Toxicology
Forensic Toxicology

The standards set forth below apply to the analysis of specimens collected from the human body for drugs and chemicals where the legal defensibility of laboratory services must be established and maintained. Relevant laboratory services include workplace drug testing programs and medico-legal investigations, including human performance testing and postmortem toxicology, where such medico-legal investigations are conducted by private sector laboratories. Public sector forensic toxicology laboratories must be approved under Executive Law, Article 49-B for services provided to the criminal justice system.

Laboratories engaged in the practice of forensic toxicology must be compliant with requirements under each of the following Fundamental Standards of Practice: Quality Management System; Human Resources; Facilities and Resource Management; Pre-Examination, Examination and Post-Examination Procedures; and Quality Assessment and Improvement. 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. Effective March 2008, FT S12 revised and effective July 14, 2014; FT S19 and FT S23 revised and effective August 5, 2016.	During the on-site visit, the surveyor will request a copy of a litigation package for a randomly selected positive donor sample to be submitted for Departmental review.

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Standard	Guidance
Specimen Collection and Handling, Laboratory Security Standards FT S1 through FT S9 apply to laboratories holding either an Initial Testing or Comprehensive Permit	
Forensic Toxicology Sustaining Standard of Practice 1 (FT S1): Specimen Collection Facility All collection sites from which the laboratory accepts donor specimens shall have the following: a) a clean surface for handling the specimen and suitable for completing the required paperwork; b) a secure temporary storage capability to maintain a specimen, including sealing of the specimen, until it is tested or shipped to the laboratory; c) a space to provide donor privacy appropriate to the specimen being collected; d) a means of restricting access to authorized personnel during the collection; e) ability to restrict access to collection supplies; f) ability to store records securely; and g) a complete SOPM on the collection and handling of donor specimens.	The laboratory shall have a written agreement with the collector, which may be another laboratory under permit, that defines the testing laboratory's procedures and requirements for specimen collection and chain of custody. A structured training and certification program provided by the laboratory to the collection sites should be considered to enhance the integrity of the specimen collection process. Where the testing laboratory provides the facilities for the collection of donor specimens, the laboratory director or designee shall verify through on-site quality audits that the collection site is appropriately designed and managed for compliance with this standard. Where collection sites are not operated by the testing laboratory, quality-audits of specimen submissions should be conducted and findings used for intervention when collection problems are identified.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 2 (FT S2): Specimen Collection Procedures The laboratory shall have an SOPM for specimen collection that minimally includes: a) a description of acceptable forms of verification of donor identity; b) The explanation and/or instructions to be given to the donor concerning the collection procedure; c) a description of the measures to be taken to remove opportunities for specimen adulteration or substitution; d) a clear statement that viewing of the specimen at all times by donor and collector prior to sealing the specimen container is required; e) a clear statement that use of tamper evident label/seal to secure the specimen, annotated by donor initials and date of collection by collector, is required; f) directions for completing the custody and control form (CCF) (test requisition); and g) directions for linkage of the specimen to the donor and the completed CCF.	Laboratories are encouraged to use the federal Department of Health and Human Services *Specimen Collection Handbook for Federal Workplace Drug Testing Programs* (available for download from the DHHS website, http://dwp.samhsa.gov) and the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs as guides in establishing policies and procedures for specimen collection. f) The custody and control form (CCF), when used as a test requisition, must 10 NYCRR Subpart 58-1.7 requirements, except that cross-reference to a standing order or client roster that allows identification of tests ordered for each donor may be used instead of listing tests on the CCF form. g) The signed CCF and the specimen container may be linked by bar-code or other unique identifier, preferably through use of evidence tape with the same unique number as on the CCF and affixed to the CCF for use at time of specimen collection.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 3 (FT S3): Specimen Acceptance Criteria The testing laboratory shall: a) monitor the completeness and adequacy of collection documents submitted with donor specimens; b) ensure that specimens are submitted for analysis in a sealed container, the seal of which is to be broken by the laboratory; c) ensure that the condition of the specimen container seal is documented upon receipt in the laboratory; d) notify collectors when problems are identified and document remediation; and, e) provide collectors a copy of the SOPM for specimen collection and training materials.	Monitoring compliance could be a QA indicator. The testing laboratory should ensure, to the extent practicable, that collectors are adequately trained on the collection procedure for each type of specimen, including donor identification and instruction, specimen identification, chain-of-custody, and record keeping. The laboratory should offer additional training to address a documented pattern of non-compliance with laboratory collection policies.