

* 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:
Acute Care Division - CLIA
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Henrico, VA 23233
Fax: (804) 527-4504

For more information contact the Virginia Department of Health, Office of Licensure at (804) 367-2107.

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 qualified lab.

For more information, visit http://www.vdh.virginia.gov/content/uploads/sites/20/2016/08/Lead_Levels_in_Children_Fact_Sheet-1.pdf

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

CLIA Certified Laboratories

Facility must: Report **ALL** detectable lead levels within 3 days.

1. Reportable lead levels are:
 - a. Any detectable blood lead level in children ages 0-15 years
 - b. Levels greater than or equal to 5 µg/dL in persons older than 15 years of age.
2. Report using an electronic format approved by the Department.
 - a. Go to www.leadcare2.com/reporting/ to download a FREE copy of LeadCare® Report Software.

For more information on reporting, visit:

https://content.govdelivery.com/attachments/VAVDHORCE/2016/10/20/file_attachments/642990/Conditions%2BReportable%2Bby%2BDirectors%2Bof%2BLaboratories%2BOctober%2B2016.pdf

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?

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