



STATE OF NEW YORK  
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.  
*Commissioner*

Wendy E. Saunders  
*Executive Deputy Commissioner*

July 2009

Dear Laboratory Director:

The purpose of this letter is to advise you of changes in New York State's Public Health Law and regulations pertaining to blood lead testing, reporting and follow-up that may affect your laboratory practices.

State law and regulations have been updated to reflect current lead testing technology and practice standards; to ensure laboratory reporting requirements are consistent with recent changes in public health law; to clarify and expand requirements for follow-up of children with lead poisoning; and to support the integration of statewide data systems to improve childhood lead testing. These changes are part of the state's ongoing work to eliminate childhood lead poisoning in New York State.

A detailed summary of the statutory and regulatory changes that relate to reporting of blood lead tests is enclosed for your reference. Complete copies of the amended law and regulations are available on the NYSDOH Web site at [www.nyhealth.gov/environmental/lead](http://www.nyhealth.gov/environmental/lead).

Thank you for your assistance in implementing these changes, and for your ongoing role in the identification and management of childhood lead poisoning in New York State. If you have any questions or would like additional information, please contact the New York State Lead Poisoning Prevention Program at 518-402-5706, the Physician Office Laboratory Evaluation Program at (518) 485-5352, or the Clinical Laboratory Evaluation Program at 518-485-5378.

Sincerely,

Guthrie S. Birkhead, M.D., M.P.H.  
Deputy Commissioner  
Office of Public Health

## **Summary of Changes to New York State Public Health Law and Regulations: Blood Lead Testing and Reporting Requirements for Laboratories**

The New York State Department of Health (NYSDOH) recently adopted changes to Department Regulations at Subparts 67-1 and 67-3 regarding lead poisoning screening, reporting and follow-up. The Notice of Adoption was published in the State Register on May 6, 2009, and the amendments are **effective on June 20, 2009**.

In addition, several changes to New York State Public Health Law related to lead testing and reporting were recently enacted as part of the 2009 state budget process. Unless otherwise stated, these changes are effective immediately.

**This guidance document summarizes the combined statutory and regulatory changes that directly affect laboratories that offer blood lead testing, including Physician Office Laboratories and Limited Service Laboratory Registrants.** It is a companion document to another guidance document that summarizes changes that affect health care providers, local health departments, child care providers and others. These guidance documents and complete copies of the amended Public Health Law and regulations are available on the NYSDOH Web site at: [www.nyhealth.gov/environmental/lead](http://www.nyhealth.gov/environmental/lead).

### **The amended public health law and regulations:**

- 1) **Authorize Physician Office Laboratories (POLs) and Limited Service Laboratory Registrants to conduct blood lead testing, using devices of complexity appropriate for their level of certification.** These changes were made to recognize the availability of, and encourage access to blood lead testing using simple, portable “point-of-care” testing technologies, such as the CLIA-waived Lead Care<sup>®</sup> II. **NOTE:** even with these changes, all entities that perform blood lead testing must still have the appropriate level of approval to conduct testing on human specimens, as determined by NYSDOH’s Wadsworth Center, as summarized below. (*NYCRR Subpart 67-1.3*)
  - Individual practitioners or group private practices that conduct in-house laboratory testing on their own patients must be certified by the federal Centers for Medicare and Medicaid Services (CMS) through the NYSDOH’s Physician Office Laboratory Evaluation Program (POLEP). For additional information call (518) 485-5352, write to [CLIA@health.state.ny.us](mailto:CLIA@health.state.ny.us) or visit [www.wadsworth.org/labcert/polep/index.html](http://www.wadsworth.org/labcert/polep/index.html). The Blood Lead Practice Standards are posted at [www.nyhealth.gov/environmental/lead](http://www.nyhealth.gov/environmental/lead)
  - Facilities that are not private practices (e.g., off-site clinics) that conduct point-of-care testing using only CLIA-waived procedures (with or without provider-performed microscopy) must be registered as **Limited Service Laboratories** with the NYSDOH Clinical Laboratory Evaluation Program (CLEP). **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. The Blood Lead Practice Standards are posted at: [www.nyhealth.gov/environmental/lead](http://www.nyhealth.gov/environmental/lead) Registration forms for Limited Service Laboratories are available at: [www.wadsworth.org/labcert/lep/Administrative/ChangeForms.htm](http://www.wadsworth.org/labcert/lep/Administrative/ChangeForms.htm). For additional information, call 518-485-5378, or write to [CLEPLTD@health.state.ny.us](mailto:CLEPLTD@health.state.ny.us).