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 4 (FT S4): Specimen Acceptance Criteria The laboratory shall develop criteria for the acceptability of donor specimens that are consistent with federal Workplace Drug Testing Program criteria. Such criteria shall be documented and available at collection and testing sites, and shall: a) identify the attributes of an acceptable specimen, including the amount of specimen, identification, temperature (urine), seal(s) condition, collector's signature, and complete documentation of chain-of-custody; and b) identify fatal flaws as including, but not limited to i. mismatch between the specimen ID number on the container and the number on the CCF; ii. lack of a specimen ID number on the container and/or CCF; iii. missing collector signature and printed name; iv. missing or broken tamper-evident seal on the specimen container; and v. insufficient specimen to conduct the required analyses. c) identify collection errors that can be recoverable through affidavit from the collector. d) describe course of action taken whenever the criteria for acceptability are not met.	These policies and procedures must be documented as part of the SOPM. a) The required amount of specimen should be adequate for retesting should a retest be ordered. b) CCFs that lack collector signature and/or documentation that specimen temperature was acceptable may be recoverable.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 5 (FT S5): Specimen Collection Recoverable Errors Specimens that fail to meet one or more criteria for acceptability shall not be tested, except that the laboratory may test such a specimen if: a) the specimen is not able to be re-collected under circumstances that duplicate those under which the rejected specimen was collected, considering the purpose of the testing, and the test findings are expected to be analytically sound and legally defensible; b) for urine specimens, the CCF does not document that specimen temperature was acceptable, the laboratory has requested a memorandum for record (MFR) from the collector stating that specimen temperature was within the acceptable range; c) the collector's signature is absent, the laboratory has requested a MFR signed by the collector attesting to his or her collection of the specimen; and, d) the CCF does not contain the name of the ordering physician, the laboratory has requested a MFR from the collector with the name of the physician.	a) For example, specimens for random drug testing can be recollected, while specimens obtained at the scene of an accident cannot be recollected. Incident-related specimens typically cannot be duplicated by a collection later in time. Fatal flaw exemptions for specimen rejection may include limited specimen amounts and missing collector identifiers. The test report must include a statement that acknowledges the collection flaws. b,d) The MFR should be on record with the laboratory prior to reporting test findings, and should be retained attached to the CCF. Test findings may be reported with comment if the urine specimen temperature is not recovered by MFR.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 6 (FT S6): Internal Chain of Custody The laboratory shall use chain-of-custody procedures to document, minimally: a) the identification of all persons handling the specimen, aliquot or batch; b) the date of each receipt, handling and transfer and/or action upon the specimen, aliquot or batch; c) the purpose of the action/transaction, including accessioning, temporary storage, analysis, long-term storage, and disposal; and d) chain of custody documentation shall be completed at the time of each action.	Chain of custody documentation may be either hard copy or electronic. Whenever chain-of-custody procedures are applied to batches of specimens and aliquots, the form used to document chain-of-custody shall identify all specimens/aliquots included in the batch, either individually, or using a range of accession numbers.
Forensic Toxicology Sustaining Standard of Practice 7 (FT S7): Laboratory Security The laboratory shall implement security measures that preserve the integrity of specimens, aliquots and analytical records, including: a) a list of authorized personnel for each section of the laboratory where specimens, aliquots and records of analyses are received and stored, and analysis is performed; b) access for authorized personnel shall be limited according to such listing by the use of physical barriers and/or locks; c) authorized personnel shall sign in and out using log book or electronic record minimally each workday; d) sign-in, sign-out and continuous escort procedures for individuals with legitimate reasons for gaining access (e.g., telephone repair technicians); and e) a system to detect any security breach.	Laboratories that perform clinical and forensic testing in the same area may designate a time when the area used for analysis will be open only to authorized personnel and closed to general laboratory personnel. For example, security measures such as key codes and/or locks prevent a technician whose job duties are limited to screening from accessing other testing and/or storage areas. Authorized personnel are employees who have received training in forensic principles and practices as appropriate for assigned duties, and are duly authorized by the director. Access records for authorized personnel need not document each entrance and exit into testing space, such as lunch and other breaks. Security and access records may be maintained either as hardcopy or in an electronic format.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 8 (FT S8): Specimen Storage The laboratory shall hold original specimens in a dedicated, secured space, under conditions necessary to ensure specimen integrity, until the specimens are discarded. Specimen chain-of-custody for stored specimens must be maintained, including annotations for specimen discard.	The secure space could be a locked room or a locked refrigerator. The laboratory director should minimize the number of personnel with authorized access to this area (e.g., for preparing aliquots for testing, or for other reasons explicitly approved by the laboratory director, such as retrieval for re-testing). Access and purpose must be documented.
Forensic Toxicology Sustaining Standard of Practice 9 (FT S9): Aliquot Discard Aliquots shall not be returned to the original container.	

