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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>Effective July 14, 2014 | **Deleted** |
| **Trace Elements Sustaining Standard of Practice 1 (TE S1): Method Detection Limit Calculation**<br><br>Initial validation of each element for each matrix shall include calculation of the method detection limit (MDL), and shall be based on the average of results from ten separate runs of the matrix blank or base level.<br><br>**Guidance –**<br><br>Calculation of the method detection limit may be based on the IUPAC convention of three standard deviations.<br><br>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.). | **Trace Elements Standard of Practice 1 (TE S1): Method Detection Limit Calculation**<br><br>Initial validation of each trace element for each biological matrix must include calculation of the method detection limit (LOD) and must be based on the average of results from at least seven (7) independent runs of a matrix blank or base level.<br><br>**Guidance –**<br><br>Calculation of the method LOD may be based on the ISO/IUPAC harmonized protocol of three (3) standard deviations.<br><br>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.). |
| **Trace Element Sustaining Standard of Practice 2 (TE S2): Materials Contamination Control**<br><br>The laboratory shall implement procedures to ensure that materials distributed for specimen collection and processing are free from significant contamination for each element tested.<br><br>**Guidance –**<br><br>To ensure that containers are free from contamination for each element tested, specimen collection tubes should be lot-tested | **Trace Element Standard of Practice 2 (TE S2): Materials Contamination Control**<br><br>The laboratory must implement procedures to ensure that materials distributed for specimen collection and supplies used for processing in the laboratory are free from significant contamination for each element tested.<br><br>**Guidance –**<br><br>To ensure that tubes or containers are free from contamination |

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| and certified as trace element-free, or manufacturer-certified for trace element use.<br><br>The laboratory should inform clients of proper collection techniques, including the importance of using appropriate trace element supplies<br><br>Where appropriate, 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. | for each element tested, specimen collection tubes should be lot-tested and certified as free from significant trace element contamination, or manufacturer-certified for trace element use.<br><br>Where appropriate, laboratory supplies (e.g., flasks, autosampler tubes, and pipet tips), used for trace element analysis 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. |
| **Trace Element Sustaining Standard of Practice 3 (TE S3): Processing Contamination Control**<br><br>To minimize contamination errors during specimen collection and testing:<br><br>a) work shall be performed in a clean area; and,<br><br>b) specimen aliquots shall be protected from dust contamination before and during analysis.<br><br>**Guidance –**<br><br>a) Clean area refers to space that is dedicated to testing for trace elements, and is regularly cleaned by wet wiping flat surfaces.<br><br>b) If 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) | **Trace Element Standard of Practice 3 (TE S3): Processing Contamination Control**<br><br>To minimize contamination errors during trace element analysis:<br><br>a) work must be performed in a dedicated clean area; and<br><br>b) specimen aliquots must be protected from dust contamination before and during analysis.<br><br>**Guidance –**<br><br>a) Clean area refers to space that is dedicated to testing for trace elements, and is regularly cleaned by wet wiping flat surfaces.<br><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; ICP-MS autosamplers should be protected from airborne contamination.) |

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| **Trace Elements Sustaining Standard of Practice 4 (TE S4): Order of Testing**<br>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.<br>**Guidance –**<br>Implementing this protocol may minimize specimen contamination from other testing areas.<br>As an alternative, the testing for trace elements may be completed prior to other testing. | **Trace Elements Standard of Practice 4 (TE S4): Order of Testing**<br>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 must be transferred to a tube or container that is certified as free from significant trace element contamination trace element-free tube under clean conditions before any other processing or testing of the specimen.<br>**Guidance –**<br>Implementing this protocol may minimize inadvertent specimen contamination from other clinical testing areas.<br>As an alternative, the testing for trace elements may be completed prior to other clinical testing. |
| **Trace Elements Sustaining Standard of Practice 5 (TE S5): Calibration**<br>On each day of testing, the laboratory must run a calibration curve that:<br>a) includes a blank and at least 3 calibration standards;<br>b) is matrix matched to the specimens being tested, unless validation studies indicate the absence of matrix effects; and<br>c) is run at least every eight hours of testing, unless longer instrument stability is validated.<br>**Guidance –**<br>b) Dilution of a sample prior to analysis may not eliminate | **Trace Elements Standard of Practice 5 (TE S5): Calibration Protocols**<br>On each day of testing, the laboratory must run a calibration curve that:<br>a) includes a blank and at least three (3) calibration standards;<br>b) is matrix matched to the specimens being tested, unless validation studies indicate the absence of matrix effects; and<br>c) is re-calibrated at least every eight (8) hours of testing, unless longer instrument stability is validated, but not longer than twenty-four (24) hours. |

