

Requirements for Lead Testing*

Pennsylvania

* This information is subject to change

Licensure

Facility must: Hold a Federal 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. Apply for PA clinical laboratory license with the Bureau of Laboratories (if not already licensed)
 - a. Complete Permit Application from Pennsylvania Department of Health.
<http://www.portal.state.pa.us/portal/server.pt?open=514&objID=556786&mode=2>
 - b. Application requires a letter of attestation, Laboratory Personnel Qualification Appraisal forms for personnel engaged in BL analysis, and a copy of the BL protocol.
 - c. Initial application fee is \$100. The annual licensure fees vary on the testing performed.

Patient Testing

Training Tools: www.LeadCare2.com/training

Facility must: Test all specimens within 5 days of collection.

Capillary blood lead test results ≥ 5 $\mu\text{g}/\text{dL}$ should be confirmed with a venous sample tested by a reference lab.

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 results the PA Department of Public Health per PA code Chapter 27 section 27.34, within one (1) day of analysis.

1. Contact PA Department of Health, Bureau of Information Technology
2. ≥ 100 BL tests/month mandates electronic reporting via PA-NEDSS - Call Vivian Books, PA Dept. of Health, Bureau of Information Technology (BIT) Ph: (717) 783-9171. Please ask for the PA-NEDSS help desk.
3. < 100 BL tests/month can utilize the hard copy reporting form and manual entry into PA-NEDSS. Reports may also be faxed. Before faxing the form, or for any questions, please contact the PA Department of Health, Childhood Lead Surveillance at (717) 772-2762

Proficiency Testing

Required: To maintain:

1. Enroll in Bureau of Laboratories, PA Blood Lead Proficiency Testing Program. (\$350/yr)
2. Maintain an average score of at least 80% on proficiency testing for the last two consecutive regulatory events

Note: Head Start programs are exempt from PT

Contact Pam Groff at (484) 870-6425 to enroll, or with proficiency testing questions.

Still Have Questions?

- Call LeadCare Product Support at (800) 275-0102
- See the Pennsylvania Department of Health's [Lead Poisoning FAQs](http://goo.gl/5mP4QR): <http://goo.gl/5mP4QR>