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 10 (FT S10): Initial Test Validation Laboratory validation of an initial drug test, in addition to meeting the requirements of *Validation Sustaining Standard 5 (VAL S5): Performance Specifications*, shall be designed to verify manufacturer claims for performance around the cutoff, and shall, for assays that are not single-use devices, assess the laboratory's ability to detect and correct any carryover that might occur between aliquots. Validation shall minimally be as follows: a) The accuracy, precision and linearity shall be evaluated through *replicate* analyses of specimens prepared to contain target drug(s) and/or metabolite(s) at assay cutoff concentration and, minimally, at approximately 50%, 75%, 125% and 150% around the cutoff; except that: b) for assays where a qualitative endpoint result is obtained by visual inspection: i. the accuracy and the ability to differentiate positive and negative specimens shall be evaluated with drug-free specimens and with specimens prepared to contain target drug(s) and/or metabolite(s) at 50%, 75%, 125% and 150% of the cutoff concentration; and, ii. variability in the interpretation of the endpoint among analysts shall be assessed.	Documentation of method validation should clearly record the study design, analytical findings and conclusions. As used in this standard, "cutoff" is the analyte concentration used to set a threshold analytical response to distinguish negative from non-negative analytical responses.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 11 (FT S11): Initial Test Quality Control For initial test methods that require periodic calibration, each batch prepared for analysis shall contain, minimally, 10% calibrators and/or quality control samples as follows: a) at least one certified to contain no drug or metabolite; b) at least one with drug or metabolite at 25% above the cutoff concentration; c) at least one with drug or metabolite at 25% below the cutoff concentration; and d) blind samples so as to comprise at least one percent of the batch.	d) A blind sample is quality control material that is indistinguishable, by the analyst, from samples submitted for routine analysis

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 12 (FT S12): Single-Use Device Quality Control Quality control for initial test methods that employ single-use devices shall be conducted using at least one control certified to contain no drug or metabolite and at least one control with drug or metabolite at 25 percent above the cutoff concentration as follows: a) each day testing is performed; or, b) for devices with integrated function checks that are designed and verified to monitor device performance under relevant environmental conditions and variance in operator performance, the laboratory may develop an individualized quality control plan, however external quality control must be analyzed at a minimum frequency of 10 percent of each lot of devices, scheduled to effectively monitor device stability over the period that the lot remains in use; or c) for 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.	b) The laboratory should refer to device stability studies as a guide in scheduling QC over the period that a lot remains in use.
Forensic Toxicology Sustaining Standard of Practice 13 (FT S13): Single-Use Device Quality Control, Referral of Negative Specimens Quality control for initial test methods that employ single-use devices shall include re-testing, by a laboratory holding a Forensic Toxicology - Comprehensive permit, of at least one of every 50 donor specimens (2%) that test negative, and discrepant results shall be investigated.	

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 14 (FT S14): Single-Use Device Quality Control, Operator Variance The laboratory shall ensure that each analyst that conducts testing using single-use devices participates in the quality control program, and such participation shall be documented.	For example, if there are five analysts, the analysis of the negative and positive control specimens should be cycled through each analyst.
Forensic Toxicology Sustaining Standard of Practice 15 (FT S15): Single-Use Device Workflow Whenever testing with single use devices is conducted contemporaneously with specimen collection, all pre-examination (donor preparation, specimen collection and accessioning), examination, and post-examination (certification and reporting of results) procedures shall be completed for this donor before the collector begins the subsequent donor encounter.	Such procedure shall be included in the laboratory's instructions to collectors for specimen collection and analysis.
Forensic Toxicology Sustaining Standard of Practice 16 (FT S16): Referral of Non-Negative Specimens Laboratories holding a permit in Forensic Toxicology - Initial Testing Only shall refer under chain of custody, for confirmation testing, to a laboratory that holds the Forensic Toxicology – Comprehensive permit: a) specimens that test non-negative for drug(s); and, b) if initial specimen validity testing is performed, specimens that meet the initial test criteria for adulteration or substitution.	Laboratories permitted for initial testing only may report a specimen as dilute if the specimen tested negative for drugs and the criteria for a dilute specimen are met. See Forensic Toxicology Sustaining Standard 33 (FT33).

