

# Requirements for Lead Testing\*

# North Carolina

\* This information is subject to change

## Licensure

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*Facility must:* Hold a CLIA Certificate of Waiver or higher.

1. Complete the application for a CLIA Certificate of Waiver (<http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>)
2. Mail or fax completed applications to:  
North Carolina Department of Health and Human Services  
Division of Health Service Regulation/CLIA Certification  
2713 Mail Service Center  
Raleigh, NC 27699  
Fax: (919) 733-0176

Additionally, POC lead analyzer laboratories must:

- Maintain documentation of instrument calibration and quality control testing;
- Record date that blood lead test result files are submitted to the state;
- Record name of reference laboratory used for confirmatory testing.

For questions or more information, please call the North Carolina CLIA Program at (919) 855-4620.

## Patient Testing

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*Facility must:* Confirm capillary blood lead test results greater than or equal to 4.5 µg/dL with a venous sample sent to an outside reference laboratory. Anything greater than 65 µg/dL should be followed up immediately as an emergency laboratory test.

Note: Follow-up is based on the rounded test result. For example, a result of 4.5 µg/dL should be rounded up to 5.

For additional information on childhood lead testing and follow-up, refer to:  
<http://ehs.ncpublichealth.com/hhccehb/cehu/lead/docs/2012-11-LeadClinicalManual.pdf>

## Quality Control

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*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

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*Facility must:*

1. Report results of ALL blood lead tests for children less than six years of age and for individuals whose age is unknown at the time of testing to the NC Childhood Lead Poisoning Prevention Program within five (5) working days after test completion.
2. Report using an electronic format approved by the Department.
  - a. Go to [www.leadcare2.com/reporting/](http://www.leadcare2.com/reporting/) to download a FREE copy of LeadCare® Report Software.

To arrange for reporting of your blood lead test results, please contact the NC Children's Environmental Health Unit.

Primary Contact: Kim Gaetz at (919) 707-5953 or [kim.gaetz@dhhs.nc.gov](mailto:kim.gaetz@dhhs.nc.gov)

Secondary Contact: Tena Hand at (919) 707-5933 or [tena.hand@dhhs.nc.gov](mailto:tena.hand@dhhs.nc.gov)

## Proficiency Testing

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*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?

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- Call LeadCare Product Support at (800) 275-0102