recommended within 60 days)..

Quality Control

Facility must: Run two levels of Quality Control according to the manufacturer's instructions, which are:

1. Each new lot of test kits.
2. Each new shipment of materials even if it's the same lot previously received.
3. Each new operator (i.e. operator who has not performed the test recently).
4. Monthly, as a check on continued storage conditions.
5. When problems (storage, operator, instrument, or other) are suspected or identified.
6. If otherwise required by your laboratory's standard QC procedures.

Critically Elevated Blood Lead Levels

For poisoned results of 10 µg/dL or greater: In addition to regular electronic reporting (within 3 working days of analysis), send a separate report to Sharon Gifford at sharon.gifford@massmail.state.ma.us; (978) 851-7261 x4031.

Result Reporting

Facility must:

1. Report ALL childhood blood lead test results to the MA Department of Public Health Childhood Lead Poisoning Prevention Program (CLPPP)
 - a. All test results less than 10 µg/dL must be reported to CLPPP within ONE WEEK of analysis
 - b. All test results 10 µg/dL or greater must be reported to CLPPP within 3 working days of analysis
2. Report ALL test results electronically via the Mass Hlway Statewide Health Information Exchange
 - a. You can use the FREE LeadCare data entry software to create your data text files. Go to www.leadcare2.com/reporting to download the data entry software. For questions about software installation and use, e-mail Magellan product support at LeadCareSupport@magellandx.com or call (800) 275-0102
 - b. Your lab must submit lead data files via the MA Hlway to meet MA state reporting requirements. To register for the Hlway, or for answers to technical questions, e-mail Masshiway@state.ma.us or call (855) 624-4929

For questions regarding childhood blood lead test reporting or reporting requirements, contact the CLPPP by phone at (617) 624-5757.

Proficiency Testing

Recommended: To comply with the Massachusetts Department of Public Health standards for blood lead testing, Magellan Diagnostics recommends that all facilities performing blood lead tests on Massachusetts residents participate in an approved Proficiency Testing (PT) program to monitor the quality of your blood lead testing program.

Magellan recommends the Wisconsin State Laboratory of Hygiene (WSLH) Blood Lead Proficiency Testing program because of its large LeadCare II peer group. For more information on the program contact (800) 462-5261 or visit: <http://www.slh.wisc.edu/proficiency/>.

Magellan offers a complimentary LeadCare II Test Kit for participating in proficiency testing and reporting blood lead results properly. Contact Product Support at LeadCareSupport@magellandx.com for the required form.

Still Have Questions?

Call LeadCare Product Support at (800) 275-0102.