

FORENSIC URINE DRUG TESTING

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If you are currently enrolled in the CAP LAP and are preparing for an inspection, please note:

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For questions about the use of Checklists in the inspection process, please e-mail the CAP at accred@cap.org, or call (800) 323-4040, ext. 6065. Suggestions for content improvement should be sent by e-mail to LAP at accred@cap.org.

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SUMMARY OF CHANGES
FORENSIC URINE DRUG TESTING Checklist
10/6/2005 Edition

The following questions have been added, revised, or deleted in this edition of the checklist, or in the two editions immediately previous to this one.

If this checklist was created for a reapplication, on-site inspection or self-evaluation it has been customized based on the laboratory's activity menu. The listing below is comprehensive; therefore some of the questions included may not appear in the customized checklist. Such questions are not applicable to the testing performed by the laboratory.

Note: For revised checklist questions, a comparison of the previous and current text may be found on the CAP website. Click on Laboratory Accreditation, Checklists, and then click the column marked Changes for the particular checklist of interest.

NEW Checklist Questions

<u>Question</u>	<u>Effective Date</u>
None.	

REVISED Checklist Questions

<u>Question</u>	<u>Effective Date</u>
None.	

DELETED Checklist Questions

<u>Question</u>	<u>Effective Date</u>
None.	

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INSPECTION TECHNIQUES – KEY POINTS

I. READ – OBSERVE – ASK – the three methods of eliciting information during the inspection process. These three methods may be used throughout the day in no particular order. Plan the inspection in a way that allows adequate time for all three components.

READ = Review of Records and Documents

Document review verifies that procedures and manuals are complete, current, available to staff, accurate and reviewed, and describe good laboratory practice. Make notes of any questions you may have, or processes you would like to observe as you read the documentation.

OBSERVE – ASK = Direct Observation and Asking Questions

Observing and asking questions accomplish the following:

- 1. Verifies that the actual practice matches the written policy or procedure
- 2. Ensures that the laboratory processes are appropriate for the testing performed
- 3. Ensures that outcomes for any problem areas, such as PT failures and issues/problems identified through the quality management process, have been adequately investigated and resolved
- 4. Ensures that previously cited deficiencies have been corrected

Use the following techniques:

- **Observe laboratory practices** – look at what the laboratory is actually doing. Compare the written policy/procedure to what you actually observe in the laboratory to ensure the written policy/procedure accurately reflects laboratory practice. Note if practice deviates from the documented policies/procedures.
- **Ask open ended, probing questions** – these are starting points that will allow you to obtain large amounts of information, and help you clarify your understanding of the documentation you’ve seen and observations you’ve made. This eliminates the need to ask every single checklist question, as the dialogue between you and the laboratory may address multiple checklist questions.

- Ask open-ended questions that start with phrases such as “show me how...” or “tell me about...” or “what would you do if...”. By asking questions that are open-ended, or by posing a hypothetical problem, you will avoid “cookbook” answers. For example, ask “Could you show me the specimen transport policy and show me how you ensure optimum specimen quality?” This will help you to determine how well the technical staff is trained, whether or not they are adhering to the lab’s procedures and policies, and give you a feel for the general level of performance of the laboratory.
- Ask follow-up questions for clarification. Generally, it is best not to ask the checklist questions verbatim. For example, instead of asking the checklist question “Is there documentation of corrective action when control results exceed defined tolerance limits?” ask, “What would you do if the SD or CV doubles one month?” A follow-up probing question could be, “What would you do if you were unable to find a cause for the change in SD or CV?”

II. Evaluate Selected Specimens and Tests in Detail

For the Laboratory General Checklist: Follow a specimen through the laboratory. By following a specimen from collection to test result, you can cover multiple checklist questions in the Laboratory General checklist: questions on the specimen collection manual; phlebotomy; verbal orders; identification of patients and specimens; accessioning; and result reporting, including appropriate reference ranges, retention of test records, maintaining confidentiality of patient data, and proper handling of critical values and revisions to reports.

For the individual laboratory sections: Consult the laboratory’s activity menu and focus on tests that potentially have the greatest impact on patient care. Examples of such tests include HIV antibodies, hepatitis B surface antigen, urine drugs of abuse, quantitative beta-hCG, cultures of blood or CSF, acid-fast cultures, prothrombin time and INR reporting, and compatibility testing and unexpected antibody detection. Other potentially high-impact tests may be identified by looking at very high or low volume tests in the particular laboratory, or problems identified by reviewing the Variant Proficiency Testing Performance Report.

