

Trace Elements		
Tag #	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.	
TE1	<p>Trace Elements Standard 1</p> <p>Initial validation of each element for each matrix shall include calculation of the method detection limit (MDL) according to the IUPAC convention of three standard deviations and based on the average of results from ten separate runs of the matrix blank or base level.</p>	<p>If a matrix blank is unavailable, such as for essential nutrient elements, an alternative approach can be used (e.g., use of a low-level QC, matrix-matched calibration standard, reagent blank, etc.).</p>
TE2	<p>Trace Element Standard 2</p> <p>The laboratory shall implement procedures to ensure that materials distributed for specimen collection and processing are free from significant contamination for each element tested.</p>	<p>To ensure that containers are free from contamination for each element tested, specimen collection tubes should be lot-tested and certified as trace element-free, or manufacturer-certified for trace element use.</p> <p>The laboratory should inform clients of proper collection techniques, including the importance of using appropriate trace element supplies</p> <p>Where appropriate, glassware and plastic ware used during the analysis should be acid-washed (e.g., in 10% nitric acid). Alternatively, disposable glassware and plastic ware should be verified as contamination-free by randomly checking materials by lot.</p>

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<p>TE3a</p> <p>TE3b</p>	<p>Trace Element Standard 3</p> <p>To minimize contamination errors during specimen collection and testing:</p> <p>a) work shall be performed in a clean area; and,</p> <p>b) specimen aliquots shall be protected from dust contamination before and during analysis.</p>	<p>a) Clean area refers to space that is dedicated to testing for trace elements, and is regularly cleaned by wet wiping flat surfaces.</p> <p>b) If a 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)</p>
<p>TE4</p>	<p>Trace Element Standard 4</p> <p>If venous blood specimens are collected for multiple analyses including trace element testing, a volume sufficient for the initial trace element test and any repeat analysis should be transferred to a trace element-free tube under clean conditions before any other processing or testing of the specimen.</p>	<p>Implementing this protocol may minimize specimen contamination from other testing areas.</p>
<p>TE5a</p> <p>TE5b</p> <p>TE5c</p>	<p>Trace Elements Standard 5</p> <p>On each day of testing, the laboratory must run a calibration curve that:</p> <p>a) includes a blank and at least 3 calibration standards;</p> <p>b) is matrix matched to the specimens being tested, unless validation studies indicate the absence of matrix effects; and</p> <p>c) is run at least every eight hours of testing, unless longer instrument stability is validated.</p>	<p>b) Dilution of a sample prior to analysis may not eliminate matrix effect. Validation studies must be performed to verify that there is no change in the slope of the calibration if aqueous standards are used</p> <p>c) Less stable methods may require more frequent calibration.</p>

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	<p>Trace Element Standard 6</p> <p>The laboratory shall:</p>	
TE6a	a) ensure that the two levels of quality control in each test run for all non-essential toxic elements, include a normal and abnormal-high concentration;	
TE6b	b) use matrix matched material;	
TE6c	c) run at least one level of quality control at the end of each batch of specimens; and	c) a batch is an auto sampler tray or carousel.
TE6d	d) adjust the frequency of calibration based on quality control results.	
	<p>Trace Element Standard 7</p> <p>Whole blood specimens with visible clots, or urine specimens with visible blood or fecal materials, shall be rejected as unsatisfactory for analysis.</p>	
TE7		

