

\* This information is subject to change

## Licensure

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

1. Complete the application for a CLIA Certificate of Waiver: ([www.cms.hhs.gov/cmsforms/downloads/cms116.pdf](http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf))
2. Completed applications can be scanned and e-mailed, faxed or mailed to:  
INDIANA DEPARTMENT OF HEALTH  
Attn: CLIA Program  
2 North Meridian Street, 4A  
Indianapolis, IN 46204  
Fax: (317) 233-7157  
E-mail: [lswitzer@isdh.in.gov](mailto:lswitzer@isdh.in.gov) or [klara@isdh.in.gov](mailto:klara@isdh.in.gov)

For more information, please contact Lorraine Switzer at (317) 233-7502 or by e-mail at: [lswitzer@isdh.in.gov](mailto:lswitzer@isdh.in.gov). For Frequently Asked Questions click: <http://www.in.gov/isdh/25360.htm>.

## 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 3.5 µg/dL with a second capillary test or with a single venous blood test.

For more information about Indiana lead testing requirements and medical management guidelines click here: [https://www.in.gov/health/lead-and-healthy-homes-division/files/Childhood-Blood-Lead-Med-Mgmt-Guidelines-for-Providers-in-IN\\_Final\\_July-2022\\_SH.pdf](https://www.in.gov/health/lead-and-healthy-homes-division/files/Childhood-Blood-Lead-Med-Mgmt-Guidelines-for-Providers-in-IN_Final_July-2022_SH.pdf)

## 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.

## Critically Elevated Blood Lead Levels

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

For more information about confirmatory testing and case management requirements, consult Indiana statute (410 IAC 29-1-6).

## Result Reporting

**Reporting Solutions by State:** [www.LeadCare2.com/reporting](http://www.LeadCare2.com/reporting)

*Facility must:*

1. Report ALL blood lead results within 7 days of analysis to the Indiana Department of Health (IDOH) Lead and Healthy Homes Division
  - a. Submit results via: HL7 messaging, direct entry into the Lead Data Flow (LDF) database, or direct entry into Indiana's Children and Hoosier Immunization Registry Program (CHIRP).
  - b. For questions about blood lead level reporting or signing up for electronic reporting, please contact at Hazarath Thanneeru at: [hthanneeru@isdh.in.gov](mailto:hthanneeru@isdh.in.gov).
2. Use the Laboratory Reporting Form for individual, single use reporting of blood lead test results. Download the form at: [https://www.in.gov/health/lead-and-healthy-homes-division/files/Private-Lab-Reporting-Form-05-2018\\_01-2022.pdf](https://www.in.gov/health/lead-and-healthy-homes-division/files/Private-Lab-Reporting-Form-05-2018_01-2022.pdf)
  - a. Submit this report by secure fax, secure e-mail or mail to:  
Lead and Healthy Homes Division, ATTN: LHHD Coordinator, 2 North Meridian Street, Indianapolis, Indiana, 46204  
Fax: 317-233-1630 ~ E-mail: [khorsley@isdh.in.gov](mailto:khorsley@isdh.in.gov)

NOTE: Indiana statute (410 IAC 29-3-1) requires the entity examining the specimen (i.e., laboratory, clinic, physician, etc.) to report the blood lead test result to IDOH not later than one (1) week after completing the test. Any provider or lab submitting more than 50 results per year is required to report electronically.

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## 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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- Call LeadCare Product Support at (800) 275-0102.
- Contact the Indiana Department of Health, Lead and Healthy Homes Program at (317) 233-1296, or go to: <https://www.in.gov/health/lead-and-healthy-homes-division/>