

Forensic Toxicology

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<p>Application of Standards as Currently Numbered:</p> <p>All Forensic Toxicology Permitted Laboratories: FT: 1–12, 18, 20, 21, 28, 29, 33–35</p> <p>Initial Testing Laboratories Only: FT: 13, 14, 30</p> <p>Comprehensive Permitted Laboratories Only: FT: 15–17, 19, 31, 32</p> <p>All Forensic Toxicology Permitted Laboratories performing SVT: 22–27</p>	
<p>Forensic Toxicology Standard of Practice 1 (FT S1): Specimen Collection Facility</p> <p>In addition to the requirements in Specimen Processing Standard of Practice 1, the laboratory must have collection instructions encompassing the following collection requirements:</p> <ul style="list-style-type: none"> a) a clean surface suitable for handling the specimen and completing paperwork is used; b) the specimen is placed into a secure, temporary storage location until tested or shipped; c) a space offering privacy appropriate to the specimen being collected is provided to the test subject; d) access to the collection area is restricted to authorized personnel during the collection; e) access to the collection supplies is restricted to authorized personnel; 	<ul style="list-style-type: none"> e) Supplies should be kept secured by authorized personnel when not in use.

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<ul style="list-style-type: none"> f) all test records are stored securely; and g) a complete standard operating procedure on the collection and handling of test subject specimens. 	
<p>Forensic Toxicology Standard of Practice 2 (FT S2): Specimen Collection Procedures</p> <p>The laboratory must have a specimen collection standard operating procedure that includes:</p> <ul style="list-style-type: none"> a) acceptable forms of test subject identity verification; b) collection procedure explanation and/or instructions for the test subject; c) measures to prevent specimen adulteration or substitution; d) a statement that the specimen must remain within view of the test subject until: <ul style="list-style-type: none"> i. the specimen container is sealed with a tamper evident label/seal; ii. the specimen seal is initialed by the test subject and dated by the collector; and e) instructions for completing the custody and control form (CCF) or alternatively, both chain of custody and Test Requisition forms (CoC+TRF); and f) instructions for linking the specimen to the test subject and the completed CCF or (CoC+TRF). 	<p>Laboratories are encouraged to use the federal Department of Health and Human Services website (https://www.samhsa.gov/workplace/resources) as a guide in establishing policies and procedures for specimen collection.</p> <ul style="list-style-type: none"> e) The custody and control form (CCF) or both chain of custody and Test Requisition form (CoC+TRF), when used as a test requisition, must meet Test Request Standard of Practice 3, except that cross-reference to a standing order or client roster that allows identification of tests ordered for each test subject may be used instead of listing tests on the CCF or COC+TRF form. f) The signed CCF or CoC+TRF and the specimen container may be linked by bar-code or other unique identifier, preferably through use of tamper-evident seals or labels with the same unique number as on the CCF OR COC+TRF and affixed to the CCF OR COC+TRF for use at time of specimen collection.

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<p>Forensic Toxicology Standard of Practice 3 (FT S3): Specimen Acceptance Criteria</p> <p>In addition to the requirements in Specimen Processing Standard of Practice 4, the laboratory must develop and document specimen acceptability criteria. Such criteria must be available at collection and testing sites, and must:</p> <ul style="list-style-type: none"> a) define acceptable specimen attributes to include: <ul style="list-style-type: none"> i. minimum specimen volume required; ii. appropriate labeling including a specimen identification (ID) number and the printed name and signature of the collector; iii. appropriate temperature for urine specimens; iv. condition of specimen container seals; v. appropriate completion of the CCF or COC+TRF; vi. matching information between the specimen and the CCF or COC+TRF; and b) identify collection errors that can be corrected through affidavit from the collector and those errors that cannot be corrected; and c) define specimen acceptance exceptions for: <ul style="list-style-type: none"> i. any specimen that cannot be re-collected under the same circumstances, and the test findings are expected to be analytically sound and 	<p>These policies and procedures must be documented in the standard operating procedures.</p> <ul style="list-style-type: none"> a) The required amount of specimen should be adequate for retesting should a retest be ordered. c) CCF or COC+TRFs that lack collector signature and/or documentation that specimen temperature was acceptable may be recoverable.