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 17 (FT S17): Specimen Preparation for Referral Laboratories holding a permit in Forensic Toxicology - Initial Testing Only shall re-seal collection containers and initiate chain-of-custody documentation before sending such containers for confirmatory testing to a laboratory that holds the Forensic Toxicology – Comprehensive permit.	This standard applies to devices that require chain-of-custody seals to be broken for removal of an aliquot for testing. Re-capping alone is not re-sealing; re-sealing means applying a new evidence seal (e.g., evidence tape) that is initialed by the person preparing the container for transfer.

Confirmation Testing

These standards apply to laboratories holding the Forensic Toxicology - Comprehensive Permit

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 18 (FT S18): Confirmation Testing Method Principle Confirmation testing shall be performed using: a) a new aliquot of the specimen taken from the original container; and, b) b) a method that differs in physical and/or chemical principle from the initial (screening) test, and where possible a procedure that combines chromatographic separation and mass spectrometric identification, or other detection method acceptable to the department.	Confirmatory testing definitively identifies the presence of a specific drug and/or its metabolite(s) to refute or substantiate the finding of the initial test. a) The aliquot used for initial testing, substitution or adulteration testing is not acceptable for confirmatory testing, with the possible exception of specimens that cannot be re-collected, such as incident-related specimens, i.e., specimens obtained at the scene of an accident b) If there exists no generally accepted confirmatory assay that employs chromatography and mass spectrometry, department approval is required if the laboratory wishes to use an alternative method for confirmation**.** Laboratories should submit validation packages as described in the Submission Guidelines, copies of which may be downloaded from www.wadsworth.org/clep.

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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.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 20 (FT S20): Confirmation Method Calibration a) the laboratory shall maintain a record of the purity of all drug standard(s) for the period they are in use, and for two years thereafter. b) calibration and/or control materials prepared from standards must be validated for drug concentration before being placed into use. c) where calibration materials do not replicate the state of drug in the biological matrix being analyzed (e.g., calibrators for hair analysis), the laboratory must verify the accuracy of assay calibration through analysis of reference materials (e.g., NIST or PT survey-validated), or when such materials are not available, through comparative analyses with a method approved by the Department. d) Control materials must be prepared using a different source or lot of standard than used in the preparation of calibrator.	Calibrators and/or control materials prepared using the standards must be linked by lot number and dates of preparation.
Forensic Toxicology Sustaining Standard of Practice 21 (FT S21): Mass Spectrometer Function Checks Mass spectrometer(s) shall undergo function checks, including tuning, at a frequency recommended by the manufacturer or established by the laboratory where the laboratory determines that function checks need to be performed more frequently. The laboratory's review of data to determine compliance with established function check criteria shall be documented.	The SOPM should contain the criteria for acceptable function checks, which may be the manufacturer's criteria or more stringent criteria established by the laboratory.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 22 (FT S22): MS Full Scan Identification Full scan identification of analytes, if used, shall be accomplished using a mass spectra reference library established by the laboratory using authentic standards on the instrument used for specimen analysis, or using a commercially available library that has been verified by the laboratory.	
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.	

