* This information is subject to change

Laboratory

Defined as: Any facility that has been approved by the Department of Health to perform blood lead testing.

Licensure

Facility must: Hold a CLIA Certificate of Waiver or higher

- 1. Complete the application for a CLIA Certificate of Waiver (https://www.cms.gov/cmsforms/downloads/cms116.pdf)
- Mail or fax completed applications to: lowa CLIA Laboratory Program State Hygienic Laboratory University of Iowa Research Park 2490 Crosspark Road Coralville, IA 52241 Phone (319) 335-4500 or (800) 421-IOWA Fax (319) 335-4174

For additional information, contact Kristine Rotzoll, BS, MT(ASCP), CLIA Compliance manager at (319) 335-4500 or by email at kristine-rotzoll@uiowa.edu or visit: <u>http://www.shl.uiowa.edu/labcert/clia/index.xml</u>

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 venous sample by a reference lab within three months.

For more information refer to: https://idph.iowa.gov/Portals/1/userfiles/106/PROTOCOL2015protected.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

- Blood lead results greater than or equal to 20 μg/dL in a child under the age of 6 years or a pregnant woman, must be reported daily by phone in addition to be being reported electronically.
 - Report to the Bureau of Lead Posioning Prevention at (800) 972-2026.

Result Reporting

Reporting Solutions by State: <u>www.LeadCare2.com/reporting</u>

Facility must:

1. Report <u>ALL</u> blood lead results electronically weekly to the Bureau of Lead Poisoning Prevention at the Iowa Department of Public Health.

2. Go to http://www.leadcare2.com/reporting/ to download a FREE copy of LeadCare® Report Software.

For additional information on reporting, visit http://idph.iowa.gov/Environmental-Health-Services/Reportable-Conditions

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 <u>http://www.slh.wisc.edu/proficiency/</u>

Still Have Questions?

- Call LeadCare Product Support at (800) 275-0102
 - Contact the Iowa Department of Public Health at (866) 227-9878 or the Iowa Bureau of Lead Poisoning Prevention at (800) 972-2026 and <u>http://idph.iowa.gov/Environmental-Health-Services/Childhood-Lead-Poisoning-Prevention</u>