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<p>acceptable to the laboratory director;</p> <p>ii. the laboratory has received a record acceptable to the laboratory director (e.g., affidavit or memorandum for record) that corrects and attests to specimen documentation acceptability for the following errors:</p> <ul style="list-style-type: none"> a. failure to document urine specimen temperature acceptability; b. absence of the collector’s signature on the CCF or COC+TRF; and c. failure to provide the name of the authorized ordering source on the CCF OR COC+TRF. 	
<p>Forensic Toxicology Standard of Practice 4 (FT S4): Specimen Acceptance Practices</p> <p>In addition to the requirements in Specimen Processing Standard of Practice 2, the laboratory must:</p> <ul style="list-style-type: none"> a) monitor the completeness and adequacy of collection documents submitted with specimens; b) ensure that specimens are received in an acceptable container and appropriately sealed; c) document the condition of the specimen container seal upon receipt (e.g., intact vs. broken); 	<p>Monitoring compliance is consistent with quality indicators (QI) as described in Quality Management System Standard of Practice 3 and 4.</p>

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<ul style="list-style-type: none"> d) notify collectors when problems are identified and document remediation; and e) provide collectors with specimen collection instructions. 	
<p>Forensic Toxicology Standard of Practice 5 (FT S5): Internal Chain of Custody</p> <p>The laboratory must use chain of custody procedures to document, minimally:</p> <ul style="list-style-type: none"> 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, analysis, transfer to and from all storage locations, and disposal; and d) chain of custody documentation shall be completed at the time of each action. 	<p>Chain of custody documentation may be either hard copy or electronic.</p> <p>Whenever chain of custody procedures are applied to batches of specimens and aliquots, the form used to document chain of custody must identify all specimens/aliquots included in the batch, either individually, or using a range of accession numbers.</p>
<p>Forensic Toxicology Standard of Practice 6 (FT S6): Laboratory Security</p> <p>The laboratory must implement security measures that preserve the integrity of specimens, aliquots and analytical records, including:</p> <ul style="list-style-type: none"> a) a list of authorized personnel for each section of the laboratory where specimens, aliquots and records of 	<p>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.</p> <ul style="list-style-type: none"> a) Access records for authorized personnel need not document each entrance and exit into testing space, such as lunch and other breaks.

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<p>analyses are received and stored, and analysis is performed;</p> <p>b) access for authorized personnel that is limited by the use of physical barriers and/or locks;</p> <p>c) authorized personnel that sign in and out using log book or electronic record minimally each workday;</p> <p>d) sign-in, sign-out and continuous escort procedures for all other individuals with legitimate reasons for gaining access (e.g. repair technicians); and</p> <p>e) a system to detect and document security breaches.</p>	<p>Security and access records may be maintained either as hardcopy or in an electronic format.</p>
<p>Forensic Toxicology Standard of Practice 7 (FT S7): Specimen Storage</p> <p>The laboratory must hold original specimens in a dedicated, secured space that ensures specimen integrity until the specimens are discarded.</p>	<p>The secure space could be a locked room or a locked refrigerator.</p> <p>The laboratory director should minimize the number of authorized personnel with access to this area (e.g., for preparing aliquots for testing, retrieval for re-testing). Access and purpose must be documented.</p>
<p>Forensic Toxicology Standard of Practice 8 (FT S8): Aliquot Discard</p> <p>Aliquots must not be returned to the original container.</p>	
<p>Forensic Toxicology Standard of Practice 9 (FT S9): Validation of Initial Tests</p> <p>In addition to the requirements in Test Performance Specification Standards of Practice 1 and 2, as applicable, validation studies must minimally include:</p>	<p>Approval by the Department is required for laboratory developed tests (LDTs).</p> <p>Information on Departmental approval of a laboratory developed test (LDT) is available at:</p>

