

* 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 or fax completed applications to:
INDIANA STATE DEPARTMENT OF HEALTH
Attn: CLIA Program
2 North Meridian Street, Room 4A
Indianapolis, IN 46204
Fax: (317) 233-7157

For more information, please contact Lorraine Switzer at (317) 233-7502 E-mail: lswitzer@isdh.in.gov or visit: <http://www.in.gov/isdh/25360.htm>

Patient Testing

Training Tools: www.LeadCare2.com/training

Facility must:

- Confirm capillary blood lead test results greater than or equal to 10 µg/dL with a second capillary or venous sample by a reference lab.
- Confirm capillary blood lead results of greater than or equal to 70 µg/dL with a venous sample.

For additional information on the latest guidelines for blood lead levels, visit <http://www.in.gov/isdh/26552.htm> or download: http://www.in.gov/isdh/files/Case_Management_Chart_Rev_H_-_2013.pdf

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

- 45-59.9 µg/dL - Confirm results within 48hrs (venous or capillary)
- 60-69.9 µg/dL - Confirm results within 24hrs (venous or capillary)
- 70 µg/dL or higher - Confirm results immediately (venous only)

For more information, consult the ISDH Lead Screening Requirements and Medical Management Recommendations for children ages 6 to 84 months (PDF) at: <https://www.in.gov/isdh/files/Medical%20Manage%20Physician%20Chart%20Feb72018.pdf>

Result Reporting

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

Facility must:

1. Report ALL blood lead results electronically within 7 days of analysis to the Lead and Healthy Homes Program (ILHHP)
 - a. Contact the department's IT Specialist to establish electronic reporting capability at (317) 233-9809
2. Reporting Form is available for download at <https://www.in.gov/isdh/files/Private%20Lab%20Reporting%20Form%20-%202005-2018.pdf>
 - b. Submit this report form by fax, e-mail or mail to:
Fax: 317-233-1630 ~ Email: khorsley@isdh.in.gov
ATTN: ILHHP Manager, 100 N Senate Ave, N855, Indianapolis, Indiana 46204

NOTE: Indiana code (410 IAC 29-3-1) requires a person that examines the blood of an individual for the presence of lead must report to the department the results of the examination not later than one (1) week after completing the examination. If a person required to report has submitted more than fifty (50) results in the previous calendar year, the person must submit subsequent reports in an electronic format determined by the department. For most laboratories reporting in HL7 format is required. For portable analyzers (e.g., LeadCare II) a website is available for online reporting.

Please contact the ISDH/ ILHPP for additional information on electronic reporting requirements
http://www.in.gov/isdh/files/410_

For additional information on reporting, visit <http://iga.in.gov/legislative/laws/2014/ic/titles/016/articles/041/chapters/39.4/>

** This information is subject to change*

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
- Contact the ISDH Lead and Healthy Homes Program at (317) 233-1250