NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Adopted Revision to Forensic Toxicology Standards
Effective August 5, 2016

Any Forensic Toxicology standards not addressed here remain in effect.

Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 19 (FT S19): Confirmation Method Periodic Re-Validation In addition to the initial validation of confirmatory test methods, the laboratory shall demonstrate, annually thereafter, the following performance characteristics: a) accuracy and precision at the cutoff concentration; b) accuracy and precision at 40 percent of the cutoff concentration; c) upper limit of linearity; d) limit of detection; e) limit of quantification; f) analytical specificity; and, g) carryover.	Documentation of method validation, as required by Validation Sustaining Standard 2 (VAL S2): Use of Validated Procedures, must clearly state the study design, the analytical findings, conclusions, and source of specimens and how they were characterized. Limit of quantification means the lowest concentration of analyte that can be identified (mass spectrometric criteria for identification are met) and measured within assay performance specifications for accuracy. Limit of detection means the lowest concentration of analyte that can be identified (mass spectrometric criteria for identification are met), but not quantified within performance specifications (typically, +/- 20%). Analytical specificity validation should entail the analysis of validation materials that contain the target drug at 40% cutoff and potentially interfering drugs at high concentrations consistent with overdose.
Forensic Toxicology Sustaining Standard of Practice 23 (FT S23): Confirmation Method Quality Control Each batch of specimens for confirmatory testing shall contain, minimally, 10% calibrators and/or quality control samples as follows: a) at least one control certified to contain no drug or metabolite; b) at least one control with drug or metabolite concentration at 25 percent above the cutoff concentration; c) at least one control or calibration material with drug or metabolite concentration at or less than 40 percent of the cutoff concentration; and, d) a control to assess the efficiency of hydrolysis, where appropriate.	