

\* This information is subject to change

## Licensure

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

1. The form can be downloaded at: <http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf>
2. Complete the application and mail to:  
MONTANA CLIA PROGRAM  
Division of Quality Assurance  
Department of Public Health & Human Services  
2401 Colonial Drive, 2nd Floor  
PO Box 202953  
Helena, MT 59620-2953  
Fax: (406) 444-3456

For questions, please contact Joyce Shepard at (406) 444-2099 or email to [mtssad@mt.gov](mailto:mtssad@mt.gov), or visit <http://dphhs.mt.gov/qad/Certification/CLIA>

## Patient Testing

**Training Tools:** [www.LeadCare2.com/training](http://www.LeadCare2.com/training)

*Facility must:* Confirm capillary blood lead test results greater than or equal to 5 µg/dL with a venous sample by a reference lab.  
(Per Rule 37.114.546)

For more information, refer to: <http://www.mtrules.org/gateway/ruleno.asp?RN=37.114.546> or contact the Department of Public Health and Human Services at (406) 444-5954.

## Quality Control

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*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:** [www.LeadCare2.com/reporting](http://www.LeadCare2.com/reporting)

*Facility must:* A laboratory that performs a blood lead analysis must submit to the department, by the 15th day following the month in which the test was performed, a copy of all blood lead analyses performed that month, including analyses in which lead was undetectable.

For more information, refer to: <http://www.mtrules.org/gateway/ruleno.asp?RN=37.114.204>

## Proficiency Testing

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*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?

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- Contact the LeadCare Product Support Team at (800) 275-0102
- Contact Connie Garrett, Epidemiologist, Office of Epidemiology and Scientific Support at (406) 444-5954.