NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM
Crosswalk of Adopted Revision to Forensic Toxicology Standards

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

Current Standard	Current Guidance	Revised Standard	Revised 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 20 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 (1.000); ii) a control targeted at 1.0020 (1.002); iii) one control in the range 1.0040 (1.004) to 1.0180 (1.018);	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	**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. [1] 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;	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

iv) one control greater than or equal to 1.0200 (1.020) but not greater than 1.0250 (1.025). e) the refractometer must display to a minimum three decimal places.	specimens are tested. See Forensic Toxicology Sustaining Standard 12 (FT S12): Single-Use Device Quality Control.	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.	specimens are tested. See Forensic Toxicology Sustaining Standard 12 (FT S12): Single-Use Device Quality Control.
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, iii)one control above the upper decision point in use.	a) Donor specimens determined by the initial test to have a creatinine concentration less than 2 mg/dL must be repoured for confirmatory testing.	**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, iii)one control above the upper decision point in use.	a) Donor specimens determined by the initial test to have a creatinine concentration less than 2 mg/dL must be repoured for confirmatory testing.
g) pH initial test (colorimetric): i) one calibrator at 3; ii) one calibrator at 11; iii) one control in the range of 2 to 2.8; iv) one control in the range 3.2 to 4; v) one control in the range of 4.5 to 9; vi) one control in the range of 10 to 10.8; vii) one control in the range of 11.2 to 12;	e) Federal Mandatory Guidelines require the refractometer to display to four decimal places. The Department continues to allow the use of refractometers that display to three decimal places.	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;	e) Federal Mandatory Guidelines and the Department require the refractometer to display to four decimal places.
h) pH initial test (pH meter): i) one calibrator at 4; ii) one calibrator at 7; iii) one calibrator at 10; iv) one control in the range of 2 to 2.8; v) one control in the range 3.2 to 4; 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 2 to 2.8; iv) one control in the range 3.2 to 4.		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:		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) **i**nitial 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 400 mcg/mL, and iv) one control in the range of 500 mcg/mL to 625 mcg/mL. **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.		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) **i**nitial 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. **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.	

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 (1.001) but less than 1.0030 (1.003) on a single aliquot.	If a refractometer is used that reads to three decimal places, the specimen must have a specific gravity equal to 1.002 to be reported as dilute.	**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. **No Change.**	**Guidance removed.**
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 (1.001) or greater than or equal to 1.0200 (1.020) 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.		**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.	No change to guidance.
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 3 or greater than or equal to 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;		**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	No change to guidance.

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.		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 3 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; c) the nitrite concentration is greater than or equal to 200 mcg/mL using a nitrite		**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;	

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.		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.	