Physician Office Laboratory

*Requirements for Lead Testing**

Maine

** This information is subject to change*

Physician Office Laboratory (POL)

Rules associated with ***"An Act to Increase the Availability of Lead Testing for Children"*** (22 MSRA 1399-D) were adopted on October 20, 2012. Providers now have 2 options for lead testing:

1. Continue to submit blood lead samples to the State Health and Environmental Testing Laboratory
2. Perform capillary blood lead analysis using a CLIA-waived blood lead testing device such as the LeadCare II and directly report all test results to the Maine Childhood Lead Poisoning Prevention Unit (MCLPPU).

Licensure

Facility must: Hold a Federal CLIA Certificate of Waiver and be approved by MCLPPU.

Federal CLIA Certification:

1. Complete the application for a CLIA Certificate of Waiver (http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf)
2. Mail or fax completed applications to:

   CLIA PROGRAM
   Division of Licensing & Regulatory Services
   41 Anthony Avenue, Station #11
   Augusta, ME 04333-0011
   Phone: (207) 287-9339 Fax: (207) 287-9304
   Contact: Dale Payne, Dale.payne@maine.gov

Approval by MCLPPU will come in the form of a formal letter. Follow this link to apply:
http://www.maine.gov/dhhs/mecdc/environmental-health/eohp/lead/ld300/approval.shtml

1. Submit a cover letter with complete contact information along with a brief protocol for testing the blood lead samples, reporting results during the office visit to the parent, and how the provider will report all test results to MCLPPU.
2. Proof of ImmPact2 Immunization Registry use. Proof should include a copy of your ImmPact User Agreement. A brief summary of your protocol for testing the blood lead samples, reporting results during the office visit to the parent, and how the provider will report all test results to MCLPPU.
3. A copy of your CLIA Certificate of Waiver.

Patient Testing

Training Tools: www.LeadCare2.com/training

Facility must: Confirm capillary blood lead test results greater than or equal to 5 µg/dL with a venous sample sent to the State Health and Environmental Testing Laboratory.

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.

Result Reporting

Reporting Solutions by State: www.LeadCare2.com/reporting

Facility must:

1. Report results of ALL blood lead tests to the state within 48 hours of analysis.
2. An approved provider must electronically report through ImmPact.
   For further reporting instructions see:
   http://www.maine.gov/dhhs/mecdc/environmental-health/eohp/lead/ld300/datareporting.shtml#how

Proficiency Testing

Recommended: To monitor the quality of your blood lead testing program.

Contact Wisconsin State Laboratory of Hygiene (WSLH) proficiency program for more information about their program at (800) 462-5261 or go to http://www.slh.wisc.edu/proficiency/.

Still Have Questions?

- Call LeadCare Product Support at (800) 275-0102
- Please refer to: http://www.maine.gov/dhhs/mecdc/environmental-health/eohp/lead/ld300/in-office-testing.shtml and *http://www.maine.gov/dhhs/mecdc/environmental-health/eohp/lead/providers.shtml*

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