* 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)
- Mail or fax completed applications to: Oregon State Public Health Division Laboratory Compliance Section 3150 NW 229th Avenue, Suite 100 Hillsboro, OR 97124-6536 (P) (503) 693-4125 (F) (503) 693-5602

For questions or more information, please email <u>LC.info@state.or.us</u> or visit <u>http://public.health.oregon.gov/LaboratoryServices/ClinicalLaboratoryRegulation/Pages/waived.aspx</u>

Patient Testing

Training Tools: www.LeadCare2.com/training

Facility must: Confirm capillary blood lead test results greater than or equal to 5 µg/dL for patients under 18 years old at time of test with a venous sample by a reference lab.

For more information, see the Oregon Administrative Rules OAR 333-018-000 Reportable diseases and conditions at http://arcweb.sos.state.or.us/pages/rules/oars_300/oar_333/333_018.html

Quality Control

Facility must: Perform QC 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: <u>www.LeadCare2.com/reporting</u>

Facility Must:

- 1. Report <u>all</u> blood lead results to the OR Department of Health within seven (7) calendar days from the date of analysis.
- 2. Report using an electronic format approved by the local DOH, consistent with the need for timely reporting as provided in OAR (333) 018-0015. Note: A licensed lab that sends > 30 records/month must report electronically per Administrative Rules.

For additional information on reporting, please contact OHA at (971) 673-0440 or visit <u>http://public.health.oregon.gov/HealthyEnvironments/HealthyNeighborhoods/LeadPoisoning/CountyHealthDepartments/Documents/Diseasegu</u> <u>idelines.pdf</u>

Elevated Blood Lead Levels

Facility Must:

- Report blood lead levels of greater than or equal to 5 µg/dL for all patients less than 18 years old within one (1) calendar day of analysis by telephone, fax or other rapid communication.
- Report blood lead levels of greater than or equal to 10 µg/dL for all patients greater than 17 years old within one (1) calendar day of analysis by telephone, fax or other rapid communication.

For more information, see the Oregon Administrative Rules OAR 333-018-000 Reportable diseases and conditions at http://arcweb.sos.state.or.us/pages/rules/oars_300/oar_333/333_018.html

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?

- Contact the LeadCare Product Support Team at (800) 275-0102
- Contact the Oregon Lead Poisoning Prevention Program at lead.program@state.or.us or (971) 673-0440