To evaluate preanalytic and postanalytic issues: Choose a representative specimen and “follow” the specimen through the laboratory or section of the laboratory, reviewing appropriate records in the preanalytic and postanalytic categories.

To evaluate analytic processes: Choose 2 or 3 analytes and perform a comprehensive review of records, including procedure manuals, quality control and proficiency testing records, instrument maintenance records and method performance validations for the last 2 years, selecting timeframes at the beginning, mid-point, and end of this timeframe. Compare instrument print-outs to patient reports and proficiency testing results to ensure accurate data entry. If problems are identified, choose additional tests or months to review.

III. Verify that proficiency testing problem have been resolved: From the inspector’s packet, review the Variant PT Performance Report that identifies, by analyte, all of the PT scores below 100%. Correlate any PT problems to QC or maintenance records from the same time period. Be thorough

FDT.00120 **Phase II** **N/A YES NO**

Does the laboratory screen for at least amphetamines, cocaine/metabolite, opiates, phencyclidine, and cannabinoids as part of a forensic urine drug test?

COMMENTARY:

The laboratory must at least screen for amphetamines, cocaine/metabolite, opiates, phencyclidine, and cannabinoids as part of a forensic urine drug test.

FDT.00200 **Phase II** **N/A YES NO**

For confirmation testing of amphetamine/methamphetamine, benzoylecgonine, codeine/morphine, phencyclidine, and delta-9-THC-COOH, is an appropriate mass spectrometry method performed?

COMMENTARY:

An appropriate mass spectrometric method must be performed for confirmation testing of amphetamine/methamphetamine, benzoylecgonine, codeine/morphine, phencyclidine, and delta-9-THC-COOH.

FDT.00300 **Phase II** **N/A YES NO**

Are all positive screening results confirmed using a well-defined and scientifically acceptable method that, when feasible, is analytically different from the screening method?

NOTE: The inspector will list the drugs that are NOT CONFIRMED on the Inspector's Summation Report.

COMMENTARY:

Positive screening test results for all drugs must be confirmed by a well-defined and scientifically acceptable method that, when feasible, is analytically different from the screening method.

FDT.00350 **Phase II** **N/A YES NO**

If positive, is ethanol tested and retested on separate aliquots of the original specimen by scientifically acceptable methods, one or both of which is/are gas chromatography?

COMMENTARY:

NOTE: The intent of this requirement is that the laboratory should treat proficiency testing (PT) samples as much like client samples as is feasible (and still be in compliance with the PT Survey instructions). Replicate analysis of PT samples is acceptable only if patient/client samples are routinely analyzed in the same manner. There must not be any interlaboratory communication on PT data before results reporting. The educational purposes of proficiency testing are best served by a rotation that allows all technologists to be involved in the proficiency testing program. Records of these studies must be kept and can be an important part of the competency and continuing education documentation in the personnel files of the individuals. When external proficiency testing materials are not available, the semi-annual alternative performance assessment process should also be integrated within the routine workload.

COMMENTARY:

Both external proficiency testing and alternative performance assessment samples must be integrated within the routine laboratory workload, and those samples must be analyzed by personnel who routinely test patient/client samples, using the same method systems as for patient/client samples. All of these requirements must be met by the laboratory. There must not be any interlaboratory communication on proficiency testing data before results reporting. The educational purposes and documentation of proficiency are best served by a rotation that allows all technologists to be involved in the proficiency testing program. Records of these studies must be kept and can be an important part of the competency and continuing education documentation in the personnel files of the individuals.

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7146 [42CFR493.801(b)].

FDT.00875

Phase II

N/A YES NO

Is there evidence of evaluation and, if indicated, corrective action in response to "unacceptable" results on the proficiency testing reports and results of the alternative performance assessment system?

NOTE: The evaluation must document the specific reason(s) for the "unacceptable" result(s) and actions taken to reduce the likelihood of recurrence. This must be done within one month after the laboratory receives its proficiency testing evaluation. In addition, each ungraded challenge, each educational challenge, and each episode of nonparticipation must be reviewed and corrective action instituted as appropriate.

