

* This information is subject to change

Limited Service Laboratory (LSL)

Defined as: Hospital extension clinics, nursing homes, home health care agencies, school/student health services, dialysis facilities, ambulatory surgery centers, county health departments, correctional facilities, ambulance/rescue squads and other direct patient care facilities performing only waived and/or provider-performed microscopy procedures (PPMP).

NOTE: Physician offices performing only waived or PPMP tests that are owned and/or operated by managed care organizations, hospitals or consulting firms are also included in this group.

Licensure

Facility must: Be registered as a Limited Service Laboratory with the NYS DOH Clinical Laboratory Evaluation Program (CLEP).

1. Application instructions for LSL Registration: <https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs>
2. Complete application for LSL Registration:
 - a. Application fee: \$200 payable to New York State Department of Health
 - b. To fulfill the requirements of Section 8A:
 - i. Print pages 5-7 of the following document and maintain for your records:
http://www.accessdata.fda.gov/cdrh_docs/pdf5/K052549.pdf
 - ii. Create a written protocol for lead testing in accordance with manufacturer's instructions:
Refer to the manufacturer's package insert (located in each test kit) and the Blood Lead Practice Standards
<https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-standards>
3. Mail completed applications, \$200 application fee, and supporting documentation to:
New York State Department of Health
Wadsworth Center
Clinical Laboratory Evaluation Program
P.O. Box 509
Albany, NY 12201-0509

NOTE: Limited Service Laboratory Registrants approved for blood lead testing are required by law to comply with manufacturer's instructions and practice standards for such testing.

For additional information or questions call (518) 402-4253 or email clepltd@health.ny.gov.

Patient Testing

Training Tools: 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.

1. Record results with a comment stating, "Results of confirmatory testing are pending."
2. Refer a venous sample to a NYS permitted laboratory for blood lead confirmation testing, or refer the patient to that laboratory's patient service center for collection of a venous blood sample. If venous blood was collected in-office, that specimen may be referred or a new specimen may be collected.

NOTE: This threshold has been set for point-of-care testing using waived test methods, such as the LeadCare® II system. NYS DOH has established a confirmation threshold level greater than or equal to 10µg/dL for non-waived methods.

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

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.

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 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.

New York Requirements for Waived Lead Testing* Limited Service Laboratory

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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' below.

Result Reporting

Reporting Solutions by State: 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 and the date of analysis.
 - a. 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). In the interim, Limited Service Laboratories may continue to report manually.

NOTE: NYS DOH staff will be contacting Limited Service Laboratories to facilitate HCS enrollment and ECLRS reporting.

For additional information please contact the NYS DOH Lead Poisoning Prevention Program at 518-402-7600 or the ECLRS Helpdesk at 866-325-7743.

LSLs 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

LSLs 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. LSLs 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 LSLs 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 LSLs will be provided separately in the near future.

For information on reporting in New York City, please contact NYCDOHMH Lead Poisoning Prevention Program at (212) 676-6352.

Proficiency Testing

Strongly Recommended: To monitor the quality of your blood lead testing program.

There are currently four providers that offer modules for this testing: American Academy of Family Physicians, American Proficiency Institute, College of American Pathologists, and Wisconsin State Laboratory of Hygiene.

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 New York State Clinical Laboratory Evaluation Program at clepltd@health.ny.gov.