

# Requirements for Lead Testing\*

\* This information is subject to change

## Clinical Lead Laboratories

---

**Defined as:** Facilities that test or intend to test the blood of Ohio children who are under the age of sixteen by using technology contained in the CLIA Certificate of Waiver category must be approved as a Clinical Lead Laboratory in Ohio.

For additional information on the Clinical Lead Laboratory Approval Requirements, visit:  
<http://www.odh.ohio.gov/odhprograms/dspc/labcert/labcert1.aspx>

## Licensure

---

**Facility must:** Be approved as a Clinical Lead Laboratory prior to performing blood lead analysis.

1. Complete the application for Clinical Lead Laboratory Approval at [www.odh.ohio.gov/pdf/forms/hea5808.pdf](http://www.odh.ohio.gov/pdf/forms/hea5808.pdf)
2. Application, including check shall be typed and sent to:  
Ohio Department of Health  
Attn: Revenue Processing Unit  
P.O. Box 15278  
Columbus, OH 43215
3. Make sure you have completed all sections of the form and have included payment. Applications that are incomplete or contain errors will result in delay in the processing of your application and issuance of your laboratory approval.
4. All information requested on this form is mandatory for the administration and processing of your application pursuant to rule 3701-82-02 of the Ohio Administrative Code.

For more information, contact Christopher Mizek at (614) 728-6844.

## 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 5 (five) µg/dL using a venous sample as soon as possible but no later than ninety days from the previous capillary test.

For more information, refer to OH Administrative Code, 3701-30-03 at: <http://codes.ohio.gov/oac/3701-30>

## Quality Control

---

**Facility must:** Perform two levels of Quality Control as specified by the manufacturer. Manufacturer's quality control instructions 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](http://www.LeadCare2.com/reporting)

**Facility must:**

1. Report all blood lead results electronically to the Ohio Department of Health within seven (7) calendar days from the date of analysis.
2. Establish electronic reporting prior to testing.
  - Submit a document requesting access to SFTP server.
  - Install reporting software.
  - Submit at least one test file.
3. Report using an electronic format approved by the DOH
  - Go to [www.leadcare2.com/reporting/](http://www.leadcare2.com/reporting/) to download a FREE copy of our LeadCare® Report Software.
  - To establish electronic reporting capabilities for the transfer of blood lead results, contact Chris Alexander, OH Surveillance Coordinator at [Chris.Alexander@odh.ohio.gov](mailto:Chris.Alexander@odh.ohio.gov) or (614) 728-6816.

For additional information on reporting, refer to: <http://www.odh.ohio.gov/healthstats/elr/elr1.aspx>

# Requirements for Lead Testing\*

\* This information is subject to change

## Proficiency Testing

---

**Required:** To maintain approval status, a laboratory using a CLIA waived procedure for blood lead analysis MUST:

1. Perform blood lead proficiency testing at least twice annually through enrollment with the Wisconsin State Laboratory of Hygiene (WSLH) proficiency program at (800) 462-5261 or visit <http://www.slh.wisc.edu/proficiency/>
2. Submit a copy of the results to the OH DOH, CLPPP within 5 days of receiving proficiency scores for the current event.
3. Maintain an average score of at least 75% on proficiency testing for either the last two or last four testing rounds.

**Please Note:** To renew annual approval as an OH Clinical Lead Laboratory, facilities MUST submit all copies of proficiency testing scores for the previous approval year.

For more information on Proficiency Testing, please refer to pages 30-31 at:  
<https://www.odh.ohio.gov/~media/ODH/ASSETS/Files/eh/lead%20poisoning%20prevention/faq.pdf>

## Still Have Questions?

---

- Call LeadCare Product Support at (800) 275-0102
- Contact the Ohio Healthy Homes and Lead Poisoning Prevention Program (OHHLPPP) at (877) 532-3723