Physician Office Laboratory and Clinical Laboratory

*Requirements for Lead Testing**

New Jersey

** This information is subject to change*

Physician Office Laboratory (POL) and Clinical Laboratory

Defined as: A clinical laboratory is any place, institution, or facility that performs testing on bodily specimens including but not limited to blood, urine, saliva or tissue for the purpose of yielding information for the diagnosis, prevention or treatment of disease or the assessment of medical conditions. For information refer to https://nj.gov/health/phel/clinical-lab-imp-services/

Certification and Licensure

Facility must: Hold a Federal CLIA Certificate of Waiver (or higher) and a State Clinical Laboratory License.

Federal CLIA Certification:

1. Complete the application for a Federal CLIA Certificate of Waiver
2. Mail or fax completed applications to:

   By FedEx/UPS:
   Bhavna Patel
   Manager, NJ CLIA Program
   Public Health, Environmental Laboratories and Agriculture Laboratories
   3 Schwarzkopf Drive Ewing, NJ 08628
   By USPS:
   NJDOH (CLIA Program)
   P.O. Box 361 Trenton, NJ 08625-0361
   (609) 406-6824 FAX: (609) 406-6863

Initial State Licensure Process – download the application directly from *www.nj.gov/health/phel/clinical-lab-imp-services*

1. Submit completed license application (CL-3 or CL-4 for Waived Tests Only) and include the appropriate fee;
2. Note: There are instructions on how to complete the CL-3 or CL-4 next to the each document.
3. Submit the appropriate application with appropriate fee and applications will be processed in order of receipt.
4. Demonstrate Blood Lead test performance competency by submitting documentation of successful participation in an approved proficiency testing survey (minimum 5 challenges). Grade of 80% or higher is required for **pre-licensure** approval.

Mail completed application to:

Joan Mikita, Licensing Unit
PHEL/Clinical Laboratory Improvement Services
New Jersey Department of Health
P.O. Box 361
Trenton, NJ 08625-0361

If you have any questions, please contact the Licensing and Regulatory Compliance Unit at (609) 406-6830.

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 laboratory.

Quality Control

Facility must: Run two levels of controls per manufacturer's instructions.

Result Reporting`

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

Facility must:

1. Report results of ALL blood lead tests to the state within 48 hours of analysis.
2. Visit http://leadcare2.com/reporting/ for obtaining information on reporting template and instructions.

Please call (609) 292-4993 for additional reporting information or email Jaydeep Nanavaty at Jaydeep.Nanavaty@doh.nj.gov

Proficiency Testing

Required for non-waived testing: Refer to https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ptlist.pdf

Still Have Questions?

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