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<p>a) evaluation of any collection devices designed to alter the specimen (such as blood collection tubes that contain preservatives, buffers, diluents, or additives, or oral fluid collection devices) as part of sample preparation; and</p> <p>b) evaluation of accuracy, precision and linearity through <i>replicate</i> analyses of specimens prepared to contain target drug(s) and/or metabolite(s) at:</p> <ul style="list-style-type: none"> i. assay cutoff concentration; and ii. at approximately fifty (50), seventy-five (75), one hundred twenty-five (125) and one hundred fifty (150) percent around the cutoff. 	<p>https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.</p> <p>a) Some examples of device alterations of the specimen include: dilution, addition of buffers and/or preservatives, addition of internal standards, addition of reagents, and absorption or adsorption by a material.</p> <p>b) 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.</p>
<p>Forensic Toxicology Standard of Practice 10 (FT S10): Quality Control of Initial Tests</p> <p>The laboratory must follow manufacturer instructions for quality control (QC) for FDA approved, cleared or exempt tests.</p> <p>For any laboratory developed test (LDT) for initial (i.e., screening) methods that require periodic calibration, each batch must contain, minimally, ten (10) percent calibrators and/or QC samples as follows:</p> <ul style="list-style-type: none"> a) at least one (1) containing no drug or metabolite; b) at least one (1) with drug or metabolite at twenty-five (25) percent above the cutoff concentration; 	<p>Information on Departmental approval of a laboratory developed test (LDT) is available at:</p> <p>https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.</p>

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<p>c) at least one (1) with drug or metabolite at twenty-five (25) percent below the cutoff concentration; and</p> <p>d) blind samples so as to comprise at least one (1) percent of the batch.</p>	<p>d) A blind sample is quality control material that is indistinguishable, by the analyst, from specimens submitted for routine analysis.</p>
<p>Forensic Toxicology Standard of Practice 11 (FT S11): Single-Use Device Quality Control</p> <p>Initial test methods using single-use devices must include at least one (1) control sample established to contain no drug or metabolite and at least one control sample with drug or metabolite at twenty-five (25) percent above the cutoff concentration as follows:</p> <p>a) each day testing is performed; or</p> <p>b) for devices with integrated function checks, the laboratory may develop an individualized quality control plan according to Quality Control Standards of Practice 2, 3 and 4.</p>	<p>b) The laboratory should refer to device stability studies as a guide in scheduling QC over the period that a lot remains in use.</p>
<p>Forensic Toxicology Standard of Practice 12 (FT S12): Single-Use Device Workflow</p> <p>When initial testing is performed using a single-use device, the entire test process must be completed on one test subject before beginning the test process on the next test subject.</p>	<p>Such procedure shall be included in the laboratory's instructions to collectors for specimen collection and analysis.</p>

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<p>Forensic Toxicology Standard of Practice 13 (FT S13): Referral of Specimens</p> <p>Laboratories holding a permit in Forensic Toxicology – Initial Testing Only must refer specimens to another laboratory holding a permit in Forensic Toxicology – Comprehensive when:</p> <ul style="list-style-type: none"> a) specimens test non-negative for drug(s); or b) specimens meet the initial test criteria for adulteration or substitution; or c) the laboratory does not offer an initial test for the analyte. 	<p>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.</p>
<p>Forensic Toxicology Standard of Practice 14 (FT S14): Specimen Preparation for Referral</p> <p>Laboratories holding a permit in Forensic Toxicology – Initial Testing Only must re-seal collection containers and initiate chain of custody documentation before referring such containers to another laboratory.</p>	<p>This standard applies to devices that require chain of custody seals to be broken to remove an aliquot for testing.</p> <p>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.</p>
<p>Forensic Toxicology Standard of Practice 15 (FT S15): Confirmation Testing Method Principle</p> <p>Confirmation testing must use:</p> <ul style="list-style-type: none"> a) a new aliquot of the specimen taken from the original container; and b) a method that differs in physical and/or chemical principle from the initial test, and where possible a 	<p>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.</p>