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 24 (FT S24): Chromatographic Criteria and Analyte Identification The laboratory shall establish and document its criteria for: a) the quality of chromatography; b) the identification of the analyte and the determination of its concentration; and, c) the detection and correction of carryover.	a) Quality of chromatography includes peak symmetry and peak resolution. b) When performing selected ion monitoring after electron ionization, a minimum of three ions must be monitored for the target analyte and a minimum of two ions for the internal standard. Ion ratios of qualifier ions should be within 20% of the target ion ratio determined from the assay calibrator(s). Ion ratios for soft-ionization techniques (chemical ionization) should be within 25% of the appropriately established target ion ratio where the reproducibility of ion-relative abundances may be expected to be less than that for electron ionization. When monitoring one precursor to get one product ion in tandem mass spectrometry, the resolution of the first mass analyzer should be set to unity. If multiple ions are monitored, ion ratios should be within 25% of the appropriately established target ion ratio. Reference: Gas Chromatography/Mass Spectrometry (GC/MS) Confirmation of Drugs; Approved Guideline. CLSI (NCCLS) Document C43-A, 2002)
Forensic Toxicology Sustaining Standard of Practice 25 (FT S25): Retest Specimen Assay Requirements When analyzing retest specimens, the laboratory shall: a) use a method with a limit of detection that is no greater than 40% of the confirmation assay cutoff used in the original analysis; and, b) limit its analysis to the drug(s) that were detected in the original analysis and to specimen validity testing.	A retest specimen is one that has been reported as a confirmed positive and has been questioned by the donor or physician (MRO), and has been authorized for reanalysis by the physician (MRO). The laboratory that receives a request for a retest to be performed by another laboratory must ensure that the laboratory is approved, forward the specimen under chain-of-custody, and supply a copy of the original confirmatory report. Refer to Forensic Toxicology 23 (FT S23): Confirmation Method Quality Control for QC requirements.

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Standard	Guidance
Specimen Validity Testing Analytical protocols and interpretive criteria for specimen validity testing (SVT) must have rigor and defensibility equivalent to that of protocols for the forensic detection of abused substances. The National Laboratory Certification Program has conducted and/or reviewed extensive studies on the physiochemical characteristics of biological specimens and has established criteria for the interpretation of SVT test findings. Laboratories that perform SVT should adopt testing, quality control and reporting requirements as provided in the Mandatory Guidelines. The Guidelines were published on October 1, 2010, and are available at http://workplace.samhsa.gov/Dtesting.html. Please note that the test findings from specimen validity testing (creatinine and specific gravity) may not be reported for purposes of clinical diagnosis or management.	
Forensic Toxicology Sustaining Standard of Practice 26 (FT S26): SVT Validation Validation protocols for specimen validity testing shall include, as applicable: a) characterization of the analytical accuracy, precision and linearity around the cutoff concentration; b) establishment of the limit of quantitation (LOQ) for quantitative tests and/or the limit of detection (LOD) as appropriate for the test performed; c) investigation of the analytical specificity of tests for specific adulterants; and, d) establishment of procedures to control for possible carryover.	Specimen validity testing means procedures to detect adulteration, substitution and/or dilution. Biomarkers may also be used to establish the authenticity of the specimen such as immunoglobulins (IgG) in collected oral fluid specimens. Documentation of method validation should clearly record the study design, analytical findings and conclusions.

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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 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); 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	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.

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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 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; 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. 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. 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.	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; 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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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.	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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Hair Specimens n) Where possible adulteration or substitution of the hair specimen exists, the laboratory should: i. determine the integrity of the head hair sample by performing a digestion test; ii. perform microscopic identification; iii. perform a dye test; iv. determine solubility of head hair in methanol; and, v. perform additional validity tests as appropriate for the observed indicators or characteristics. **Oral Fluid Specimens** o) Where possible adulteration or substitution of the oral fluid **specimen** exists, the laboratory should perform validity tests as appropriate for the observed indicators or characteristics. **Sweat Patch Specimens** p) Where possible adulteration or substitution of the sweat patch specimen exists, the laboratory should: i. determine the lactic acid concentration; and, ii. perform additional validity tests as appropriate for the observed indicators or characteristics.	Validity tests of hair, oral fluid and sweat patches should be performed when the following conditions are observed: b) Abnormal physical characteristics (e.g., split hair collections have different hair color, mixture of different types of head hair; unusual oral fluid color or texture, unusual odor, semi-solid characteristics; sweat patches collected from an individual have different color or unusual odor); or, e) Reactions or responses characteristic of an adulterant are obtained during initial or confirmatory drug tests (e.g., non-recovery of standards, unusual response). The determination the immunoglobulins (IgG) biomarker concentration should be considered in the assessment of potential substitution of oral fluid specimens.

