

APPENDIX A

Blood Lead Screening Standards of Practice for WAIVED Testing Devices (e.g., Lead Care[®] II)	
Standard	Guidance
<p>Consent for Testing of a Minor</p> <p>To offer lead screening of children during community screening events, the laboratory must establish a procedure for determining whether the person arranging for testing for a minor has a legal right and the capacity to consent to testing of the minor.</p>	<p>Consent for Testing of a Minor</p> <p>A minor is an unmarried person under the age of 18 (Public Health Law, Section 2504). As part of the process for obtaining approval to perform lead testing in outreach settings, the laboratory must attest that it has a procedure for establishing proof of a person's right of guardianship and eligibility to provide informed consent for any test subject who is a minor.</p>
<p>Specimen Collection</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 or 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>Specimen Collection</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>Record keeping</p> <p>Keep records of instrument calibration, and kit lot numbers and quality control results for each day's runs.</p>	<p>Record keeping</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>Confirmatory Testing</p> <p>Refer for confirmation testing all cases with a lead test result greater than or equal to 8 micrograms per deciliter (µg/dL).</p> <p>NOTE: The level of 8 µg/dL is the confirmation threshold recommended by the manufacturer of the Lead Care[®] II device to minimize possible false negatives.</p>	<p>Confirmatory Testing</p> <p>Whenever lead results generated by a waived device are greater than or equal to 8 µg/dL:</p> <p>record results with a comment that <i>results of confirmatory testing are pending</i></p> <p>refer a properly collected 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.</p>

Standard	Guidance
<p>Quality Assurance</p> <p>Have product insert and device user's guide available to staff in the testing area. Periodically compare blood lead results obtained from the waived device with results reported by the confirmatory laboratory.</p> <p>Periodically compare blood lead results obtained from the waived device with results obtained from confirmatory laboratories.</p> <p>Periodically review quality control records for irregularities.</p>	<p>Quality Assurance</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>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>Differences greater than 3 µg/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>Public Health Reporting</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 µg/dL.</p>	<p>Public Health Reporting</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>
<p>Effective 4/18/11</p>	

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