Blood Lead – Comprehensive Testing

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Refer to 10NYCRR Subpart 67-3 for additional blood lead reporting requirements.	
Blood Lead Standard of Practice 1 (BL S1): Materials Contamination Control The laboratory must implement procedures to ensure that materials used for blood lead collection and processing are free from significant lead contamination.	Significant lead contamination refers to an amount of lead that would change the blood lead level by more than 0.2 micrograms/dL. Blood collection tubes/containers should be either lot-tested, and certified by the testing laboratory as fit for purpose, or manufacturer-certified for blood lead use (or trace element testing) to ensure that they are free from significant lead contamination. Collection tubes/containers are suitable for use when the mean lead concentration or difference in blood lead is less than or equal to 0.2 micrograms/dL. Collection materials such as alcohol swabs and blood tubes/containers must be fit for purpose. The laboratory must inform clients of proper collection techniques, especially the importance of thorough patient hand washing prior to collecting capillary specimens. Where appropriate, laboratory supplies (e.g., flasks, autosampler tubes, and pipet tips), used for blood lead testing must be pre-checked for contamination and/or acid-washed (e.g., with dilute nitric acid), and certified as fit for purpose. Disposable plastic ware can be verified as contamination-free by randomly checking materials by lot number.

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Blood Lead Standard of Practice 2 (BL S2): Processing Contamination Control To minimize lead contamination during specimen testing: a) work must be performed in a dedicated clean area; and b) specimen aliquots must be protected from dust contamination before and during analysis.	a) Clean area refers to space that is dedicated to testing for lead and/or other trace metals, and is regularly cleaned by wet wiping flat surfaces. b) If an ISO 5 (a.k.a. Class 100) clean room is unavailable, specimen aliquots should be protected by use of dust protection devices (e.g., furnace AAS carousels containing unanalyzed samples should be protected with dust covers before and during analysis; ICP-MS autosamplers should be protected from airborne contamination.)
Blood Lead Standard of Practice 3 (BL S3): Order of Testing If blood specimens are collected for multiple analyses including lead testing, a volume sufficient for the initial lead test and any repeat testing should be transferred to a container/tube certified as free of significant lead contamination under clean conditions before any other processing or testing occurs to the specimen.	Implementing this protocol may minimize inadvertent specimen contamination from other clinical testing areas. As an alternative, the testing for blood lead may be completed prior to other clinical testing.
Blood Lead Standard of Practice 4 (BL S4): Calibration Protocols On each day of testing, the laboratory must run a calibration curve that: a) includes a blank and at least three (3) calibration standards; b) is matrix matched to the specimens being tested, unless validation studies indicate the absence of matrix effects; and	Information on Departmental approval of laboratory developed tests (LDTs) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval. a) For laboratory developed tests (LDTs), this type of calibration is considered robust. b) Typically, graphite furnace AAS can be calibrated with aqueous lead standards, plus modifier; however, ICP-MS is more sensitive to matrix effects and must be matrix-

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c) is run at least every eight (8) hours of testing, unless longer instrument stability is validated, but no longer than twenty-four (24) hours.	matched, i.e., base blood is added to calibration standards for simple dilution methods, unless validation studies indicate the absence of matrix effects.
Blood Lead Standard of Practice 5 (BL S5): Quality Control Three (3) levels of quality control (QC) must be included with each test run to include a low, intermediate and elevated concentration.	The controls should include a low (approximately three (3) to five (5) micrograms/dL), an intermediate (ten (10) to fifteen (15) micrograms/dL), and an elevated level (greater than twenty (20) micrograms/dL) level material. The Department anticipates that these suggested ranges will be modified as control materials from commercial vendors that are in compliance with CDC recommendations become available. Laboratories using furnace AAS methods with an upper calibration point of thirty (30) micrograms /dL must also run an elevated control (greater than or equal to thirty (30) micrograms /dL) when diluting samples greater than or equal to thirty (30) micrograms/dL. Laboratories using ICP-MS methods for blood lead may be unable to simply dilute specimens exceeding the upper calibration standard because of matrix effects. Alternative protocols may need to be used to handle such samples and must be validated as appropriate.
Blood Lead Standard of Practice 6 (BL S6): Unacceptable Specimens In addition to the requirements in Specimen Processing Standard of Practice 4, blood specimens with visible clots must be rejected as unsatisfactory for analysis.	