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Standard	Guidance
Reporting and Specimen and Records Retention Requirements (Applicable to Initial and Comprehensive Testing Categories)	
Forensic Toxicology Sustaining Standard of Practice 28 (FT S28): Report to Authorized Test Orderer a) Laboratory reports shall be released only to the ordering physician / medical review officer (MRO) or other persons authorized by law to order laboratory services, who shall be named on the report. b) Unconfirmed non-negative results shall not be reported.	This standard precludes the release of reports to an institution, a human resources department of a firm, or a company official not qualified to authorize testing.
Forensic Toxicology Sustaining Standard of Practice 29 (FT S29): Report Certification a) A person qualified as a certifying scientist shall certify all reports before they are released. A test report is certified only if: b) documentation for external and internal chain of custody form is complete; c) quality control and assay performance requirements were satisfied; and, d) the analytical data support the test findings and interpretive criteria are applied appropriately.	Minimally, the certifying scientist must qualify as a technologist pursuant to 10 NYCRR Part 58-1 and must have: Documented training and experience in each analytical method and procedure used by the laboratory that is relevant to the reports of results that the individual certifies; and Documented training and experience in reviewing and reporting test results, maintenance of chain of custody, and remedial action.
Forensic Toxicology Sustaining Standard of Practice 30 (FT S30): Criteria for a Negative Test Result A specimen is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each validity test result indicates that the specimen is a valid specimen.	

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 31 (FT S31): Authorized Reporting – Initial Testing Only Laboratories a) Laboratories holding a permit in Forensic Toxicology - Initial Testing Only shall report only specimens that are determined to be negative on initial drug testing. Reports must include: b) drug(s) and/or metabolite(s) tested for; c) initial test cut-off concentration for each drug and metabolite; d) a statement that the specimen was dilute if criteria for dilution are met; and, e) the name of the certifying scientist releasing the report.	Laboratories holding a permit in Forensic Toxicology - Initial Testing Only may issue a report that a specimen is dilute if the methods for creatinine and specific gravity are properly validated, analytical runs are designed to include requisite control materials, and the specimen validation test results meet criteria for a dilute specimen, as noted in standard Forensic Toxicology Sustaining Standard 34 (FT34).
Forensic Toxicology Sustaining Standard of Practice 32 (FT S32): Criteria for a Positive Test Result A specimen is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive.	

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 33 (FT S33): Confirmation Testing Report Content Reports issued by laboratories holding a permit in Forensic Toxicology - Comprehensive shall identify: a) drug(s) and/or metabolite(s) tested for; b) initial and confirmation test cut-off concentrations for each drug and metabolite; c) the result of all drug test findings recorded as either positive or negative; d) the name of the certifying scientist releasing the report; e) the method used for confirmation testing, if the presence of a drug is detected; f) results of specimen validity testing if the specimen was determined to be dilute, adulterated, substituted or invalid; g) all non-negative test results; h) disclaimers as necessary to assist interpretation of test findings. i) the result of retesting as “Reconfirmed” or “Failed to Reconfirm”, if the test ordered was a retest.	c) The laboratory may report the drug concentration for drug(s) reported as positive. f) g) The laboratory should report numerical values that support a specimen that is reported dilute, adulterated, or substituted. h) Confirmed positive drug test(s) are to be reported when the specimen is also determined to be adulterated, substituted or invalid. i) Examples of disclaimers include: acknowledgement when the integrity of specimens through validity testing has not been evaluated; and, acknowledgement when testing algorithms for hair do not assess environmental contamination.
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.

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Standard	Guidance
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 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; 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.	

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Standard	Guidance
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 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.	

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 38 (FT S38): Reporting Criteria – Oral Fluid SVT An oral fluid specimen is reported substituted when the laboratory performs validity tests as appropriate for the observed indicators and determines the specimen does not possess the characteristics of an authentic oral fluid specimen. An oral fluid specimen is reported adulterated when the concentration of the adulterant is above the concentration of the calibrator used to verify that the adulterant was present in the specimen. An oral fluid specimen is reported as an invalid result when: a) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained); b) 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; or, c) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments.	Determination of IgG concentration as less than 0.10 mcg/mL may serve as a biomarker for substitution.

