Toxicology	
Blood Lead – Comprehensive Testing	
Former Standard and Guidance	***Proposed Standard and Guidance***
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. **Guidance –** Refer to 10NYCRR Subpart 67-3 for additional blood lead reporting requirements. Contact information for reporting blood lead is also found in Public Health Reporting Sustaining Standard of Practice 1 (Public Health S1). Effective August 5, 2016.	Refer to 10NYCRR Subpart 67-3 for additional blood lead reporting requirements.
Blood Lead Sustaining Standard of Practice 1 (BL S1): Materials Contamination Control The laboratory shall implement procedures to ensure that materials used for blood lead collection and processing are free from significant lead contamination. **Guidance –** Significant lead contamination refers to an amount of lead that would change the blood lead level by more than 1 microgram/dL. Blood collection tubes should be lot-tested, certified as lead-free, or manufacturer-certified for trace element use to ensure that containers are free from lead contamination. Collection tubes are suitable for use when the mean lead concentration or difference in blood lead is less than or equal to 0.5 micrograms/dL.	**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. **Guidance –** Significant lead contamination refers to an amount of lead that would change the blood lead level by more than 0.25 microgram/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

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Collection materials such as alcohol swabs and blood containers should be lead-free. The laboratory should inform clients of proper collection techniques, including the importance of patient hand washing prior to collection of capillary specimens. Glassware and plastic ware used during the analysis should be acid-washed (e.g., in 10% (by volume) nitric acid). Alternatively, disposable glassware and plastic ware should be verified as contamination-free by randomly checking materials by lot.	less than or equal to 0.25 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.
Blood Lead Sustaining Standard of Practice 2 (BL S2): Processing Contamination Control To minimize lead contamination during specimen collection and testing: a) work shall be performed in a clean area; and, b) specimen aliquots shall be protected from dust contamination before and during analysis. **Guidance –** 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	**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. **Guidance –** 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

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protection devices (e.g., furnace AAS carousels containing unanalyzed samples should be protected with dust covers before and during analysis).	unanalyzed samples should be protected with dust covers before and during analysis; ICP-MS autosamplers should be protected from airborne contamination.)
Blood Lead Sustaining 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 lead-free tube under clean conditions before any other processing or testing occurs to the specimen. **Guidance –** Specimen contamination from other testing areas may be minimized by implementing this protocol. As an alternative, the test for blood lead can be completed prior to other testing.	**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. **Guidance –** 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 Sustaining Standard of Practice 4 (BL S4): Calibration The laboratory shall perform instrument calibration: a) with a minimum of three standards plus a blank, or in accordance with the manufacturer's requirements where they exist specifically for blood lead analysis; and b) at least every eight hours of testing, unless longer instrument stability is validated.	**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

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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. **Guidance –** 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; ICP-MS is more sensitive to matrix effects and must be matrix-matched, i.e., base blood is added to calibration standards for simple dilution methods.
Blood Lead Sustaining Standard of Practice 5 (BL S5): Quality Control Three levels of quality control shall be included with each test run. **Guidance –** The controls should include a low (approximately 5 micrograms/dL), an intermediate (10 - 30 micrograms/dL), and a high (greater than 30 micrograms/dL) level material. The Department anticipates that these suggested ranges will be modified as control materials from commercial vendors	**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. **Guidance –** 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

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that are in compliance with CDC recommendations become available. Laboratories with methods having an upper calibration limit of 30 µg/dL would only need to run an elevated control when diluting elevated samples ≥30 µg/dL.	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 **cannot** simply dilute specimens exceeding the upper calibration standard because of matrix effects. Alternative protocols must be used to handle such samples, and must be validated as appropriate.
Blood Lead Sustaining Standard of Practice 6 (BL S6): Unacceptable Specimens Blood specimens with visible clots shall be rejected as unsatisfactory for analysis.	**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.
Blood Lead Sustaining Standard of Practice 8 (BL S8): Repeat Analysis All specimens which initially result in blood lead levels greater than or equal to 5 micrograms/dL shall be reanalyzed a second time if the volume of the original specimen permits. Use the average of the two consecutive test results to determine whether the discrepancy is large enough (see guidance for definitions) to require a third analysis. A third	**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