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Blood Lead Standard of Practice 7 (BL S7): Repeat Analysis If the volume of the original specimen permits, the laboratory must: a) retest all specimens which initially result in blood lead levels greater than or equal to five (5) micrograms/dL; and b) analyze a third time if: i. large discrepancies are obtained between two (2) consecutive results; or ii. initial test results are greater than forty (40) micrograms/dL.	A new aliquot from the original specimen should be used for the repeat analysis. Specimen volume for capillary samples may be insufficient for repeat analysis purposes. Large differences between two (2) consecutive tests are defined as differences exceeding three (3) micrograms/dL for blood lead levels between five (5) to twenty (20) micrograms/dL; four (4) micrograms/dL for values between twenty-one (21) to forty (40) micrograms/dL; or ten (10) percent for values exceeding forty (40) micrograms/dL. In these cases, the specimen should be reanalyzed a third time, the outlier discarded and either report the average or the first result.
Blood Lead Standard of Practice 8 (BL S8): Reporting Potential Contamination In addition to the requirements in Reporting Standard of Practice 2, if a specimen is received in a blood collection tube/container that is not certified for blood lead testing, and the result is above the New York State reference value in children (greater than or equal to five (5) micrograms /dL), the report must state that the use of unverified containers might produce a falsely elevated result.	When a specimen is received in a blood collection tube that is either not provided by the testing laboratory or not certified for blood lead testing, and the blood lead level is less than five (5) micrograms/dL, the result can be reported without comment. Trace element “free” tubes or containers that have been lot-tested in-house are acceptable alternatives to manufacturer certified blood lead tubes, and need not be footnoted in the test report.

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Blood Lead Standard of Practice 9 (BL S9): Reporting Potential for Fingerstick Contamination In addition to the requirements in Reporting Standard of Practice 2, elevated capillary blood lead levels must be reported with a comment that capillary blood levels greater than five (5) micrograms/dL may be due to contamination from lead found on the finger surface and require confirmation with venous blood.	Elevated is defined as the New York State reference value in children, currently greater than five (5) micrograms/dL. Comments on test report must indicate the need to confirm with venous blood specimen.
Blood Lead Standard of Practice 10 (BL S10): Single Use Devices Laboratories using blood lead analyzers that are based on single-use, disposable sensors i.e., ASV screen-printed electrode technology must follow the Blood Lead Standards for ASV Screen-Printed Sensors.	
Blood Lead Standard of Practice 11 (BL S11): Reporting In addition to the requirements in Reporting Standard of Practice 2, the laboratory report must include: a) the analytical method used for the analysis; and b) for test results on all patients, including exposed adults, a reference range of less than five (5) micrograms/dL.	

Blood Lead – ASV Screen-Printed Sensors

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Laboratories using lead analyzers that are based on single-use, disposable sensors, i.e., ASV screen-printed electrode technology, must follow these standards. Refer to 10NYCRR Subpart 67-3, for additional blood lead reporting requirements.	
Blood Lead ASV Sensors Standard of Practice 1 (BLS S1): Materials Contamination Control The laboratory must implement procedures to ensure that materials used for blood lead collection and processing are free from significant lead contamination.	Significant lead contamination refers to an amount of lead that would change the blood lead level by more than 0.2 micrograms/dL. Blood collection tubes must be either lot-tested, and certified by the testing laboratory as fit for purpose, or manufacturer-certified for trace element use (or blood lead testing) to ensure that they are free from significant lead contamination. Collection tubes are suitable for use when the mean lead concentration or difference in blood lead is less than or equal to 0.2 micrograms/dL. Collection materials such as alcohol swabs and blood containers must be fit for purpose. The laboratory must inform clients of proper collection techniques, especially the importance of thorough patient hand washing prior to collecting capillary specimens. Should an unexpected number of elevated blood lead test results occur, contamination from materials and/or containers would merit an investigation. Work with clinical health care providers to ensure proper collection techniques, including the importance of preparing the skin collection site prior to collection of capillary specimens.