COMMENTARY:

There must be evidence of complete evaluation and, if indicated, corrective action in response to each "unacceptable" result on the proficiency testing reports and results of the alternative performance assessment system. The evaluation must document the specific reason(s) for the "unacceptable" result(s) and actions taken to reduce the likelihood of recurrence. This must be done within one month after the laboratory receives its proficiency testing evaluation.

FDT.00950

Phase II

N/A YES NO

Is there evidence of scientific director review of proficiency testing results since the last on-site inspection, and evaluation and appropriate corrective action?

COMMENTARY:

There must be evidence of review by the scientific director of all proficiency testing results since the last on-site inspection, with evaluation and corrective action in response to each "unacceptable" result.

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7173 [42CFR493.1407(e)(4)(iii); 2) NCCLS. Using proficiency testing (PT) to improve the clinical laboratory; approved guideline GP27-A. Wayne, PA: NCCLS, 1998.

QUALITY MANAGEMENT

There shall be an ongoing quality management (QM) program designed by the laboratory to monitor and evaluate objectively and systematically the quality and appropriateness of the information/service provided by the FUDT laboratory. This QM program should be integrated with the institution's overall program, and the scientific director or designee should be an active participant in the institution's QM program.

The inspection team should review the QM program and the documentation that shows that the laboratory is actively following this program.

FDT.01100

Phase II

N/A YES NO

Does the laboratory have a documented quality management program that applies specifically to the services provided by the FUDT laboratory?

COMMENTARY:

The laboratory must have a documented quality management program designed to monitor and evaluate objectively and systematically the quality and appropriateness of the information/service provided.

FDT.01200**Phase I****N/A YES NO**

Is there evidence that the laboratory is involved in influencing the correct collection of client samples?

NOTE: This should include the monitoring of collection problems, chain-of-custody problems, transportation delays, etc. A system should be in place to inform and influence the improvement of these processes. The laboratory must discuss with each client the issues of potential adulteration or excessive dilution of samples and how these affect the analytical methods used by the laboratory. If requested by its clients, the laboratory must be able to perform ancillary tests that may aid in the detection of excessive dilute or potentially adulterated samples, e.g., pH, specific gravity, urine urea nitrogen (UUN), or creatinine.

COMMENTARY:

There must be evidence that the laboratory is involved in monitoring and/or influencing the correct collection of client samples, the quality of the specimens collected, collection problems, chain-of-custody problems, transportation delays, etc. A system should be in place to inform and influence the improvement of these processes. The laboratory must discuss with each client the issues of potential adulteration or excessive dilution of samples and how these affect the analytical methods used by the laboratory. If requested by its clients, the laboratory must be able to perform ancillary tests that may aid in the detection of excessive dilute or potentially adulterated samples, e.g., pH, specific gravity, UUN, or creatinine.

FDT.01400**Phase I****N/A YES NO**

Is there evidence that the laboratory is actively involved in consultation with clients about interpretive problems?

COMMENTARY:

The laboratory should be actively involved in consultation with clients about interpretive problems.

FDT.01500**Phase I****N/A YES NO**

Is there evidence that the laboratory is involved with the education of its clients about correction of problems, new developments, etc.?

NOTE: This may be done through newsletters, on-site educational programs, or other appropriate methods.

COMMENTARY:

with a defined system to permit regular review by appropriate supervisory personnel and the scientific director.

The inspection team should review QC records for each analytical procedure for the past year. The records should reflect the system described in the QC procedures. QC results should be recorded or plotted in a fashion that allows for continuous review. Out-of-control results should be clearly identified and associated with the corrective actions taken along with evidence of review by supervisory personnel, scientific director, or designee.

Judgment of the acceptability of QC data must be made before patient results are reported. Oversight review must occur at least weekly by the Scientific Director or designee, and at least monthly by the scientific director.

 GENERAL QUALITY CONTROL

FDT.02000

Phase II

N/A YES NO

Is there a documented comprehensive QC procedure for each analytical procedure performed?