- All other facilities that offer laboratory testing must hold a permit issued by the NYSDOH Clinical Laboratory Evaluation Program (CLEP) in the category of Toxicology – Blood Lead. For additional information, call 518-485-5378, write to [CLEP@health.state.ny.us](mailto:CLEP@health.state.ny.us), or visit [www.wadsworth.org/CLEP](http://www.wadsworth.org/CLEP).

2) **Require all laboratories that conduct blood lead testing, including POLs and Limited Service Laboratory Registrants, to report all results of such testing to the NYSDOH.**

Reporting of all blood lead test results is essential to assure timely and appropriate follow-up and complete data for public health surveillance purposes. The regulations specify the information that must be reported, the timeframes for reporting and the mechanisms for reporting, which vary by type of laboratory, as summarized below. (*PHL Sections 576-c, 579(3)c, 1370-e and 2168; NYCRR Subparts 67-1.2 and 67-1.3*)

- **Permitted clinical laboratories** are required to report results of all blood lead tests to the Department of Health within **five** business days of the date of analysis. The 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. In addition, to facilitate timely follow-up, it is recommended that reports include parent or guardian information (for children < 18 years of age) or employer information (for adults). 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.
- **Limited Service Laboratory Registrants** are required to report results of all blood lead tests to the Department of Health within **five** business days of the date of analysis (see #1 above for additional information on Limited Service Laboratory registration). Reports must include the same information as is required for permitted clinical laboratories. Public Health Law requires Limited Service Laboratory Registrants to report in the same manner as permitted clinical laboratories, i.e. via ECLRS. Limited Service Laboratories will need to have access to the Health Commerce System (HCS) to report electronically via ECLRS. NYSDOH staff will be contacting Limited Service Laboratories on record as performing blood lead testing to facilitate HCS enrollment and ECLRS reporting. In the interim, Limited Service Laboratories may continue to report manually. For additional information on reporting, please contact the NYSDOH Lead Poisoning Prevention Program at 518-402-5706 or the ECLRS Helpdesk at 866-325-7743.
- **Physician Office Laboratories (POLs)** must report results of all blood lead tests to the Department of Health within **fourteen** business days of the date of analysis. The 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. In addition, to facilitate timely follow-up, it is recommended that reports include parent or guardian information (for children < 18 years of age) or employer information (for adults). Initially POLs may report using either paper or electronic methods to submit reports. The Department is in the process of developing reporting capability through the New York State Immunization Information System

(NYSIIS). Once this capability is implemented, POLs will be required to report results of all blood lead tests conducted on children under the age of eighteen years electronically through the New York State Immunization Information System (NYSIIS). NYSDOH will provide additional information about requirements for NYSIIS reporting when available, which is anticipated to be in Fall 2009. For additional information on reporting, please contact the NYSDOH Lead Poisoning Prevention Program 518-402-5706 or [cbo01@health.state.ny.us](mailto:cbo01@health.state.ny.us).

- **Note: POLs that conduct blood lead testing on persons, regardless of age, who reside in New York City are required to report those results within specific timeframes to the New York City Department of Health and Mental Hygiene (NYCDOHMH) pursuant to New York City Health Code reporting requirements.** Blood lead test results of 10 mcg/dL or greater must be reported to the NYCDOHMH within 24 hours of receipt of the test results (NYC Health Code §11.03 (b)(2)). Blood lead test results below 10 mcg/dL that are not otherwise reported to the NYSDOH must be reported to NYCDOHMH within five business days of results availability. (NYC Health Code §11.09, reporting requirements). 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. For information on reporting in New York City, please contact NYCDOHMH Lead Poisoning Prevention Program at (212) 676-6352.
  - NYSDOH 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.
- **POLs that conduct blood lead testing on adults** (i.e., any individual 18 years of age or older) can report manually or using other electronic reporting mechanisms. For additional information on reporting of adult blood lead test results, please contact the NYSDOH Bureau of Occupational Health at 518-402-7900. For information on reporting adult blood lead test results in NYC, contact the Environmental and Occupational Epidemiology Program at 212-788-4290.

