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
Specimen Collection To avoid lead contamination from dust, regularly clean work surfaces by wet wiping. Prior to skin puncture thoroughly clean finger by scrubbing area with soap and water and then with an alcohol swab. Obtain whole blood samples using lead-free capillary collection tubes provided with the test kit or use vacuum tubes certified for lead (or trace element) analysis. 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.	**Specimen Collection** 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. 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 For venous blood collected in a vacuum tube, use lead-free capillary tubes to transfer sample to the treatment reagent tube 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.
Record keeping Keep records of instrument calibration, and kit lot numbers and quality control results for each day's runs.	**Record keeping** 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.
Confirmatory Testing Refer for confirmation testing all cases with a lead test result **greater than or equal to 8 mcg/dL.** **NOTE:** The level of **8 micrograms/dL** is the confirmation threshold recommended by the manufacturer of the Lead Care® II device to minimize possible false negatives.	**Confirmatory Testing** There is emerging consensus that levels below the CDC confirmation threshold of 10 micrograms/dL are associated with adverse health effects. Whenever lead results generated by a waived device are greater than or equal to **8 mcg/dL** : ▪ record results with a comment that *results of confirmatory testing are pending* ▪ 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.

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Quality Assurance 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. Periodically compare blood lead results obtained from the waived device with results reported by the confirmatory laboratory. Periodically review quality control records for irregularities.	**Quality Assurance** 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. Differences greater than 3 micrograms/dL should be investigated. If a control material value is not within proper range, refer to the trouble shooting section of user guide.
Public Health Reporting 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. 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.	**Public Health Reporting** 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. Whenever a specimen is referred to a permitted laboratory for confirmatory blood lead analysis, the information listed above should be provided to the laboratory.

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