

Requirements for Lead Testing*

Delaware

* 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:
Delaware State Public Health Laboratory
Timothy Smith
30 Sunnyside Rd.
Smyrna, DE 19977
(302) 223-1392 Fax: (302) 653-2877
Email: Timothy.Smith@state.de.us

Patient Testing

Training Tools: 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.

Below is the recommendation for venous confirmatory testing from the Advisory Committee. (Reference value is 5)

Blood Lead Result µg/dL	Time frame to confirm
Great than or equal to reference value (5) - 9	1 – 3 months
10 - 44	1 week – 1 month
45 – 59	48 hours
60 – 69	24 hours
Greater than or equal to 70	Urgently, as an emergency test

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.

Elevated Blood Lead Levels

Facility must: Elevated results (>10 µg/dL) must be reported within 24 hours.

Result Reporting

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

Facility must: Report all results within 1 week via fax or encrypted email.

Reporting Contact: Bill Leitzinger, Fax: (302) 739-3839; william.leitzinger@state.de.us

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?

- Contact the LeadCare Product Support Team at (800) 275-0102
- Contact DE Program Director: William Leitzinger at (302) 744-4546 or by email at William.Leitzinger@state.de.us