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<p>procedure that combines chromatographic separation and mass spectrometric identification, or method acceptable to the laboratory director.</p>	
<p>Forensic Toxicology Standard of Practice 16 (FT S16): Confirmation/Definitive Method Periodic Re-Validation</p> <p>In addition to the initial validation of confirmatory test methods, and the requirements in Test Performance Specification Standards of Practice 1 and 2, the laboratory must verify and document, annually, the following performance characteristics:</p> <ul style="list-style-type: none"> a) accuracy and precision at all reported cutoff concentrations; b) accuracy and precision at the lower limit of quantitation; c) accuracy and precision at the upper limit of quantitation; d) limit of detection with statistical significance as determined by the director; e) analytical specificity; f) carryover at physiologically relevant concentrations; and g) evaluation of any collection devices designed to alter the specimen (such as blood collection tubes that contain preservatives, buffers, diluents, or additives, or oral fluid collection devices) that have not previously been evaluated, or have been substantially changed by the manufacturer, as part of sample preparation. 	<p>Analytical specificity validation should include validation materials that contain the potentially interfering drugs at physiologically relevant concentrations.</p> <p>Some examples of device alterations of the specimen include: dilution, addition of buffers and/or preservatives, addition of internal standards, addition of reagents, and adsorption or adsorption by a material.</p>

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<p>Forensic Toxicology Standard of Practice 17 (FT S17): Confirmation/Definitive Method Reference Standards</p> <p>The laboratory must:</p> <ul style="list-style-type: none"> a) maintain a record of the purity of all drug standard(s) for the period they are in use, and for two (2) years thereafter, according to Document and Specimen Retention Standard of Practice 8; b) verify drug concentration(s) for calibration standards (standard curves, solutions) and/or control materials before being placed into use; and c) if appropriate calibrators for the matrix and state of the drug (e.g., calibrators for hair analysis) are not available, the laboratory must calibrate: <ul style="list-style-type: none"> i. using samples that include reference materials (e.g., NIST traceable or PT survey-validated), or ii. when such materials are not available, through comparative analyses. 	<p>Calibrator materials and/or control materials prepared using the standards must be linked by lot number and dates of preparation.</p>
<p>Forensic Toxicology Standard of Practice 18 (FT S18): Full Scan Analyte Identification</p> <p>The laboratory must identify untargeted analytes by:</p> <ul style="list-style-type: none"> a) performing a full scan identification of analytes using a commercially available library that is verified by the laboratory; or 	<p>This standard only applies to the untargeted or “open-scan” identification of analytes.</p>

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<p>b) using a mass spectra reference library established on the same instrument by the laboratory using authentic standards.</p>	
<p>Forensic Toxicology Standard of Practice 19 (FT S19): Confirmation/Definitive Method Quality Control</p> <p>Each batch of specimens for confirmatory testing must contain, minimally, ten (10) percent calibrators and/or quality control samples as follows:</p> <ul style="list-style-type: none"> a) at least one (1) control established to contain no drug or metabolite; b) at least one (1) positive control with drug or metabolite concentration at twenty-five (25) percent above the cutoff concentration; c) at least one (1) control or calibration material with drug or metabolite concentration at or below the cutoff; d) a control to assess the efficiency of hydrolysis, where appropriate; and e) a control to assess extraction efficiency where appropriate. 	<p>a), b) and c) Additional recommended concentrations for calibrators and controls are: cutoff (or other decision) concentrations; the test method Limit of Quantitation (LOQ) concentration; Upper limit of linearity (ULOL) or quantitation (ULOQ) concentration.</p> <p>d) and e) These controls do not need to be separate samples, if compliance can be demonstrated with the current experimental design.</p>
<p>Forensic Toxicology Standard of Practice 20 (FT S20): Test Performance Criteria and Analyte Identification</p> <p>For laboratory developed tests (LDTs), in addition to the requirements in Test Performance Specification Standard of</p>	<p>Information on Departmental approval of a laboratory developed test (LDT) is available at:</p> <p>https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.</p>