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Blood Lead ASV Sensors Standard of Practice 2 (BLS S2): Processing Contamination Control To minimize lead contamination during specimen collection and testing: a) work must be performed in a clean area; and b) specimen aliquots shall be protected from dust contamination before and during analysis.	a) Clean area refers to space that is dedicated to testing for lead and is regularly cleaned by wet wiping flat surfaces.
Blood Lead ASV Sensors Standard of Practice 3 (BLS S3): Use of Capillary Blood If a capillary tube is used to collect a blood specimen, the laboratory must implement procedures to ensure there are no air gaps present in the capillary tube during collection. In addition to the requirements in Specimen Processing Standard of Practice 4, capillary blood specimens with visible clots or air gaps must be rejected as unsatisfactory for analysis.	This specimen is appropriate for screening purposes only and is typically used with a point-of-care (POC) device. Consult the manufacturer's packaging/package insert(s) for additional details including the mixing of blood with anticoagulant reagents.
Blood Lead ASV Sensors Standard of Practice 4 (BLS S4): Repeat Analysis If the volume of the original specimen permits, the laboratory must: a) retest all specimens which initially result in blood lead levels greater than or equal to five (5) micrograms/dL; and b) analyze a third time:	A new aliquot from the original specimen should be used for the repeat analysis. Specimen volume for capillary samples may be insufficient for repeat analysis purposes. Large differences between two (2) consecutive tests are defined as differences exceeding three (3) micrograms/dL for blood lead levels between five (5) to twenty (20) micrograms/dL; four (4) micrograms/dL for values between twenty-one (21) to forty (40) micrograms/dL; or ten (10) percent

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i. if large discrepancies are obtained between two (2) consecutive results; or ii. report test results as inconclusive and, in addition to the requirements in Reporting Standard of Practice 2, add a comment that there was insufficient specimen to repeat the analysis.	for values exceeding forty (40) micrograms/dL. In these cases, the specimen should be reanalyzed a third time, the outlier discarded and either report the average or the first results.
Blood Lead ASV Sensors Standard of Practice 5 (BLS S5): Potential for Fingerstick Contamination In addition to the requirements in Reporting Standard of Practice 2, elevated capillary blood lead levels (greater than five (5) micrograms/dL) must be reported with a comment that capillary blood levels greater than five (5) micrograms/dL may be due to contamination from lead found on the finger surface and require confirmation with venous blood.	
Blood Lead ASV Sensors Standard of Practice 6 (BLS S6): Method Comparison When specimens have been referred for confirmatory testing, laboratories must compare and maintain a log of blood lead results obtained from their device(s) with results reported using the confirmatory reference method.	Differences in results greater than three (3) micrograms/dL for blood lead levels five (5) to (20) micrograms/dL; four (4) micrograms/dL for values twenty-one (21) to forty (40) micrograms/dL; or ten (10) percent for values exceeding forty (40) micrograms/dL require further investigation. A review of competency assessments of testing personnel as well as data from quality control and proficiency testing can provide insights on testing performance.

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Blood Lead ASV Sensors Standard of Practice 7 (BLS S7): Reporting In addition to the report requirements defined in Reporting Standard of Practice 2, the laboratory report must include: a) the analytical device used in analysis; and b) for test results on all patients, including exposed adults, a reference interval of greater than five (5) micrograms/dL must be used.	