# *Toxicology*

# *Blood Lead – Comprehensive Testing*

| Standard | 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.<br><br>Adopted June 13, 2014, Effective July 14, 2014 | Refer to 10NYCRR Part 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). |
| **Blood Lead Sustaining Standard of Practice 1 (BL S1): Materials Contamination Control**<br>The laboratory shall 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 1 microgram/dL.<br><br>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.<br><br>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.<br><br>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. |

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# *Blood Lead – Comprehensive Testing*

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| **Blood Lead Sustaining Standard of Practice 2 (BL S2): Processing Contamination Control**<br>To minimize lead contamination during specimen collection and testing:<br>a) work shall be performed in a clean area; and,<br>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/or other trace metals, and is regularly cleaned by wet wiping flat surfaces.<br>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). |
| **Blood Lead Sustaining Standard of Practice 3 (BL S3): Order of Testing**<br>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. | Specimen contamination from other testing areas may be minimized by implementing this protocol.<br>As an alternative, the test for blood lead can be completed prior to other testing. |
| **Blood Lead Sustaining Standard of Practice 4 (BL S4): Calibration**<br>The laboratory shall perform instrument calibration:<br>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<br>**b)** at least every eight hours of testing, unless longer instrument stability is validated. | |

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| **Blood Lead Sustaining Standard of Practice 5 (BL S5): Quality Control**<br>Three levels of quality control shall be included with each test run. | 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.<br>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. |
| **Blood Lead Sustaining Standard of Practice 6 (BL S6): Unacceptable Specimens**<br>Blood specimens with visible clots shall be rejected as unsatisfactory for analysis. | |
| **Blood Lead Sustaining Standard of Practice 7 (BL S7): Unacceptable ASV Specimens**<br>Venous specimens submitted for lead analysis by anodic stripping voltammetry (ASV) that are collected in EDTA tubes and are less than 50% of the recommended draw volume shall be rejected as unsatisfactory for analysis. | |

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| **Blood Lead Sustaining Standard of Practice 8 (BL S8): Repeat Analysis**<br><br>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 analysis shall be performed when:<br>a) large discrepancies are obtained between two consecutive results; or<br>b) initial test results are greater than 40 micrograms/dL. | A new aliquot from the original specimen should be used for the reanalysis.<br><br>Specimen volume for capillary samples may be insufficient for retesting purposes.<br><br>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. |
| **Blood Lead Sustaining Standard of Practice 9 (BL S9): Reporting Potential Contamination**<br><br>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. | 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.<br><br>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 Sustaining Standard of Practice 10 (BL S10): Potential for Fingerstick Contamination**<br>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 Sustaining Standard of Practice 11 (BL S11): Single Use Screening Devices**<br>Laboratories using point-of-care lead analyzers that are based on single-use, disposable sensors i.e., screen-printed electrode technology must follow the Blood Lead Standards for Screening Tests. | |

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# *Blood Lead – Screening Test Only*

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| 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.<br><br>Adopted June 13, 2014, Effective July 14, 2014 | Refer to 10NYCRR Part 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).<br><br>Laboratories using point-of-care (POC) lead analyzers, such as the LeadCare II, that are based on single-use, disposable sensors, i.e., screen-printed electrode technology, must follow these standards.<br><br>**Reference**:<br><br>Guidelines for Measuring Lead in Blood Using Point of Care Instruments, Advisory Committee on Childhood Lead Poisoning Prevention, October 24, 2013. |

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# *Blood Lead – Screening Test Only*

| Standard | Guidance |
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| **Blood Lead Screening Tests Sustaining Standard of Practice 1 (BLS S1): Materials Contamination Control**<br><br>The laboratory shall 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 1 microgram/dL.<br><br>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.<br><br>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.<br><br>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.<br><br>Should an unexpected number of elevated blood lead test results occur, contamination from materials and/or containers would merit an investigation.<br><br>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 – Screening Test Only*

| Standard | Guidance |
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| **Blood Lead Screening Tests Sustaining Standard of Practice 2 (BLS S2): Processing Contamination Control**<br>To minimize lead contamination during specimen collection and testing:<br>a) work shall be performed in a clean area; and,<br>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 Screening Tests Sustaining Standard of Practice 3 (BLS S3): Order of Testing**<br>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. | Specimen contamination from other testing areas may be minimized by implementing this protocol.<br>As an alternative, the test for blood lead can be completed prior to other testing. |
| **Blood Lead Screening Tests Sustaining Standard of Practice 4 (BLS S4): Calibration**<br>The laboratory shall perform instrument calibration in accordance with the manufacturer's requirements. | |
| **Blood Lead Screening Tests Sustaining Standard of Practice 5 (BLS S5): Use of Capillary Blood**<br>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 | 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. |