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<p>Practice 2, the laboratory must establish and document acceptability criteria for:</p> <ul style="list-style-type: none"> a) the quality of chromatography, when used; b) the identification of the analyte; c) the accuracy and bias in determining an analyte's concentration; d) the detection and correction of carryover; and e) detection of interfering substances. 	<ul style="list-style-type: none"> a) Quality of chromatography includes peak symmetry and peak resolution. b) Number and type of ions monitored, their ratios, and accuracy requirements (for high-resolution MS experiments).
<p>Forensic Toxicology Standard of Practice 21 (FT S21): Retest Specimen Assay Requirements</p> <p>When analyzing retest specimens, the laboratory performing the retesting must:</p> <ul style="list-style-type: none"> a) use a method able to achieve the same cutoff or lower, while meeting all performance criteria; and b) limit analysis to the drug(s) detected in the original analysis and to specimen validity testing. 	<p>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.</p> <p>Refer to Forensic Toxicology Standard of Practice 19 (FT S19).</p>
<p>Forensic Toxicology Standard of Practice 22 (FT S22): Specimen Validity Testing Validation</p> <p>Validation protocols for specimen validity testing (SVT) must include, as applicable:</p> <ul style="list-style-type: none"> a) characterization of the analytical accuracy, precision and linearity around the cutoff concentration; 	<p>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.</p> <p>Documentation of method validation should clearly record the study design, analytical findings and conclusions.</p>

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<ul style="list-style-type: none"> b) establishment of the limit of quantitation (LOQ) for quantitative tests and/or the limit of detection (LOD) as appropriate for the test performed; and c) procedures to control for possible carryover. 	
<p>Forensic Toxicology Standard of Practice 23 (FT S23): (Urine only) Specimen Validity Testing Calibration and Control Requirements – Creatinine</p> <p>For urine specimen validity testing (SVT), each batch of test subject specimens must include the following calibrators and controls for tests performed by the laboratory.</p> <p>Creatinine SVT (all methods)</p> <p>Creatinine tests must include:</p> <ul style="list-style-type: none"> a) at least one (1) calibrator in the measurement range; b) a non-blank ‘dilute’ control; and c) at least two (2) additional control concentrations covering the measurement range. 	<p>Laboratories that hold the Forensic Toxicology – Initial Testing Only permit may conduct tests for specimen validity; however, in accordance with Forensic Toxicology Standard of Practice 13 (FT S13), 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.</p> <p>Specimen Validity criteria decision points for test subject are required to be listed in the laboratory’s standard operating procedure. The current specimen validity criteria from SAMHSA are recommended.</p>
<p>Forensic Toxicology Standard of Practice 24 (FT S24): (Urine only) Specimen Validity Testing Calibration and Control Requirements – Specific Gravity</p> <p>For urine specimen validity testing (SVT), each batch of test subject specimens must include the following calibrators and controls for tests performed by the laboratory.</p>	<p>Laboratories that hold the Forensic Toxicology – Initial Testing Only permit may conduct tests for specimen validity; however, in accordance with Forensic Toxicology Sustaining Standard of Practice 13 (FT S13), 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.</p>