- 3) **Require health care providers to confirm a child’s capillary blood lead test result of  $\geq 10$  micrograms per deciliter (mcg/dL) using a venous blood sample.** This updates the previous regulation, which required confirmation of capillary test results above 15 mcg/dL, and is consistent with national guidelines from the Centers for Disease Control and Prevention (CDC) to maximize the identification of children with lead poisoning. Note that for point-of-care testing using waived test methods, such as the Lead Care<sup>®</sup> II device, NYS DOH has established a confirmation threshold level of 8 mcg/dL. See practice standards at [www.nyhealth.gov/environmental/lead](http://www.nyhealth.gov/environmental/lead). (NYCRR Subpart 67-1.2)
- 4) **Clarify requirements for transmission of information from laboratories that are not permitted to perform blood lead analyses that accept blood lead samples and refer the**

**samples elsewhere for analysis.** The laboratory accepting the blood lead sample must transmit to the laboratory performing the analysis all of the information that is required for reporting of the blood lead test result. The laboratories may agree on which laboratory will report in compliance with the regulations, but both laboratories will be accountable to insure that a report is made. (*NYCRR Subpart 67-3.1*)

- 5) **Expand the requirements for immediate notification of critically elevated blood lead levels to include all children less than eighteen years of age.** Laboratories must notify the health care provider ordering the test of blood lead levels of  $\geq 45$  mcg/dL for all children under the age of eighteen years within 24 hours of analysis. Health care providers in turn must notify the local health department of blood lead levels  $\geq 45$  mcg/dL for all children under the age of eighteen years within 24 hours of notification by the laboratory. Previous regulations required these urgent notifications only for children less than six years of age.
- **Note:** Current New York City Health Code reporting requirements, which require that blood lead test results  $\geq 10$  mcg/dL for all persons, regardless of age, residing in New York City be reported to the New York City Department of Health and Mental Hygiene (NYCDOHMH) within 24 hours of receipt of analysis by all laboratories and other providers, including provider office laboratories, remain unchanged. (*NYCRR Subparts 67-3.1 and 67-3.2*)

**In addition to these statutory and regulatory changes, laboratories that conduct blood lead testing should be aware of a recent change in practice standards for blood lead reporting.**

Health care providers and laboratories were notified of a change in practice standards for blood lead reporting by letters issued in June 2009. Effective September 1, 2009, reference ranges on laboratory-generated patient reports must indicate that blood lead levels 5-9 mcg/dL have been associated with adverse health effects in children 6 years and younger. Reports should not indicate that blood lead levels less than 10 micrograms/dL are "Normal." This commentary language has been designated as **Blood Lead Standard 11 (BL 11)**, and it will be required of all laboratories holding a New York State permit in the category Toxicology-Blood Lead. New patient educational materials were distributed to health care providers in conjunction with this change. Additional information on the revised reporting standard is available at: [www.wadsworth.org/labcert/lep/inthenews/inthenews.htm](http://www.wadsworth.org/labcert/lep/inthenews/inthenews.htm) Questions regarding laboratory standards can be directed to Ms. Beth Johansen at 518-402-4186. Technical questions regarding blood lead testing can be directed to Dr. Mary Fran Verostek at 518-474-4924.

**LIMITED SERVICES LABORATORY and PHYSICIAN OFFICE LABORATORY Blood Lead Screening  
Standards of Practice for WAIVED Testing Devices (e.g., Lead Care® II)**

