

* 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:
Illinois Department of Public Health
Division of Health Care Facilities & Programs
525 W. Jefferson Street Fourth Floor
Springfield, IL 62761
Fax: (217) 782-0382

For questions or more information, please contact Jena Baumann at (217) 782-6747 or jena.baumann@illinois.gov (email preferred) or visit <http://www.dph.illinois.gov/topics-services/health-care-regulation/clia/faq>.

Patient Testing

Training Tools: www.LeadCare2.com/training

Facility must: Confirm capillary blood lead test results ≥ 5 $\mu\text{g}/\text{dL}$ with a with a venous sample by a reference lab.

- All capillary blood lead level (BLLs) results 5-9 $\mu\text{g}/\text{dL}$ must be performed within 1 month;
- Capillary BLLs from 10-24 $\mu\text{g}/\text{dL}$ must be confirmed between 1 week to 1 month;
- Capillary BLLs from 24-45 $\mu\text{g}/\text{dL}$ must be confirmed within 2 days;
- Capillary BLLs ≥ 45 $\mu\text{g}/\text{dL}$ or with symptoms of lead poisoning should have an immediate (within 24 hr) confirmatory test; and
- Response actions should be initiated only after elevated blood lead levels are confirmed.

For additional information on lead testing, please contact the Illinois Lead Program at (217) 782-3517 or visit Lead Screening and Case Follow-up Guidelines for Local Health Departments:

<http://dph.illinois.gov/sites/default/files/publications/lead-testing-and-case-followup-guidelinesfor-local-health-departments-042116.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.

Result Reporting

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

Facility must: Report **ALL** blood lead analyses to the Illinois Department of Public Health (IDPH) in format approved by the department. <http://www.lead-safe-illinois.org/uploads/documents/benchbook-3-illinois-laws-with-summary.pdf>

1. Report blood lead results < 5 $\mu\text{g}/\text{dL}$ within 30 days from the end of the month in which the sample was taken.
2. Report blood lead results 5-35 $\mu\text{g}/\text{dL}$ within 48 hours.
3. Report blood lead results > 35 $\mu\text{g}/\text{dL}$ within 24 hours.
4. For electronic reporting:
 - a. Contact the State of Illinois for the Move It software, provided at no cost to all LeadCare II users. Once connection is established, your site will be notified of where to send reports.
 - b. Go to www.leadcare2.com/reporting to download a FREE copy of the LeadCare[®] Report Software.

For additional information on reporting, please contact the Illinois Lead Program at (217) 782-3517 or visit www.dph.illinois.gov

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.