NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Adopted Revision to Forensic Toxicology Standards
Adopted and Effective October 1, 2017

Any Forensic Toxicology standards not addressed here remain in effect.
(changes are underlined)

Adopted Standard	Adopted Guidance
Forensic Toxicology Sustaining Standard of Practice 27 (FT S27): Urine SVT Calibration and QC Requirements For **urine specimen validity testing**, each batch of donor specimens must include the following calibrators and controls for tests performed by the laboratory as follows: **Creatinine** a) creatinine initial test: i) a calibrator at 2 mg/dL; ii) a control in the range of 1.0 mg/dL to 1.5 mg/dL; iii) a control in the range 3 mg/dL to 20 mg/dL; and, iv) a control in the range 21 mg/dL to 25 mg/dL. b) creatinine confirmatory test: i) a calibrator at 2 mg/dL; ii) a control in the range of 1.0 mg/dL to 1.5 mg/dL; and iii) a control in the range 3 mg/dL to 4 mg/dL. c) the creatinine concentration must be measured to one decimal place on both the initial and confirmatory tests. **Specific Gravity** d) specific gravity initial and confirmatory tests: i) a calibrator at 1.0000; ii) a control targeted at 1.0020; iii) one control in the range 1.0040 to 1.0180; iv) one control greater than or equal to 1.0200 but not greater than 1.0250. e) the refractometer must display to a minimum four decimal places **pH** f) pH Screen: i) one control below the lower decision point in use, ii)one control in the pH range 4.5 to 9; and,	Laboratories that hold the Forensic Toxicology –Initial Testing Only permit may conduct tests for specimen validity; however, in accordance with Forensic Toxicology Sustaining Standard 16 (FT S16): Referral of Non-Negative Specimens, any specimen (including negatives) identified as adulterated, substituted or invalid must be forwarded to an approved laboratory for additional testing to confirm adulteration or substitution before any finding can be reported. Negative, dilute specimens need not be referred. Laboratories that hold the Forensic Toxicology – Initial Testing Only permit and conduct validity point-of-collection tests, each day testing is performed, at least one control that is normal for the specific validity test and one control that is abnormal must be tested. The results must be correct before donor specimens are tested. See Forensic Toxicology Sustaining Standard 12 (FT S12): Single-Use Device Quality Control. a) Donor specimens determined by the initial test to have a creatinine concentration less than 2 mg/dL must be repoured for confirmatory testing. e) Federal Mandatory Guidelines and the Department require the refractometer to display to four decimal places. f) pH Screening Assay: Colorimetric pH tests, dipsticks, and pH paper that have a narrow dynamic range and do not support the cutoffs for specimen adulteration (pH less than 3 or greater than or equal to 11) may be used only to determine if an initial pH validity test must be performed;

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iii)one control above the upper decision point in use. g) pH initial test (colorimetric): i) one calibrator at 4; ii) one calibrator at 11; iii) one control in the range of 3 to 3.8; iv) one control in the range 4.2 to 5; v) one control in the range of 5.0 to 9; vi) one control in the range of 10 to 10.8; vii) one control in the range of 11.2 to 12; h) pH initial test (pH meter): i) one calibrator at 3; ii) one calibrator at 7; iii) one calibrator at 10; iv) one control in the range of 3 to 3.8; v) one control in the range 4.2 to 5; vi) one control in the range of 10 to 10.8; vii) one control in the range of 11.2 to 12. i) pH initial or confirmatory test (pH meter test), when the screening result indicates that the pH is below the lower decision point in use: i) one calibrator at 4; ii) one calibrator at 7; iii) one control in the range of 3 to 3.8, iv) one control in the range 4.2 to 5. j) pH initial or confirmatory test (pH meter test), when the screening result indicates that the pH is above the upper decision point in use: i) one calibrator at 7; ii) one calibrator at 10; iii) one control in the range of 10 to 10.8; iv) one control in the range 11.2 to 12. **Nitrite** k) initial and confirmatory nitrite tests must have: i) a calibrator at the cutoff concentration, ii) a control without nitrite (i.e., certified negative urine), iii) one control in the range of 200 mcg/mL to 250 mcg/mL, and iv) one control in the range of 500 mcg/mL to 625 mcg/mL;	g) Colorimetric pH tests that have the dynamic range of 2 to 12 to support the 3 and 11 pH cutoffs must be capable of measuring pH to one decimal place. The pH meter may be used for the initial test, and where a pH screen was not performed to establish whether the specimen pH is high or low, the pH meter must be calibrated and quality control performed for the full range of pH.

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Oxidizing adulterant tests (other than nitrite): l) initial tests must include: i) an appropriate calibrator at the cutoff used by the laboratory for the compound of interest, ii) a control without the compound of interest (i.e., a certified negative control), and iii) at least one control with one of the compounds of interest at a measurable concentration; and m) confirmatory tests must: i) use a different analytical method than that used for the initial test, ii) include an appropriate calibrator, iii) include a control without the compound of interest (i.e., a certified negative control), and iv) include a control with the compound of interest at a measurable concentration.	l) The laboratory should design calibration and quality control protocols to be consistent with those provided in the Mandatory Guidelines for Federal Workplace Drug Testing Programs when detecting the presence of general oxidants, chromium (VI), halogens, glutaraldehyde, pyridine (pyridinium chlorochromate) and surfactants.
Forensic Toxicology Sustaining Standard of Practice 34 (FT S34): Reporting Criteria – Dilute Urine Specimen A urine specimen is reported dilute when the creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.	
Forensic Toxicology Sustaining Standard of Practice 35 (FT S35): Reporting Criteria – Substituted Urine Specimen A urine specimen is reported substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.	

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Forensic Toxicology Sustaining Standard of Practice 36 (FT S36): Reporting Criteria – Adulterated Urine Specimen A urine specimen is reported adulterated when: a) the pH is less than 4 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot; b) the nitrite concentration is greater than or equal to 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multiwavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot; or c) the presence of other adulterants is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.	
Forensic Toxicology Sustaining Standard of Practice 37 (FT S37): Reporting Criteria – Invalid Urine Specimen A urine specimen is reported invalid when: a) inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test; or the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is greater than or equal to 2 mg/dL on either or both the initial or confirmatory creatinine tests); b) the pH is greater than or equal to 4 and less than 4.5 or greater than or equal to 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;	

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c) the nitrite concentration is greater than or equal to 200 mcg/mL using a nitrite colorimetric test or greater than or equal to the equivalent of 200 mcg/ mL nitrite using a general oxidant colorimetric test for both the initial test and the confirmatory test or using either initial test and the nitrite concentration is greater than or equal to 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots; d) the possible presence of oxidants (Cr VI, pyridine, glutaraldehyde, halogens, surfactants) is detected by an initial test and a confirmatory test on a second aliquot, but the confirmatory test does not differ in analytic principle from the initial test; e) interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained); or, f) interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance.	