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<p>Specific Gravity SVT (all methods)</p> <p>Specific gravity initial and confirmatory tests must include:</p> <ul style="list-style-type: none"> a) a calibrator (within the measurement range); b) at least two (2) different control concentrations covering the measurement range; and c) the refractometer must display to a minimum <u>four</u> (4) decimal places. 	<p>Specimen Validity criteria decision points test subject are required to be listed in the laboratory’s standard operating procedure. The current specimen validity criteria from SAMHSA are recommended.</p>
<p>Forensic Toxicology Standard of Practice 25 (FT S25): (Urine only) Specimen Validity Testing Calibration and Control Requirements – pH</p> <p>For urine specimen validity testing (SVT), each batch of test subject specimens must include the following calibrators and controls for tests performed by the laboratory.</p> <p>pH SVT (all methods)</p> <p>pH initial and confirmatory tests must include:</p> <ul style="list-style-type: none"> a) at least two (2) calibrators of different pH concentrations; and b) at least three (3) control levels, covering the measurement range. 	<p>Laboratories that hold the Forensic Toxicology – Initial Testing Only permit may conduct tests for specimen validity; however, in accordance with Forensic Toxicology Sustaining Standard of Practice 13 (FT S13), 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.</p> <p>Specimen Validity criteria decision points test subject are required to be listed in the laboratory’s standard operating procedure. The current specimen validity criteria from SAMHSA are recommended.</p>

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<p>Forensic Toxicology Standard of Practice 26 (FT S26): (Urine only) Specimen Validity Testing Calibration and Control Requirements – Other Adulterant Tests</p> <p>For urine specimen validity testing (SVT), each batch of test subject specimens must include the following calibrators and controls for tests performed by the laboratory.</p> <p>Adulterant tests (including nitrite)</p> <p>Tests must include:</p> <ul style="list-style-type: none"> a) an appropriate calibrator near the laboratory’s cutoff for the adulterant; b) a control without the adulterant (i.e., a confirmed negative control); and c) at least one (1) control containing an adulterant at a measurable concentration. 	<p>Laboratories that hold the Forensic Toxicology – Initial Testing Only permit may conduct tests for specimen validity; however, in accordance with Forensic Toxicology Standard of Practice 13 (FT S13), 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.</p> <p>Specimen Validity criteria decision points test subject are required to be listed in the laboratory’s standard operating procedure. The current specimen validity criteria from SAMHSA are recommended.</p>
<p>Forensic Toxicology Standard of Practice 27 (FT S27): Non-Urine Matrix Specimen Validity Testing Calibration and Control Requirements – Non-Urine Matrix SVT</p> <p>Laboratories must establish written test procedures and test acceptance criteria for specimen validity testing (SVT) on matrices where specimen collection is unmonitored or reasonably subject to adulteration.</p>	<p>Laboratories that hold the Forensic Toxicology – Initial Testing Only permit may conduct tests for specimen validity; however, in accordance with Forensic Toxicology Standard of Practice 13 (FT S13), 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.</p>

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<p>Non-Urine Matrix SVT</p> <p>Tests must include:</p> <ul style="list-style-type: none"> a) an appropriate calibrator near the laboratory’s cutoff for the adulterant; b) a control without the adulterant (i.e., a confirmed negative control); and c) at least one (1) control containing an adulterant at a measurable concentration. 	
<p>Forensic Toxicology Standard of Practice 28 (FT S28): Report Certification</p> <p>A person qualified as a certifying scientist must certify all reports before they are released.</p> <p>A test report is certified only if:</p> <ul style="list-style-type: none"> a) documentation for the external and internal chain of custody form(s) are complete; b) quality control and assay performance requirements are acceptable; and c) the analytical data support the test findings and interpretive criteria are applied according to written standard procedures. 	<p>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</p> <p>Documented training and experience in reviewing and reporting test results, maintenance of chain of custody, and remedial action.</p>

