Requirements for Lead Testing*

North Dakota

* 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
 - (https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf)
- For Laboratory Certification, mail completed applications to: North Dakota Department of Health Division of Health Facilities 600 E Boulevard Avenue Dept. 301 Bismarck, ND 58505-0200 Fax: (701) 328-1890 <u>http://www.ndhealth.gov/hf/ndclia.htm</u>

For questions or more information, please contact Bridget Weidner at (701) 328-2352 or email bweidner@nd.gov

 For Personnel Licensure: Mail completed applications to: North Dakota Board of Clinical Laboratory Practice P.O. Box 1403 Bismarck, ND 58502-4103

For questions or more information, please visit: http://www.ndclinlab.com/ or contact the Administrative Office at: (701) 530-0199

4. Per 43-48-02: No person may practice as a clinical laboratory scientist or a clinical laboratory technician unless the person is the holder of a current license issued by the board or is exempt from licensure.

For the list of exemptions, please visit: http://www.legis.nd.gov/cencode/T43C48.pdf

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.

For more information, refer to http://www.nd.gov/dhs/info/mmis/docs/health-tracks.pdf

Quality Control

Facility must: Perform QC as specified by the manufacturer. Run two levels of QC:

- 1. Each new lot of test kits.
- 2. Each new shipment of materials.
- 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.
- (* ND would prefer that the LeadCare® II owner run QC once per week.)

Result Reporting

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

Facility must: Report ALL blood lead results to the NDDH (Division of Air Quality) within seven (7) calendar days from the date of analysis.

- Report blood lead levels of 10 μg/dL or greater to the NDDH immediately by telephone, electronically or through other means designated by the state department of health.
 - a. Report immediately via telephone at (701) 328-5188 or fax at (701) 328-5185

For additional information on reporting, please visit: <u>http://www.ndhealth.gov/disease/disease%20reporting/report.htm</u> or email: <u>swashek@nd.gov</u>

Proficiency Testing

Recommended: To monitor the quality of your blood lead testing program, refer to: <u>http://www.ndhealth.gov/hf/ndclia.htm</u> for a list of approved proficiency testing providers.

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/

Requirements for Lead Testing*

North Dakota

Still Have Questions?

* This information is subject to change

- Contact the LeadCare Product Support Team at (800) 275-0102
 Contact: Sandi Washek, North Dakota Department of Health, <u>swashek@nd.gov</u>, (701) 328-5188 or visit <u>https://deq.nd.gov/aq/lead/</u>