NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

COMMENTS and RESPONSES to PROPOSED CLINICAL TOXICOLOGY STANDARDS

The Proposed Standards in the areas of Toxicology – Forensic Toxicology were circulated for comment on July 13, 2017. The announcement was sent to NYS-permitted facilities that held or were in application for a permit (facilities). This distribution was by e-mail to the facility and laboratory contact person's e-mail address. The documents were posted to the CLEP website.

The comment period ended August 25, 2017. Two comments were received.

The standards are accepted and will be adopted with an effective of October 1, 2017.

Standard	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, 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;	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 require the refractometer to display to four decimal places. The Department continues to allow the use of refractometers that display to three 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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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.	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.
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;	
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:	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.

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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.	

Comment 1:

e) The requirement of the refractometer to display a minimum of four decimal places can be accomplished but requires the laboratory adequate time to perform additional method validation prior to implementation.

h) The proposed change to the calibration scheme (pH 4.0 to 4.0) would be burdensome on the laboratory as this calibration point deviates from previously established requirements form other regulated testing agencies; furthermore, the requirement of a control in the range of 3 to 3.8 would serve to verify that the multi-point calibration (pH 4, 7 10) is performing accurately.

RESPONSE 1:

This proposed change parallels the SAMHSA standard. (82 FR 7920 (p. 7955) (published 1/23/2017), Subpart K Section 11.18(c)(5)(i) Link: https://www.federalregister.gov/d/2017-00979/p-902).

Standard	Guidance
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 5 mg/dL but less than 20 mg/dL and the specific gravity greater than or equal to 1.0020, but less than 1.0030 on the primary (A) specimen.	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.

Comment 1:

The proposed change to the dilute specimen reporting criteria would be burdensome on the laboratory to differentiate as the pH ≤ 5.0 decision point is inconsistent with the previously established requirements from other regulated testing agencies; furthermore, the current standard of pH ≤ 2.0 currently encompasses the proposed decision point.

RESPONSE 1:

The proposed change has been withdrawn.