

# New York Physician Office Laboratory Requirements for Lead Testing\*

## Physician Office Laboratory

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*Defined as:* A practice must be operated by individual health care providers or be part of a legally constituted, independently owned and managed partnership or group practice.

NOTE: Laboratories that are owned, managed and/or operated by managed care organizations, hospitals or consulting firms do not qualify for the POL exception and should apply for a clinical laboratory permit through the Clinical Laboratory Evaluation Program.

## Licensure

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*Facility must:* Be certified by the federal Centers for Medicare and Medicaid Services (CMS) through the NYS DOH's Physician Office Laboratory Evaluation Program (POLEP).

1. Complete application for a CLIA Certificate of Waiver (<http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf>)
2. Mail or fax completed applications to:  
Physician Office Laboratory Evaluation Program  
New York State Department of Health  
Wadsworth Center  
P.O. Box 509  
Albany, NY 12201-0509  
Fax: (518) 485-5355

For more information call POLEP at 518-485-5352.

## 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 5µg/dL using a venous blood sample.

For more information, see practice standards at [www.nyhealth.gov/environmental/lead](http://www.nyhealth.gov/environmental/lead) (NYCRR Subpart 67-1.2)

## Quality Control

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*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.

## Critically Elevated Blood Lead Levels

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*Laboratory must:* Notify the health care provider ordering the test of blood lead levels of greater than or equal to 40 µg/dL for all children under the age of eighteen years within 24 hours of analysis.

NOTE: If said person, regardless of age, resides in New York City, current New York City Health Code reporting requirements take effect. See 'Result Reporting for NYC Residents' below.

*Providers must:* Notify the local health department of blood lead levels greater than or equal to 40 µg/dL for all children under the age of eighteen years within 24 hours of notification by the laboratory.

NOTE: If said person, regardless of age, resides in New York City, current New York City Health Code reporting requirements take effect. See 'Result Reporting for NYC Residents'.

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## Result Reporting

Reporting Solutions by State: [www.LeadCare2.com/reporting](http://www.LeadCare2.com/reporting)

### Facility must:

1. Report results of ALL blood lead tests to the NYS DOH within fourteen (14) business days of the date of analysis.
  - a. Report MUST include: the subject's name, date of birth, race, gender, address, county of residence, type of sample (venous or fingerstick) and blood lead level; the health care practitioner ordering the test, laboratory identifiers, the date the sample was collected and the date of analysis.
  - b. Recommended that reports include: parent or guardian information (for children < 18 years of age).
2. POLs must report electronically through the New York State Immunization Information System (NYSIIS).

For additional information on reporting, please contact the NYS DOH Lead Poisoning Prevention Program 518-402-7600 or [lppp@health.ny.gov](mailto:lppp@health.ny.gov)

## POLs Conducting Lead Testing on Adults

May report manually or using other electronic reporting mechanisms.

For additional information on reporting of adult blood lead test results, please contact the NYS DOH Bureau of Occupational Health at 518-402-7900.

## Result Reporting for New York City Residents

POLs that conduct blood lead testing on persons, regardless of age, who reside in New York City are REQUIRED to:

Report results to the New York City Department of Health and Mental Hygiene (NYCDOHMH) pursuant to New York City Health Code reporting requirements.

1. BLLs greater than or equal to 10 µg/dL MUST be reported to the NYCDOHMH within 24 hours of receipt of the test results (NYC Health Code §11.03 (b)(2)).
2. BLLs < 10 µg/dL that are not otherwise reported to the NYS DOH must be reported to NYCDOHMH within five business days of results availability. (NYC Health Code §11.09, reporting requirements).

NOTE: Reporting of these lead test results to NYCDOHMH will be considered to fulfill the state reporting requirement, i.e. POLs that report to NYCDOHMH will not be required to also submit reports to the state through NYSIIS.

NOTE: NYS DOH is currently working with NYCDOHMH to clarify requirements for lead test reporting from POLs whose patient population includes both children who reside within and outside New York City, i.e. "border providers". Additional information for this specific subset of POLs will be provided separately in the near future.

For information on reporting in New York City, please contact NYCDOHMH Lead Poisoning Prevention Program at (518) 402-7600.

## Proficiency Testing

Proficiency Education: [www.LeadCare2.com/proficiency](http://www.LeadCare2.com/proficiency)

*Strongly 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