Forensic Toxicology

Workplace Drug Testing

Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 39 (FT S39): Reporting Criteria – Hair and Sweat Patch SVT A hair and sweat patch sample is reported adulterated when the concentration of the adulterant is above the concentration of the calibrator used to verify that the adulterant was present in the sample. A hair and sweat patch sample is reported as an invalid result when: a) interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained); b) 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; or, c) the physical appearance of the specimen is such that testing the system may damage the laboratory's instruments.	
Forensic Toxicology Sustaining Standard of Practice 40 (FT S40): Reporting Criteria – Split Specimen Appearance Where a split specimen is collected, if the physical appearances of the split specimen are clearly different and the primary specimen was screened negative for drugs, the specimen is reported as invalid.	

Forensic Toxicology

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 41 (FT S41): Specimen Retention Laboratories holding a permit in Forensic Toxicology - Comprehensive shall retain specimens that were reported positive, adulterated, substituted or invalid for a minimum of one year in secured storage under conditions appropriate for ensuring stability for valid retesting. Specimen retention must be extended on written request by the authorized person who ordered the test.	Laboratories holding a permit in Forensic Toxicology – Initial Testing Only may discard specimens that test negative after the report has been released.
Forensic Toxicology Sustaining Standard of Practice 42 (FT S42): Records Retention The laboratory shall retain for a minimum of two years, or, for analyses that are under legal challenge, for an indefinite period, all records that would be required for a valid re-creation and scientific review of the testing process.	This includes the following records: a. Standards, calibrators, controls and reagents associated with each analytical run, including the identification of the person who prepared each material, and/or the source and date of receipt; b. Instrument printouts, chromatograms and similar documentation of data or results generated during the analysis, such as worksheets; c. Cross-reference between chain-of-custody forms and the identity of the individual tested; d. Identity of analyst(s); and, e. Evidence of review and certification of the report by a person qualified as a certifying scientist.
Forensic Toxicology Sustaining Standard of Practice 43 (FT S43): Database Security Electronic databases of test results and reports stored in any media shall be secure from access by unauthorized individuals.	Unless the laboratory has a means of verifying the person receiving the results is authorized to receive the results, verbal reporting, including by telephone, is not permitted. Pursuant to 10NYCRR Part 58-1, all verbal reports shall be followed by a written report in a timely manner.

Forensic Toxicology

Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Laboratories engaged in the analysis and interpretation of drugs and chemicals in biological samples for legal purposes other than analyses performed in support of drug-free workplace drug testing programs must be compliant with requirements under each of the following Fundamental Standards of Practice: Quality Management System; Human Resources; Facilities and Resource Management; Pre-Examination, Examination and Post-Examination Procedures; and Quality Assessment and Improvement, with qualification as expressed in this section. These qualifications shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
Quality Management System Fundamental Standard of Practice (QMS F1)	The forensic toxicology laboratory must be in full compliance with the Quality Management System Fundamental Standard of Practice and its sustaining standards QMS S1 through S4.
Director Fundamental Standard of Practice 1 (DIR F1) : Director Oversight	The forensic toxicology laboratory must be in full compliance with the Director Fundamental Standard of Practice and the sustaining standards DIR S1 through 3, except that: DIR S2(k): Consultation is provided to clients authorized to order laboratory services in medico-legal investigation.
Human Resources Fundamental Standard of Practice 1 (HR F1): Staff Qualifications	The forensic toxicology laboratory must be in full compliance with the Human Resources Fundamental Standard and the sustaining standards HR S1 through 10, except that: a) HR F1: Supervisors and technical personnel must have training and experience in forensic science commensurate with responsibilities; b) HR S2: Technical personnel engaged solely in forensic testing do not require licensure through the State Education Department.

Forensic Toxicology

Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Facility Design and Resource Management Fundamental Standard of Practice 1 (FDRM F1)	The forensic toxicology laboratory must be in full compliance with the Facility Design and Resource Management Fundamental Standard and its sustaining standards under General Facilities, Laboratory Equipment, Reagents & Supplies, Laboratory Safety and Laboratory Information Systems, where applicable to medico-legal testing, except that: FDRM F1: Non-conformance does not present imminent jeopardy to the integrity of laboratory services, to employee safety, or to medico-legal investigations. In addition, the laboratory shall be in compliance with the following Forensic Toxicology standard(s): a) Forensic Toxicology Sustaining Standard 7 (FT S7): Laboratory Security, and b) Forensic Toxicology Sustaining Standard 21 (FT S21): Mass Spectrometer Function Checks
Operating Procedures and Compliance Fundamental Standard of Practice 1 (SOP F1)	The forensic toxicology laboratory must be in full compliance with the Operating Procedures and Compliance Fundamental Standard and its sustaining standards SOPM S1 through S7, except that: SOPM S2(d): requirements for study subject preparation rather than patient preparation; SOPM S2(g)(ix): reporting case results rather than patient results; and, SOPM S2(h): reportable range for the analytical method rather than for patient test results.

