

# Requirements for Lead Testing\*

# New York Clinical Laboratory

\* This information is subject to change

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## Licensure

**Facility must:** Hold a permit issued by the NYS DOH Clinical Laboratory Evaluation Program (CLEP) in the category of Toxicology – Blood Lead - ASV Using Screen Printed Sensors.

To add blood lead to your testing menu visit <https://www.wadsworth.org/regulatory/clep/clinical-labs/change-permit> for instructions.

Questions should be directed to the Clinical Laboratory Evaluation Program by telephone at (518) 485-5378 or by email to: [CLEP@health.ny.gov](mailto:CLEP@health.ny.gov).

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

NOTE: The new blood lead standards have been released by the NY DOH and are effective August 5, 2016. The standards are available at <https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-standards>

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## Quality Control

**Facility must:** Run two levels of Quality Control daily or develop an Individualized Quality Control Plan (IQCP) which follows 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.

Please refer to the New York State Clinical Laboratory Standards describing the necessary elements of an IQCP. These standards are available at <https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-standards>.

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## Critically Elevated Blood Lead Levels

**Laboratory must:** Notify the health care provider ordering the test of blood lead levels of greater than or equal to 45 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 45 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' below.

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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 five (5) 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, the date of analysis, and the methodology used in analysis.
  - b. Recommended that reports include: parent or guardian information (for children < 18 years of age).
2. Reporting must be done electronically using the Department's Electronic Clinical Laboratory Reporting System (ECLRS).

For additional information on reporting via ECLRS, please call 866-325-7743.

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## Labs 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.

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## Result Reporting for New York City Residents

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Labs 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 (5) 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. Labs that report to NYCDOHMH will not be required to also submit reports to the state through NYSIS.

NOTE: NYS DOH is currently working with NYCDOHMH to clarify requirements for lead test reporting from Labs 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 Labs 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

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**Laboratory must:** Participate in proficiency testing from a CMS-approved provider using a module determined to be acceptable to New York. A PT Survey Search Tool to find acceptable PT modules is available at: <https://www.wadsworth.org/regulatory/clep/pt/provider-search>.

## Still Have Questions?

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- Contact the Clinical Laboratory Evaluation Program at [CLEP@health.ny.gov](mailto:CLEP@health.ny.gov) or call (518) 485-5378.