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<p>Forensic Toxicology Standard of Practice 29 (FT S29): Criteria for a Negative Test Result</p> <p>A specimen is reported negative when either:</p> <ul style="list-style-type: none"> a) the specimen meets validity criteria (if performed); and b) each initial drug test is negative; or c) the test is negative on a confirmatory drug test. 	
<p>Forensic Toxicology Standard of Practice 30 (FT S30): Authorized Reporting – Initial Testing Only Laboratories</p> <p>Laboratories holding a permit in Forensic Toxicology – Initial Testing Only must report only specimens that are determined to be negative on initial drug testing.</p> <p>In addition to the requirements in Reporting Standard of Practice 2, reports must include:</p> <ul style="list-style-type: none"> a) drug(s) and/or metabolite(s) tested; b) initial test cut-off concentration for each drug and metabolite; c) for specimens determined to be ‘dilute,’ a statement to this effect; and d) the name of the certifying scientist releasing the report. 	<p>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. The sample must not be pending any referral or confirmatory tests.</p>

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<p>Forensic Toxicology Standard of Practice 31 (FT S31): Criteria for a Positive Test Result</p> <p>A specimen is reported positive for a specific drug when:</p> <ul style="list-style-type: none"> a) the initial drug test is positive, and the related confirmatory drug test is positive; or b) when an initial screening or qualitative test is not available: <ul style="list-style-type: none"> i. two differing definitive tests using alternate techniques give positive results; or ii. a second technique acceptable to the laboratory director may be substituted. 	<ul style="list-style-type: none"> b) When an initial screening or qualitative test is not available a specimen may be referred for additional confirmation at an independent laboratory, before the laboratory may report the drug concentration for drug(s) reported as positive.
<p>Forensic Toxicology Standard of Practice 32 (FT S32): Confirmation Testing Report Content</p> <p>In addition to the requirements in Reporting Standard of Practice 2, reports issued by laboratories holding a permit in Forensic Toxicology – Comprehensive must include:</p> <ul style="list-style-type: none"> a) initial and confirmatory test cut-off concentrations for all drugs and metabolites tested; b) each result presented as either positive or negative; c) the method used for confirmatory testing, if performed; d) results and test cut-off concentrations of specimen validity testing; e) the name of the certifying scientist releasing the report; 	<ul style="list-style-type: none"> b) The laboratory may report the drug concentration for drug(s) reported as positive. d) Only the cut-off concentrations and a qualitative reporting of the interpretation are required by this standard.

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f) all non-negative test results; and g) for retests, each result presented as “Reconfirmed” or “Failed to Reconfirm”.	f) The laboratory should report numerical values that support a specimen that is reported dilute, adulterated, or substituted.
<p>Forensic Toxicology Standard of Practice 33 (FT S33): Reporting Criteria – Split Specimen Agreement</p> <p>Where a split specimen is collected:</p> <ul style="list-style-type: none"> a) if the physical appearances of the split specimen are clearly different; <u>and</u> b) the primary specimen was screened negative for drugs, then specimen must be reported as invalid. 	
<p>Forensic Toxicology Standard of Practice 34 (FT S34): Specimen Retention</p> <p>Laboratories must retain specimens that were reported positive, adulterated, substituted or invalid for a minimum of one (1) year in secured storage under conditions appropriate for retesting, according to Document and Specimen Retention Standard of Practice 10, or for postmortem investigation samples, follow all specimen retention regulations of the referring Medical Examiner, when applicable. Specimen retention must be extended on written request by the persons authorized to order the test.</p>	<p>Laboratories holding a permit in Forensic Toxicology – Initial Testing Only may discard specimens that test negative after the report has been released.</p>

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<p>Forensic Toxicology Standard of Practice 35 (FT S35): Records Retention</p> <p>The laboratory must retain all records necessary to re-create the test process for a minimum of two (2) years according to Document and Specimen Retention Standard of Practice 8, unless the analyses are under legal contest, in which case the records must be retained for an indefinite period.</p>	<p>This includes the following records:</p> <ul style="list-style-type: none"> • 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; • Instrument printouts, chromatograms and similar documentation of data or results generated during the analysis, such as worksheets; • Cross-reference between chain of custody forms and the identity of the individual tested; • Identity of analyst(s); and • Evidence of review and certification of the report by a person qualified as a certifying scientist.