

\* This information is subject to change

---

## Physician Office Lab & Clinical Laboratory

---

*Defined as:* Any facility that conducts on site blood lead analysis in the State of Florida or on Florida residents.

---

## 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:  
State of Florida  
Agency for Health Care Administration  
Laboratory Licensing Unit  
2727 Mahan Drive, Mail Stop 32  
Tallahassee, FL 32308  
Fax: (850) 410-1511

For questions or more information call 850-412-4375 contact Laura Marker at [Laura.Marker@ahca.myflorida.com](mailto:Laura.Marker@ahca.myflorida.com).

---

## 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 10 µg/dL with a venous sample or another capillary within 12 weeks (84 days) of the first capillary blood lead test by a reference laboratory.

---

## 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](http://www.LeadCare2.com/reporting)

*Facility must:*

1. Report to Florida Department Of Health:
  - a. Blood lead results less than 5 µg/dL within 10 business days of blood lead analysis.
  - b. Blood lead results greater than or equal to 5 µg/dL by end of next business day of blood lead analysis.
2. Contact the [County Health Department](#) for additional local requirements, if needed.
  - a. Download the FREE LeadCare Reporting Software, **z.LeadCare Report v2.0 Beta**: [www.leadcare2.com/reporting](http://www.leadcare2.com/reporting)
  - b. Submit results electronically using the Florida Department's Electronic Laboratory Reporting System (ELR).
    - i. Request access on SFTP server [www7.doh.state.fl.us](http://www7.doh.state.fl.us) by contacting:  
Sudha Rajagopalan at (850) 245-4003 or by email at [Sudha.Rajagopalan2@flhealth.gov](mailto:Sudha.Rajagopalan2@flhealth.gov)

NOTE: If ELR is currently not available then results may be submitted in an approved alternate format temporarily by Confidential Fax: 407-858-5517 until the secure FTP Access is granted.

---

## 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
- Refer to: <http://www.floridahealth.gov/healthy-environments/lead-poisoning/lab-reporting-lead.html>