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	<p>Trace Element Standard 8</p> <p>All trace element results that are above or below the laboratory's defined action threshold must be verified by repeat analysis. The laboratory shall:</p>	<p>A new aliquot from the original specimen should be used when reanalysis is performed.</p> <p>The action threshold is defined as that level where clinical intervention would be expected. For many trace elements, where there is no consensus on the clinical threshold for concern, the laboratory must define one and should be based on toxicity, deficiency or both.</p> <p>Repeat analysis is not required for values that fall within the normal reference interval. For non-essential elements, only values that exceed the upper threshold need to be repeated, while for essential elements, values that are either above the upper threshold (abnormal-high) or below the lower threshold (abnormal-low), must be repeated.</p>
TE8a	a) define action thresholds for abnormal-high and, where necessary, abnormal-low trace element levels except for those elements reportable under 10NYCRR Sections 22.6 and 22.7;	
TE8b	b) establish criteria for the maximum discrepancy allowable which is consistent with proficiency testing performance criteria; and	
TE8c	c) perform a third analysis when the discrepancy between the first two results is greater than the maximum allowed in (b) above.	
	<p>Trace Element Standard 9</p> <p>When a specimen is received in a collection container that is not certified as trace element-free, the report shall indicate that a non-certified trace element-free specimen collection was used and might produce a falsely elevated result.</p>	<p>When a specimen is received in a collection tube that is either not provided by the testing laboratory or not certified as trace element-free, the trace element result can be reported without comment when the element has no lower action level and the result is below the high action level.</p>
TE9		

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TE10	<p>Trace Elements Standard 10</p> <p>Laboratories shall report to NYS DOH Heavy Metals Registry all elevated levels of reportable metal as provided in 10NYCRR Sections 22.6 and 22.7.</p>	<p>Laboratories wishing to report electronically to NYS DOH may call the ECLRS Help desk at 1-866-325-7743 for information.</p> <p>To report by mail, contact Childhood Lead Poisoning Prevention Program at 518-473-4602.</p> <p>Copies of the regulation are available at www.wadsworth.org/labcert/regaffairs/index.htm.</p> <p>Laboratories must report to NYS DOH:</p> <ul style="list-style-type: none"> ➤ blood cadmium concentrations greater than or equal to 10 ng/ml (10 µg/L) and urine cadmium concentrations greater than or equal to 5 µg/L; ➤ blood mercury concentrations greater than or equal to 5 ng/ml (5 µg/L) and urine mercury concentrations greater than or equal to 20 ng/ml (20 µg/L); and ➤ urine arsenic concentrations greater than or equal to 50 µg/L.
TE11	<p>Trace Elements Standard 11</p> <p>The laboratory shall use urine, whole blood or serum/plasma for testing. Other matrices such as hair, nails or packed red cells shall be used only with the written approval of the Department.</p>	<p>Validation studies for matrices other than urine, whole blood and serum/plasma must be submitted for review and must be approved prior to offering testing. Please refer to the Submission Guidelines – Trace Elements when submitting a validation package. Guidelines are posted on the CLEP website at www.wadsworth.org/labcert/clep/clep.html</p>

Blood Lead		
Tag #	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.	Refer to Part 67, Subpart 67-3, of Title 10 NYCRR for additional blood lead reporting requirements. Contact information for reporting blood lead is also found in Public Health Reporting Sustaining Standard of Practice 1.
BL1	<p>Blood Lead Standard 1</p> <p>The laboratory shall implement procedures to ensure that materials used for blood lead collection and processing are free from significant lead contamination.</p>	<p>Significant lead contamination refers to an amount of lead that would change the blood lead level by more than 1 μg/dL.</p> <p>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 equal to or greater than 0.5 μg/dL.</p> <p>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.</p> <p>Glassware and plastic ware used during the analysis should be acid-washed (e.g., in 10% nitric acid). Alternatively, disposable glassware and plasticware should be verified as contamination-free by randomly checking materials by lot.</p>
BL2a BL2b	<p>Blood Lead Standard 2</p> <p>To minimize lead contamination during specimen collection and testing:</p> <p>a) work shall be performed in a clean area; and,</p> <p>b) specimen aliquots shall be protected from dust contamination before and during analysis.</p>	<p>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.</p> <p>b) If a class 100 clean room is unavailable, specimen aliquots should be protected by use of dust protection devices (e.g., furnace AAA carousels containing unanalyzed samples should be protected with dust covers before and during analysis).</p>