Forensic Toxicology

Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Pre-Examination Procedures Fundamental Standard of Practice 1 (PEP F1)	The forensic toxicology laboratory must be in full compliance with the Pre-Examination Fundamental Standard and its sustaining standards under Examination Requisition and Specimen Processing, except that: a) Requisition S1: No private-sector establishment other than a laboratory under NYS forensic toxicology permit shall accept specimens for the purpose of toxicological medico-legal investigation; and, b) Requisition S3, S4: References to patients and patient preparation are replaced with study subjects and study subject preparation. In addition, the laboratory shall be in compliance with the following Forensic Toxicology standard(s) to the extent practical and appropriate for the medico-legal investigation: a) Forensic Toxicology Sustaining Standard 2 (FT S2): Specimen Collection Procedures b) Forensic Toxicology Sustaining Standard 3 (FT S3): Specimen Acceptance Criteria c) Forensic Toxicology Sustaining Standard 4 (FT S4): Specimen Acceptance Criteria d) Forensic Toxicology Sustaining Standard 6 (FT S6): Internal Chain of Custody e) Forensic Toxicology Sustaining Standard 9 (FT S9): Aliquot Discard

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Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Examination Procedures Fundamental Standard of Practice 1 (EP F1)	The forensic toxicology laboratory must be in full compliance with the Examination Procedures Fundamental Standard and its sustaining standards under Validation of Laboratory Procedures, Determination of Calibration and Calibration Verification Procedures, Establishment of Quality Control Procedures and Process Quality Control, except that: a) EP F1: Non-conformance shall not present imminent jeopardy to the integrity of laboratory services, to employee safety, or to medico-legal investigations. b) Validation S5(d): If the instrument will be hand-carried or otherwise transported to the site of the investigation, the laboratory shall document the portability of the system. c) QC Design S3 and QC Design S4: References to accepted medical and analytical requirements mean medico-legal and analytical requirements. n addition, the laboratory shall be in compliance with the following Forensic Toxicology standard(s) to the extent practical and appropriate for the medico-legal investigation: a) Forensic Toxicology Sustaining Standard 18 (FT S18): Confirmation Testing Method Principle b) Forensic Toxicology Sustaining Standard 20 (FT S20): Confirmation Method Calibration c) Forensic Toxicology Sustaining Standard 22 (FT S22): MS Full Scan Identification d) Forensic Toxicology Sustaining Standard 24 (FT S24): Chromatographic Criteria and Analyte Identification

Forensic Toxicology

Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Post- Examination (Process Review – Reporting – Records Retention Fundamental) Standard of Practice 1 (Process Review F1)	The forensic toxicology laboratory must be in full compliance with the Post-Examination Fundamental Standard and its sustaining standards under Process Review, Reporting, Records Retention, and Confidentiality, except that: a) Process Review F1: Non-conformance does not present imminent jeopardy to the integrity of laboratory services, to employee safety, or to medico-legal investigations. In addition, the laboratory shall be in compliance with the following Forensic Toxicology standard(s) to the extent practical and appropriate for the medico-legal investigation: a) Forensic Toxicology Sustaining Standard 28 (FT S28): Report to Authorized Test Orderer b) Forensic Toxicology Sustaining Standard 29 (FT S29): Report Certification c) Forensic Toxicology Sustaining Standard 32 (FT S32): Criteria for a Positive Test Result d) Forensic Toxicology Sustaining Standard 33 (FT S33): Confirmation Testing Report Content e) Forensic Toxicology Sustaining Standard 41 (FT S41): Specimen Retention f) Forensic Toxicology Sustaining Standard 42 (FT S42): Records Retention

Forensic Toxicology

Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Quality Assessment and Improvement Fundamental Standard of Practice (QA F1)	The forensic toxicology laboratory must be in full compliance with the Quality Assessment and Improvement Fundamental Standard and its sustaining standards under Proficiency Testing, Referral and Contract Laboratories, Resolution of Complaints and Identification and Control of Nonconformities, and Corrective Action.