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analysis shall be performed when: a) large discrepancies are obtained between two consecutive results; or b) initial test results are greater than 40 micrograms/dL. **Guidance –** A new aliquot from the original specimen should be used for the reanalysis. Specimen volume for capillary samples may be insufficient for retesting purposes. Large differences between two consecutive tests are defined as differences exceeding 3 micrograms/dL for blood lead levels 5 to 20 micrograms/dL; 4 micrograms/dL for values 21 to 40 micrograms/dL; or 10% for values exceeding 40 micrograms/dL. In these cases, the specimen should be analyzed a third time, the outlier result should be discarded and either report the average or the first obtained of the remaining results.	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. **Guidance –** 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 Sustaining Standard of Practice 9 (BL S9): Reporting Potential Contamination If a specimen is received in a blood collection container that is not certified for blood lead testing, and the result is above the reference value (≥ 5µg/dL), the report shall indicate that the use of unverified containers might produce a falsely elevated result. **Guidance –**	**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

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When a specimen is received in a blood collection tube that is either not provided by the testing laboratory or not certified as lead-free and the blood level is less than 5 micrograms/dL, the blood lead 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.	produce a falsely elevated result. **Guidance –** 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.
Blood Lead Sustaining Standard of Practice 10 (BL S10): Potential for Fingerstick Contamination Elevated capillary blood lead levels (greater than 5 micrograms/dL) shall be reported with a comment that capillary blood levels greater than 5 micrograms/dL may be due to contamination from lead found on the finger surface and require confirmation with venous blood.	**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. **Guidance –** 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.

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Blood Lead Sustaining Standard of Practice 11 (BL S11): 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 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 Sustaining Standard of Practice 12 (BL S12): Reporting In addition to the report requirements defined in Reporting Sustaining Standard of Practice 1 (Reporting S1): Report Content, the laboratory report must contain: a) the methodology used in analysis; and b) for test results on exposed adults, a reference interval of <5 ug/dL.	**Blood Lead Sustaining 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.

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Former Standard and Guidance	***Proposed Standard and Guidance***
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective August 5, 2016. Guidance – Refer to 10NYCRR Subpart 67-3, for additional blood lead reporting requirements. Contact information for reporting blood lead is also found in Public Health Reporting Sustaining Standard of Practice 1 (PH S1). Laboratories using lead analyzers that are based on single-use, disposable sensors, i.e., ASV screen-printed electrode technology, must follow these standards. **Reference**: Guidelines for Measuring Lead in Blood Using Point of Care Instruments, Advisory Committee on Childhood Lead Poisoning Prevention, October 24, 2013. http://www.cdc.gov/nceh/lead/ACCLPP/20131024_POCguidelines_final.pdf	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 Sustaining Standard of Practice 1 (BLS S1): Materials Contamination Control The laboratory shall implement procedures to ensure that materials used for blood lead collection and processing are free from significant lead contamination.	**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. **Guidance –**

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Guidance – Significant lead contamination refers to an amount of lead that would change the blood lead level by more than 1 microgram/dL. Blood collection tubes should be lot-tested, certified as lead-free, or manufacturer-certified for trace element use to ensure that containers are free from lead contamination. Collection tubes are suitable for use when the mean lead concentration or difference in blood lead is less than or equal to 0.5 micrograms/dL. Collection materials such as alcohol swabs and blood containers should be lead-free. The laboratory should inform clients of proper collection techniques, including the importance of patient hand washing prior to collection of capillary specimens. Glassware and plastic ware used during the analysis should be acid-washed (e.g., in 10% (by volume) nitric acid). Alternatively, disposable glassware and plastic ware should be verified as contamination-free by randomly checking materials by lot. 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.	Significant lead contamination refers to an amount of lead that would change the blood lead level by more than 0.25 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 0.25 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 Sustaining Standard of Practice 2 (BLS S2): Processing Contamination Control To minimize lead contamination during specimen collection and testing: a) work shall be performed in a clean area; and, b) specimen aliquots shall be protected from dust contamination before and during analysis. **Guidance –** 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 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. **Guidance –** 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 Sustaining Standard of Practice 3 (BLS 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 lead-free tube under clean conditions before any other processing or testing of the specimen. **Guidance –** Specimen contamination from other testing areas may be minimized by implementing this protocol. As an alternative, the test for blood lead can be completed prior to other testing.	**Standard deleted**