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| matrix effect. Validation studies must be preformed to verify that there is no change in the slope of the calibration if aqueous standards are used<br>c) Less stable methods may require more frequent calibration. | **Guidance –**<br>b) Dilution of a specimen 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 curve if aqueous standards are used.<br>c) Less stable instruments or methods may require more frequent calibration. |
| **Trace Elements Sustaining Standard of Practice 6 (TE S6): Quality Control**<br>The laboratory shall:<br>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;<br>b) use matrix matched material;<br>c) run at least one level of quality control at the end of each batch of specimens; and<br>d) adjust the frequency of calibration based on quality control results.<br>**Guidance –**<br>c) a batch is an auto sampler tray or carousel. | **Trace Elements Standard of Practice 6 (TE S6): Quality Control**<br>The laboratory must:<br>a) ensure that at least two (2) levels of quality control (QC) are included in each test run for all non-essential toxic elements, e.g., normal and abnormal-high concentration;<br>b) ensure three (3) levels of QC for the essential trace elements, QC must include abnormal low, normal and abnormal high;<br>c) use matrix-matched QC materials;<br>d) run at least one (1) level of QC at the end of each batch of specimens; and<br>e) adjust the frequency of instrument re-calibration based on quality control data.<br>**Guidance –**<br>d) an analytical batch is the maximum number of samples that can be run with an autosampler (ICP-MS) or carousel tray (GFAAS). |

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| **Trace Elements Sustaining Standard of Practice 7 (TE S7): Unacceptable Specimens**<br><br>Whole blood specimens with visible clots, or urine specimens with visible blood or fecal materials, shall be rejected as unsatisfactory for analysis. | **Trace Elements Standard of Practice 7 (TE S7): Unacceptable Specimens**<br><br>In addition to the requirements in Specimen Processing Standard of Practice 4, whole blood specimens with visible clots, or urine specimens with visible blood or fecal materials, must be rejected as unsatisfactory for analysis. |
| **Trace Elements Sustaining Standard of Practice 8 (TE S8): Repeat Analysis**<br><br>All trace element results that are above or below the laboratory's defined action threshold must be verified by repeat analysis. The laboratory shall:<br><br>a) define action thresholds for abnormal-high and, where necessary, abnormal-low trace element levels except for those elements reportable under 10NYCRR Parts 22.6 and 22.7;<br><br>b) establish criteria for the maximum discrepancy allowable which is consistent with proficiency testing performance criteria; and<br><br>c) perform a third analysis when the discrepancy between the first two results is greater than the maximum allowed in (b) above.<br><br>**Guidance –**<br><br>A new aliquot from the original specimen should be used when reanalysis is performed.<br><br>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 | **Trace Elements Standard of Practice 8 (TE S8): Repeat Analysis**<br><br>All trace element results that are above the laboratory's definition of abnormally high (or below the definition of abnormally low) must be verified by repeat analysis.<br><br>The laboratory must:<br><br>a) define trace element concentrations for abnormal-high and, where appropriate, abnormal-low;<br><br>b) define critical call values for trace elements where appropriate;<br><br>c) establish reportable protocols for lead, cadmium, mercury and arsenic consistent with the requirements of 10NYCRR Parts 22.6 and 22.7 (NYS Heavy Metals Registry) and report results, as applicable, according to Public Health Reporting Standard of Practice 1;<br><br>d) establish criteria for the maximum discrepancy allowable on duplicate measurements that are consistent with the expected method repeatability; and<br><br>e) perform a third analysis (triplicate) when the discrepancy between the first two (2) results exceeds |

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| concern, the laboratory must define one and should be based on toxicity, deficiency or both.<br><br>Repeat analysis is not required for values that fall within the normal reference interval. For non-essential trace 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. Note that a lower threshold (abnormal- low) is not required for "non-essential" trace elements. | the maximum allowed in (c) above.<br><br>**Guidance –**<br><br>A new aliquot from the original specimen should be used when a repeat analysis is performed.<br><br>A clinical action threshold is defined as that level where clinical intervention would be recommended. Where no action threshold has been established (e.g., biomonitoring studies), the laboratory may define elevated based on published or laboratory derived data.<br><br>Repeat analysis is not normally required for values that fall within the reference range. For non-essential trace elements such as mercury and arsenic, 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. Note that a lower threshold (abnormal-low) is not required for "non-essential" trace elements. |
| **Trace Elements Sustaining Standard of Practice 9 (TE S9): Reporting Potential Contamination**<br><br>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.<br><br>**Guidance –**<br><br>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 | **Trace Elements Standard of Practice 9 (TE S9): Reporting Potential Contamination**<br><br>In addition to the requirements in Reporting Standard of Practice 2, when a specimen is received in a collection tube or container that is not certified for trace elements, the report must state that a non-certified trace element specimen collection tube was used and might produce a falsely elevated result.<br><br>**Guidance –**<br><br>When a specimen is received in a collection tube that is either not pre-certified by the testing laboratory or not certified by the manufacturer for trace elements, the test result can be reported |

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| result is below the high action level. | without comment when the result is within the reference range. |