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# *Blood Lead – Screening Test Only*

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| **Blood Lead Screening Tests Sustaining Standard of Practice 6 (BLS S6): Use of Venous Blood**<br><br>When using a venous blood specimen for the analysis, the laboratory shall:<br><br>a) Use blood tubes containing either ethylenediaminetetraacetic acid (EDTA) or heparin as anticoagulants during blood collection;<br><br>b) reject specimens for anodic stripping voltammetry (ASV) analysis that are in EDTA tubes and are less than half full;<br><br>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;<br><br>d) reject blood specimens with visible clots. | Venous blood is the preferred specimen for blood lead testing purposes.<br><br>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 Screening Tests Sustaining Standard of Practice 7 (BLS S7): Repeat Analysis**<br><br>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:<br><br>a) perform a third analysis; or;<br><br>**b)** report test results as inconclusive and add a comment that there was insufficient specimen to repeat the analysis. | 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).<br><br>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). |

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# *Blood Lead – Screening Test Only*

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| **Blood Lead Screening Tests Sustaining Standard of Practice 8 (BLS S8): Reporting Potential Contamination**<br>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. | 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.<br>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 – Screening Test Only*

| Standard | Guidance |
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| **Blood Lead Screening Tests Sustaining Standard of Practice 9 (BLS S9): Confirmatory Testing**<br><br>When blood lead concentrations greater than or equal to 5 micrograms/dL are obtained the laboratory must either:<br><br>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 method categorized as a high complexity test; or<br><br>b) request a venous blood specimen from the provider for confirmatory testing; or<br><br>c) indicate on the report the method used, that the result is for screening purposes only, and that the result needs to be confirmed by a reference method. | 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."<br><br>a) Preliminary results may be released with a comment that results of confirmatory testing are pending.<br><br>c) Examples of reference methods include high complexity tests such as inductively coupled mass spectrometry (ICP-MS) and graphite furnace atomic absorption spectrometry (GFAAS).<br><br>c) 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'." |

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# *Blood Lead – Screening Test Only*

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| **Blood Lead Screening Tests Sustaining Standard of Practice 10 (BLS S10): Method Comparison**<br>When specimens have been referred for confirmatory testing, laboratories must compare and maintain a log of blood lead results obtained from their point-of-care (POC) device(s) with results reported using the confirmatory reference method. | Differences in results greater than 3 µg/dL for blood lead levels 5 to 20 µg/dL; 4 µg/dL for values 21 to 40 µg/dL; or 10% for values exceeding 40 µg/dL require further investigation.<br>A review of competency assessments of testing personnel as well as data from quality control and proficiency testing can provide insights on testing performance. |

# *Toxicology*

# *Erythrocyte Protoporphyrin*

| Standard | 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. | |
| **Erythrocyte Protoporphyrin Standard 1 (EP S1)**<br><br>Blood specimens with visible clots shall be rejected as unsatisfactory for analysis. | |
| **Erythrocyte Protoporphyrin Standard 2 (EP S2)**<br><br>Specimens shall be protected from exposure to light. | Venous specimen collection tubes should be wrapped in aluminum foil.<br><br>For extraction methods, analysis should be performed under subdued light. |
| **Erythrocyte Protoporphyrin Standard 3 (EP S3)**<br><br>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:<br><br>a) large discrepancies are obtained between two consecutive results; or,<br>b) initial test results are greater than 100 µg/dL. | 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. |

# *Toxicology*

# *Erythrocyte Protoporphyrin*

| Standard | Guidance |
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| **Erythrocyte Protoporphyrin Standard 4 (EP S4)**<br><br>If specimens are routinely analyzed for erythrocyte protoporphyrin in duplicate (or triplicate, etc.), e.g., with acid extraction methods, repeat testing shall be performed when a discrepancy exists between the replicate results. | Such a discrepancy is defined as:<br><br>a) A difference greater than 6 µg/dL between two replicate values for erythrocyte protoporphyrin values greater than 40 µg/dL; or,<br>b) A difference of 15% between two replicate values for erythrocyte protoporphyrin values of greater than or equal to 40 µg/dL. |