NOTE: The comprehensive QC procedure must include policies and protocols for the following elements:

1. *Control material used, including content and concentration*
2. *Frequency of analysis*
3. *Sequence location within the batch*
4. *Recording of QC results*
5. *Criteria for acceptance/rejection of QC results*
6. *Corrective actions taken for QC failures*
7. *Protocol used to document the recording and review of QC results and any corrective Actions taken for QC failures*
8. *Requirement and protocol for weekly and monthly QC review*
9. *Delegation of authority for weekly and monthly QC review*
10. *Documenting weekly and monthly QC review*
11. *Monitoring precision of each screening and confirmatory assay, at or near the cutoff(s)*
12. *Detection and correction of significant clerical and analytical errors before reporting the results*

COMMENTARY:

There must be documented protocols for control procedures, and protocols must include the following required elements:

1. Control material used for each assay, including content and concentration
2. Frequency of analysis
3. Sequence location within the batch
4. Recording of QC results
5. Criteria for acceptance/rejection of QC results
6. Corrective actions taken for QC failures
7. Documentation of corrective actions taken for QC failures
8. Requirement and protocol for weekly and monthly QC review
9. Delegation of authority for weekly and monthly QC review
10. Documentation of weekly and monthly QC review
11. Monitoring precision of each screening and confirmatory assay, at or near the cutoff(s)
12. Detection and correction of significant clerical and analytical errors before reporting results

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7166 [42CFR493.1216(b)(1)].

FDT.02005**Phase II****N/A YES NO**

Are appropriate controls used for all SCREENING tests?

NOTE: The following urine controls must be used for all commonly used screening cutoffs to challenge the cutoffs. A control 25% below cutoff may not be practical for some drugs and some cutoffs, i.e. cannabinoids at 20 ng/mL and some benzodiazepines at 100 ng/mL. The blind controls may be internal blind controls, known by the analyst to be blind controls, but blind as to content.

1. *Drug-free*
2. *Approximately 25% below screening cutoff*
3. *Approximately 25% above screening cutoff*
4. *Blind, at least 1% of batch and at least one per batch*
5. *Controls must comprise at least 10% of the samples in a batch, and*
6. *At least one fortified control must be at the end of the batch*

COMMENTARY:

Appropriate controls must be included in all screening tests. Appropriate controls include a drug-free urine, urine controls approximately 25% below and 25% above each of the cutoffs in use, and blind urine controls. Internal blind controls, known by the analyst to be blind controls, but blind as to content, may be used. Blind controls must comprise at least 1% of batch specimens and at least one per batch. Controls must comprise at least 10% of the samples in a batch, and at least one fortified control must be at the end of the batch.

FDT.02010**Phase II****N/A YES NO****Are appropriate controls used for all CONFIRMATION tests using SINGLE POINT CALIBRATION?**

NOTE: The following urine controls must be used for all confirmation tests using single point calibration, for the most common cutoffs in use:

1. *Drug-free*
2. *Approximately 25% below confirmation cutoff(s), or near the limits of quantitation (LOQ)*
3. *Approximately 25% above confirmation cutoff(s), and*
4. *Controls must comprise at least 10% of the samples in a batch*

COMMENTARY:

Appropriate controls must be included in all confirmation tests using single point calibration. Appropriate controls include a drug-free urine, and urine controls approximately 25% below and 25% above the most common cutoffs in use. At least 10% of the samples in a batch must be controls.

FDT.02015**Phase II****N/A YES NO****Are appropriate controls used for all CONFIRMATION tests using MULTIPLE POINT CALIBRATION?**

NOTE: The following urine controls must be used for all confirmation tests using multiple point calibration, for the most common cutoffs in use:

1. *Drug-free*
2. *Positive, at a concentration to challenge the cutoff(s) in use, and*
3. *Controls must comprise at least 10% of the samples in a batch*

COMMENTARY:

Appropriate controls must be included in all confirmation tests using multiple point calibration. Appropriate controls include a drug-free urine and a positive urine control at a concentration at or near the most common cutoff(s) in use. At least 10% of the samples in a batch must be controls.

FDT.02020**Phase I****N/A YES NO****Are conjugated drug controls included, when available, in procedures where conjugates are hydrolyzed?****COMMENTARY:**

In procedures where conjugates are hydrolyzed, conjugated drug controls should be included (when available) to verify satisfactory hydrolysis.

FDT.02025**Phase II****N/A YES NO**

Does the QC procedure include an internal blind QC program as an integral part of the laboratory's QC system?