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Blood Lead ASV Sensors Sustaining Standard of Practice 4 (BLS S4): Calibration The laboratory shall perform instrument calibration in accordance with the manufacturer's requirements.	**Standard deleted** **Required under Test Performance Specification Standard of Practice 1**
Blood Lead ASV Sensors Sustaining Standard of Practice 5 (BLS S5): 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 during collection. Capillary blood specimens with visible clots shall be rejected as unsatisfactory for analysis **Guidance –** 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 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 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. **Guidance –** 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 Sustaining Standard of Practice 6 (BLS S6): Use of Venous Blood When using a venous blood specimen for the analysis, the laboratory shall: a) Use blood tubes containing either ethylenediaminetetraacetic acid (EDTA) or heparin	**Standard deleted**

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as anticoagulants during blood collection; b) reject specimens for anodic stripping voltammetry (ASV) analysis that are in EDTA tubes and are less than half full; c) use tan topped tubes (certified lead free), royal blue topped tubes containing EDTA (certified for a limited number of trace elements including lead) or other tubes, containing an anti- coagulant, which have been tested and found to be suitable for blood lead measurements; d) reject blood specimens with visible clots. **Guidance –** Venous blood is the preferred specimen for blood lead testing purposes. Refer to manufacturer's insert for instructions on sample mixing. Make sure to thoroughly mix the blood before withdrawing an aliquot for processing.	
Blood Lead ASV Sensors Sustaining Standard of Practice 7 (BLS S7): Repeat Analysis All specimens which initially result in blood lead levels greater than or equal to 5 micrograms/dL shall be reanalyzed a second time if the volume of the original specimen permits. Use the average of the two consecutive test results to determine whether the discrepancy is large enough (see guidance for definitions) to require a third analysis. When large discrepancies are obtained between two consecutive test results, the laboratory must either:	**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: i. if large discrepancies are obtained between two

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a) perform a third analysis; or; b) report test results as inconclusive and add a comment that there was insufficient specimen to repeat the analysis. **Guidance –** A new aliquot from the original specimen should be used for the reanalysis. Specimen volume for capillary specimens may be insufficient for retesting purposes. In this case, report initial result and refer patient for confirmatory testing (See BLS S9). Large discrepancies between two consecutive tests are defined as differences exceeding 3 µg/dL for blood lead levels 5 to 20 µg/dL; 4 µg/dL for values 21 to 40; or 10% for values exceeding 40 µg/dL. In these cases, the specimen should be analyzed a third time, the outlier result should be discarded and either report the average or the first obtained of the remaining results. For any result exceeding 5 µg/dL, or if there is any uncertainty in the validity of the test, the patient should be referred for confirmatory testing (See BLS S10).	(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. **Guidance –** 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 results.
Blood Lead ASV Sensors Sustaining Standard of Practice 8 (BLS S8): Reporting Potential Contamination If a specimen is received in a blood collection container that is not certified for blood lead testing, and the result is above the reference value (≥ 5µg/dL), the report shall indicate that the use of unverified containers might	**Standard deleted**

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produce a falsely elevated result. **Guidance –** When a specimen is received in a blood collection tube that is either not provided by the testing laboratory or not certified as lead-free and the blood level is less than 5 micrograms/dL, the blood lead 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.	
Blood Lead ASV Sensors Sustaining Standard of Practice 9 (BL S9): Potential for Fingerstick Contamination Elevated capillary blood lead levels (greater than 5 micrograms/dL) shall be reported with a comment that capillary blood levels greater than 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 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 Sustaining Standard of Practice 10 (BLS S10): Confirmatory Testing with LeadCare and/or LeadCare II When blood lead concentrations greater than or equal to 5 micrograms/dL are obtained from a venous sample the laboratory must either:	**Standard deleted**