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BL3	<p>Blood Lead Standard 3</p> <p>If venous 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.</p>	<p>Specimen contamination from other testing areas may be minimized by implementing this protocol.</p> <p>Capillary blood specimens are used for screening purposes and are not covered by this standard since contamination errors will be corrected when the follow up venous blood specimen is analyzed.</p>
BL4a BL4b	<p>Blood Lead Standard 4</p> <p>The laboratory shall perform instrument calibration:</p> <p>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,</p> <p>b) at least every eight hours of testing, unless longer instrument stability is validated.</p>	
BL5	<p>Blood Lead Standard 5</p> <p>Three levels of quality control shall be included with each test run.</p>	<p>The controls should include a low (less than 10 µg/dL), an intermediate (20-30 µg/dL), and a high (greater than 40 µg/dL) level material.</p>
BL6	<p>Blood Lead Standard 6</p> <p>Blood specimens with visible clots shall be rejected as unsatisfactory for analysis.</p>	
BL7	<p>Blood Lead Standard 7</p> <p>Venous specimens submitted for lead analysis by anodic stripping voltammetry that are collected in EDTA tubes and are less than 50% of the recommended draw volume shall be rejected as unsatisfactory for analysis.</p>	

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<p>BL8a</p> <p>BL8b</p>	<p>Blood Lead Standard 8</p> <p>All specimens which initially result in blood lead levels greater than or equal to 10 µg/dL shall be repeated a second time, and in addition, a third analysis shall be performed when:</p> <p>a) large discrepancies are obtained between two consecutive results; or,</p> <p>b) initial test results are greater than 60 µg/dL.</p>	<p>A new aliquot from the original specimen should be used for the reanalysis.</p> <p>Specimen volume for capillary samples may be insufficient for retesting purposes.</p> <p>If the difference in results between the first and second specimen exceeds 2 □g/dL for blood lead levels 8 to 20 □g/dL; 3 □g/dL for values 21 to 30 □g/dL; 4 □g/dL for values 31 to 40 □g/dL, or 10% for values of 41 to 60 □g/dL, the specimen should be analyzed a third time. The outlier result should be discarded and the two remaining values averaged and reported.</p>
<p>BL9a</p> <p>BL9b</p>	<p>Blood Lead Standard 9</p> <p>When a specimen is received in a blood collection tube that is not certified as lead-free and the blood lead level is greater than or equal to 10 µg/dL, the report shall indicate that:</p> <p>a) the use of non-certified lead-free tubes might produce a falsely elevated result; and,</p> <p>b) repeat testing is recommended prior to initiating chelation therapy or conducting environmental investigations of potential lead sources.</p>	<p>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 10 µg/dL, the blood lead result can be reported without comment.</p> <p>Royal blue-top trace element tubes are acceptable alternatives to lead-free certified tubes and need not be footnoted in the test report.</p>
<p>BL10</p>	<p>Blood Lead Standard 10</p> <p>Elevated capillary blood levels (greater than 10 µg/dL) shall be reported with a comment that capillary blood levels greater than 10 µg/dL may be due to contamination from lead found on the finger surface and require confirmation with venous blood.</p>	

Erythrocyte Protoporphyrin (EP)		
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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.	
EP1	Erythrocyte Protoporphyrin Standard 1 Blood specimens with visible clots shall be rejected as unsatisfactory for analysis.	
EP2	Erythrocyte Protoporphyrin Standard 2 Specimens shall be protected from exposure to light.	Venous specimen collection tubes should be wrapped in aluminum foil. For extraction methods, analysis should be performed under subdued light.
EP3a EP3b	Erythrocyte Protoporphyrin Standard 3 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, 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.

Erythrocyte Protoporphyrin (EP)

Tag #	Standard	Guidance
EP4	<p>Erythrocyte Protoporphyrin Standard 4</p> <p>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.</p>	<p>Such a discrepancy is defined as:</p> <p>a) a difference greater than 6 μg/dl between two replicate values for erythrocyte protoporphyrin values greater than 40 μg/dl; or,</p> <p>b) a difference of 15% between two replicate values for erythrocyte protoporphyrin values of greater than or equal to 40 μg/dl.</p>