NOTE: An internal blind quality control program is a required part of the laboratory's QC program. Single-blind controls, known to the analyst to be controls, but blind as to content are acceptable. At least one specimen per screening batch and at least 1% of the screening samples must be blind controls. There is no requirement for positive internal screening blind controls to be confirmed. The results of the blind control analysis must be reviewed and accepted before release of any positive or negative results. The internal blind QC samples should include at least 20% positive samples that include challenges from all drugs being tested by the laboratory in a forensic urine drug test. The review of the internal blind QC program must be a part of the routine QC review responsibilities of the laboratory supervisory personnel and the scientific director. An internal or external double blind QC program, where the analyst does not know the identity or content of the blind, is encouraged but not mandatory.

COMMENTARY:

The laboratory must have an internal blind quality control program as an integral part of the laboratory's QC program. Single-blind controls, known by the analyst to be controls, but blind as to content, are acceptable. At least one specimen per screening batch and at least 1% of the screening samples must be blind controls. There is no requirement for positive internal blind controls to be confirmed. The results of the blind control analysis must be reviewed and accepted before release of any positive or negative specimens. The internal blind QC samples should include at least 20% positive samples that include challenges from all drugs being tested. The review of the internal blind QC program must be a part of the routine QC review responsibilities of the laboratory supervisory personnel and the scientific director. An internal or external double blind QC program, where the analyst does not know the identity or content of the blind, is encouraged but not mandatory.

FDT.02030**Phase II****N/A YES NO**

Are criteria for acceptance and rejection of controls defined and appropriate?

NOTE: The criteria for qualitative screening assays must be such that the positive control at approximately 25% above the cutoff gives a positive response to be acceptable, and the 25% below cutoff control gives a negative result. The criteria for acceptance/rejection of quantitative QC results should at a minimum include the rejection of QC results that exceed $\pm 20\%$ of the established control mean. Other criteria may be used to more closely monitor an assay's performance, i.e., use of Westgard multirules based on an assay's actual precision characteristics.

NOTE: Appropriate actions taken when QC failures occur include repeating the analytical batch, but may also involve recalibration of the assay, investigation of potential analytical system malfunction, use of new control material, etc. Whatever corrective actions are taken must be documented.

COMMENTARY:

Control records must show evidence that corrective actions have been taken when values exceed the defined tolerance limits. Appropriate actions taken when QC failures occur include repeating the analytical batch, but may also involve recalibration of the assay, investigation of potential analytical system malfunction, use of new control material, etc. Whatever corrective actions are taken must be documented.

PROCEDURE MANUAL

The procedure manual should be used by personnel at the workbench and should include: test principle, clinical significance, specimen type, required reagents, test calibration, quality control, procedural steps, calculations, reference intervals, and interpretation of results. The manual should address relevant pre-analytic and post-analytic considerations, as well as the analytic activities of the laboratory. The specific style and format of procedure manuals are at the discretion of the laboratory director. The procedure manual must also include documentation of initial and annual reviews by the scientific director.

The inspection team should review the procedure manual in detail to understand the laboratory's standard operating procedures, ensure that all significant information and instructions are included, and that actual practice matches the contents of the procedure manuals.

FDT.02720

Phase II

N/A YES NO

Is a complete procedure manual available at the workbench or in the work area?

NOTE 1: The use of inserts provided by a manufacturer is not acceptable in place of a procedure manual. Such inserts, however, may be used as part of a procedure description, if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from the manufacturer's printed or electronic procedure must be detailed in the procedure manual. In all cases, appropriate reviews must occur and be documented.

NOTE 2: A manufacturer's procedure manual for an instrument/reagent system may be acceptable as a component of the overall departmental procedures. Any modification to or deviation from the procedure manual must be clearly documented.

NOTE 3: Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that:

- a. *A complete manual is available for reference*
- b. *The card file or similar system corresponds to the complete manual and is subject to document control*

NOTE 4: Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies, so long as the electronic versions are readily available to all personnel. Such electronic versions must be subjected to proper document control (i.e., only authorized persons may make changes, changes are dated/signed (manual or electronic), and there is documentation of periodic review). Current paper copies of electronically stored procedures should be available at the time of the CAP inspection, or rapidly generated at the request of the inspector.

COMMENTARY:

A documented procedure manual must be developed for the FUDT laboratory and be available at the workbench. Its elements should include: test principle, clinical significance, specimen type(s), required reagents, calibration, quality control, procedural steps, calculations, reference intervals, and interpretation, as applicable.