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a) if sufficient sample remains, refer the specimen to a NYS- permitted laboratory holding the permit category of Toxicology – Blood Lead - Comprehensive for confirmatory testing by a high complexity reference method (ICP-MS or GFAAS); or b) indicate on the report the method used and that the result needs to be confirmed by a high complexity reference method (ICP-MS or GFAAS). **Guidance –** a) An unopened venous specimen is preferable for confirmatory testing. When this is not possible or feasible (e.g. with young children), and the confirmed result is also elevated, the confirming laboratory can acknowledge the issue on the test report. Test result comment example: "The test specimen may have been compromised during previous testing. Result should be confirmed with another venous blood specimen." b) Preliminary results may be released with a comment that results of confirmatory testing by a high complexity reference method are pending. b) Examples of reference methods include high complexity tests such as inductively coupled mass spectrometry (ICP-MS) and graphite furnace atomic absorption spectrometry (GFAAS). b) The following comment can be used on laboratory test reports to clinical health care providers: "For children 5 years old and younger, blood lead levels ≥5 µg/dl indicate that they may have been exposed to lead at	

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levels higher than most children. The blood lead level should be confirmed using a venous blood sample and a NYS-permitted high complexity analytic method according the recommendations of the CDC Advisory Committee on Childhood Lead Poisoning Prevention. Since no safe BLL in children has been identified, no detectable level should be considered 'normal'."	
Blood Lead ASV Sensors Sustaining Standard of Practice 11 (BLS S11): Confirmatory Testing with LeadCare Plus or LeadCare Ultra When blood lead concentrations greater than or equal to 40 micrograms/dL are obtained from a venous sample the laboratory must either: a) if sufficient venous blood remains, refer the specimen to a NYS- permitted laboratory holding the permit category of Toxicology – Blood Lead - Comprehensive for confirmatory testing by a high complexity reference method (ICP-MS or GFAAS); or b) indicate on the report the method used and that the result needs to be confirmed by a high complexity reference method (ICP-MS or GFAAS). **Guidance –** a) An unopened venous specimen is preferable for confirmatory testing. When this is not possible or feasible (e.g. with young children), and the confirmed result is also elevated, the confirming laboratory can acknowledge the issue on the test report. Test result	**Standard deleted**

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comment example: "The test specimen may have been compromised during previous testing. Result should be confirmed with another venous blood specimen." a) Preliminary results may be released with a comment that results of confirmatory testing are pending. b) Examples of reference methods include high complexity tests such as inductively coupled mass spectrometry (ICP-MS) and graphite furnace atomic absorption spectrometry (GFAAS). b) The following comment can be used on laboratory test reports to clinical health care providers: "For children 5 years old and younger, blood lead levels ≥5 µg/dl indicate that they may have been exposed to lead at levels higher than most children. The blood lead level should be confirmed using a venous blood sample and a NYS-permitted high complexity analytic method according the recommendations of the CDC Advisory Committee on Childhood Lead Poisoning Prevention. Since no safe BLL in children has been identified, no detectable level should be considered 'normal'."	

Toxicology	
Erythrocyte Protoporphyrin	
Former Standard and Guidance	***Proposed Standard and Guidance***
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	**Deleted**
Erythrocyte Protoporphyrin Standard 1 (EP S1) Blood specimens with visible clots shall be rejected as unsatisfactory for analysis.	**Standard deleted**
Erythrocyte Protoporphyrin Standard 2 (EP S2) Specimens shall be protected from exposure to light. **Guidance –** Venous specimen collection tubes should be wrapped in aluminum foil. For extraction methods, analysis should be performed under subdued light.	**Standard deleted**
Erythrocyte Protoporphyrin Standard 3 (EP S3) If specimens are routinely analyzed for erythrocyte protoporphyrin as a single replicate only, all specimens which initially result in erythrocyte protoporphyrin levels greater than or equal to 35 µg/dL shall be repeated a second time, and in addition, a third analysis shall be performed when: a) large discrepancies are obtained between two consecutive results; or,	**Standard deleted**

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b) initial test results are greater than 100 µg/dL. **Guidance –** If the difference in results between the first and second specimen exceeds 15% for values of 35 to 100 µg/dL, the specimen should be analyzed a third time. The outlier result should be discarded and the two remaining values averaged and reported.	