Standards of Practice	NYSDOH Guidance
<p><b>Specimen Collection</b></p> <p>To avoid lead contamination from dust, regularly clean work surfaces by wet wiping.</p> <p>Prior to skin puncture thoroughly clean finger by scrubbing area with soap and water and then with an alcohol swab.</p> <p>Obtain whole blood samples using lead-free capillary collection tubes provided with the test kit <u>or</u> use vacuum tubes certified for lead (or trace element) analysis.</p> <p>Reject venous blood specimens with visible clots, and, when using EDTA as anticoagulant, reject specimens when the collection tube is not at least one half full.</p>	<p><b>Specimen Collection</b></p> <p>Directions for specimen collection, handling, and storage are included in the product insert and must be followed explicitly. Staff should document their having read and understood the insert.</p> <p>Persons collecting patient specimens should have a thorough understanding of the specimen type, proper collection method (including the need to clean the skin area), and specimen handling</p> <p>For venous blood collected in a vacuum tube, use lead-free capillary tubes to transfer sample to the treatment reagent tube</p> <p>Be conscious of environmental requirements as described in the user's guide to ensure reliable test results. Test environment requirements apply to all test settings, e.g., in-office and community outreach venues including mobile vans.</p>
<p><b>Record keeping</b></p> <p>Keep records of instrument calibration, and kit lot numbers and quality control results for each day's runs.</p>	<p><b>Record keeping</b></p> <p>Records should allow cross-reference of each patient's results with kit lot number and quality control data to retrospectively identify patients in order to contact them for retesting if there is a product recall or problem with test performance.</p>
<p><b>Confirmatory Testing</b></p> <p>Refer for confirmation testing all cases with a lead test result <b>greater than or equal to 8 mcg/dL</b>.</p> <p><b>NOTE:</b> The level of <b>8 micrograms/dL</b> is the confirmation threshold recommended by the manufacturer of the Lead Care® II device to minimize possible false negatives.</p>	<p><b>Confirmatory Testing</b></p> <p>Whenever lead results generated by a waived device are greater than or equal to <b>8 mcg/dL</b> :</p> <ul style="list-style-type: none"> <li>▪ record results with a comment that <i>results of confirmatory testing are pending</i></li> <li>▪ refer a venous sample to a NYS DOH laboratory permitted 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.</li> </ul>

**LIMITED SERVICES LABORATORY and PHYSICIAN OFFICE LABORATORY Blood Lead Screening  
Standards of Practice for WAIVED Testing Devices (e.g., Lead Care® II)**

Standards of Practice	NYSDOH Guidance
<p><b>Quality Assurance</b></p> <p>Have product insert and device user’s guide available to staff in the testing area. Ensure device operators are familiar with requirements for routine quality control (new lot, new shipment, new operator) and use of control materials to investigate suspect problems.</p> <p>Periodically compare blood lead results obtained from the waived device with results reported by the confirmatory laboratory.</p> <p>Periodically review quality control records for irregularities.</p>	<p><b>Quality Assurance</b></p> <p>Compile a procedures manual that minimally includes written policies to: ensure compliance with manufacturer’s requirements for quality control; report results as applicable to your provider type; and assess personnel competency. Competency reviews of testing personnel should consider collection technique as well as performance of quality control and proficiency testing. Participation in proficiency testing is strongly recommended.</p> <p>Differences greater than 3 micrograms/dL should be investigated.</p> <p>If a control material value is not within proper range, refer to the trouble shooting section of user guide.</p>
<p><b>Public Health Reporting</b></p> <p>Report all results of blood lead analyses to NYS DOH, with demographic data as required by Subparts 67-1 and 67-3. NOTE: residents of NYC must have their results reported to the NYCDOHMH.</p> <p>Within 24 hours of analysis, notify the health care practitioner ordering the lead screening of the results of any analysis in a child (less than eighteen years of age) that is equal to or greater than 45 micrograms/dL.</p>	<p><b>Public Health Reporting</b></p> <p>Department regulations call for reporting of test results and subject’s name, date of birth, race, gender, address, county of residence, type of sample (fingerstick or venous), health care practitioner ordering the test, date sample was collected, date sample was analyzed, and identification of the testing laboratory.</p> <p>Whenever a specimen is referred to a permitted laboratory for confirmatory blood lead analysis, the information listed above should be provided to the laboratory.</p>

**Effective 6/30/09**

**NOTE: For standards applicable to laboratories holding a NYS permit clinical laboratory permit in Toxicology – Blood Lead see [www.wadsworth.org/labcert/clep/files/BloodLeadTraceElementsEP.pdf](http://www.wadsworth.org/labcert/clep/files/BloodLeadTraceElementsEP.pdf)**