NOTE 1: The use of inserts provided by manufacturers is not acceptable in place of a procedure manual. However, such inserts may be used as part of a procedure description, if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from the manufacturer's procedure must be detailed in the procedure manual. In all cases, the procedure must be signed by the responsible person.

NOTE 2: A manufacturer's procedure manual for an instrument/reagent system may be acceptable as a component of departmental procedures. Any modification to, or deviation from, the procedure manual, must be clearly documented.

NOTE 3: Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that:

- a. *A complete manual is available for reference*
- b. *The card files or similar system correspond to the complete manual and is subject to document control*

NOTE 4: Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies, so long as the electronic versions are readily available to all personnel. Such electronic versions must be subjected to proper document control (i.e., only authorized persons may make changes, changes are dated/signed (manual or electronic), and there is documentation of periodic review). Current paper copies of electronically stored procedures should be available at the time of the CAP inspection, or rapidly generated at the request of the inspector.

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7164 [42CFR493.121; 2) van Leeuwen AM. 6 steps to building an efficiency tool. *Advance/Laboratory*. 1999;8(6):88-9; 3) Borkowski A, *et al*. Intranet-based quality improvement documentation at the Veterans Affairs Maryland health care system. *Mod. Pathol*. 2001;14:1-5; 4) NCCLS. Clinical laboratory technical procedure manuals - fourth edition; approved guideline GP2-A4. Wayne, PA: NCCLS, 2002.

FDT.03100**Phase II****N/A YES NO**

Is each procedure reviewed annually, dated, and signed or initialed by the scientific director?

NOTE: The scientific director must ensure that the collection of technical protocols is complete, current, and has been thoroughly reviewed. Technical approaches must be scientifically valid. To minimize the burden on the laboratory and reviewer(s), it is suggested that a schedule be developed whereby roughly 1/12 of all procedures are reviewed monthly. Paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. A single signature on a Title Page or Index of all procedures is not sufficient documentation that each procedure has been carefully reviewed. Signature or initials on each page of a procedure is not required.

COMMENTARY:

There must be documentation of at least annual review of all procedures by the current scientific director. The director is responsible for ensuring that the collection of technical protocols is complete, current, and has been thoroughly reviewed. Technical approaches must be scientifically valid. To minimize the burden on the laboratory and reviewer(s), it is suggested that a schedule be developed whereby roughly 1/12 of all procedures are reviewed monthly. Paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. A single signature on a title page or index of all procedures is not sufficient documentation that each procedure has been carefully reviewed. Signature or initials on each page of a procedure is not required.

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7173 [42CFR493.1407(e)(13); 2) Borkowski A, *et al*. Intranet-based quality improvement documentation at the Veterans Affairs Maryland health care system. *Mod. Pathol*. 2001;14:1-5.

FDT.03150**Phase II****N/A YES NO**

Does the director or designee review and approve all new policies and procedures, as well as substantial changes to existing documents, before implementation?

NOTE: Current practice must match the policy and procedure documents.

FDT.03350**Phase II****N/A YES NO**

Does the laboratory have a system in operation documenting that all laboratory personnel are knowledgeable about the contents (including changes) of the procedure manual that are relevant to the scope of their responsibilities?

NOTE: This does not specifically require annual procedure sign-off by testing personnel. The form of this system is at the discretion of the laboratory director.

COMMENTARY:

The laboratory must have a system in place documenting that all laboratory personnel are knowledgeable about the contents of the procedure manual (including changes) that are relevant to the scope of their responsibilities. This does not specifically require annual procedure sign-off by testing personnel. The form of this system is at the discretion of the laboratory director.

FDT.03400**Phase II****N/A YES NO**

Is there a complete procedure written for each analytical test?

NOTE: Information must include, where appropriate:

1. Principles of each test
2. Preparation of reagents, standards/calibrators, and controls
3. Protocol for performing the analysis
4. Directions for calibration and calibration verification
5. Derivation of results (i.e., direct readout, calibration from a standard or against a multi-point curve, definitions for semi-quantitative readout)
6. LOQ, linearity of quantitative methods and the course of action taken if results exceed this linearity
7. Limit of detection (LOD)
8. Specificity of the method (i.e., interferences)
9. Cutoff values used for screening and confirmation
10. How to report when the result is below the cutoff value
11. Controls used in the assay
12. Criteria for unacceptable result,
13. Notes, special requirements, safety precautions, etc.
14. Carryover potential and the actions to take when carryover is detected
15. Pharmacokinetic information about the drug or drug group
16. References

COMMENTARY:

The procedure manual must include the following information for each analytical procedure (where appropriate):

1. Principles of each test
2. Preparation of reagents, standards/calibrators, and controls
3. Protocol for performing the analysis
4. Directions for calibration and calibration verification
5. Derivation of results (*i.e.*, direct readout, calibration from a standard or against a multi-point curve, definitions for semi-quantitative readout)
6. Limits of quantitation (LOQ) and linearity of quantitative methods and the course of action taken if results exceed this linearity
7. Detection limits of the method (LOD)
8. Specificity of the method (*i.e.*, interferences)
9. Cutoff values used for screening and confirmation
10. How to report when the result is below the cutoff value
11. Controls used in the assay
12. Criteria for unacceptable results
13. Notes, special requirements, safety precautions, *etc.*
14. Carryover potential and the actions to take when carryover is detected
15. Pharmacokinetic information about the drug or drug group
16. References

FDT.04700

Phase II

N/A YES NO

Does the procedure manual have an index or is it organized in a fashion that allows for quick retrieval of information?

COMMENTARY:

The procedure manual must have an index or be organized in a fashion that allows for quick retrieval of information.

SPECIMEN HANDLING

Review the documented procedures and thoroughly inspect the specimen handling in the laboratory. This may require a prearranged inspection during the evening or night shifts in some laboratories. Particular attention should be paid to specimen receipt, verification of identity, accessioning, external and internal chain-of-custody, labeling, specimen examination, evaluation of sample volume, any adulteration and dilution checks, evaluation of integrity of seals or secured containers and leakage, documentation of exceptions, aliquoting, placing into batches, storing, and completion of records. The inspector should verify that the process follows the documented procedure and that the process is satisfactory in all aspects. Any observed problems should be detailed to the scientific director at the summation conference and in the Inspector's Summation Report.

FDT.04890 **Phase II** **N/A YES NO**

Does the documented accessioning procedure require unique labeling of each specimen by the laboratory?

COMMENTARY:

The accessioning procedure must require unique labeling of each specimen by the laboratory.

FDT.04910 **Phase II** **N/A YES NO**

Does the laboratory generate and properly complete internal chain-of-custody documents to legally account for the specimens and aliquots, as appropriate?

NOTE: The chain-of-custody procedure must account for all individuals who handle the specimens/aliquots, the storage location of the specimens/aliquots when not in the possession of an authorized individual, the reason for the transfer of custody, and the date of the transfer.

COMMENTARY:

The laboratory must generate, complete, and maintain internal chain-of-custody documents to account for the specimens and aliquots. The chain-of-custody procedure must account for all individuals who handle the specimens/aliquots, the storage location of the specimens/aliquots when not in the possession of an authorized individual, the reason for the transfer of custody, and the date of the transfer.

FDT.04930 **Phase II** **N/A YES NO**

Are the specimens always maintained in their original containers in a secured area to which only authorized individuals have access?

NOTE: The secured area may be a refrigerator, freezer, storage room, or a separate area within the laboratory.

COMMENTARY:

Specimens must be maintained in their original container and in a secured area when not in the custody of an authorized individual. The secured area may be a refrigerator, freezer, storage room, or a separate area within the laboratory.

FDT.04950 **Phase II** **N/A YES NO**

Is access to specimens, aliquots, and any extracts thereof restricted to authorized laboratory personnel?

COMMENTARY:

Access to specimens, aliquots, and any extracts thereof must be restricted to authorized laboratory personnel assigned to preparation and analysis, or to supervisory personnel.

FDT.05000 **Phase II** **N/A YES NO**

Does the documented accessioning procedure have defined criteria for determining the acceptability of specimens for analysis, and is there a documented protocol for the course of action that must be followed when unacceptable specimens are identified?

NOTE: Evaluation criteria such as chain-of-custody failures, missing information, specimen leakage, etc. must be documented in the accessioning procedure, along with the required actions that laboratory personnel must take in reporting these problems to the client.

COMMENTARY:

There must be a procedure defining criteria for evaluating the quality of the submitted urine samples for acceptability. There must be instructions for the actions to take if unacceptable specimens are detected.

FDT.05020 **Phase II** **N/A YES NO**

Is there a documented procedure for determining the quality of specimens received for analysis, and course of action to take when unacceptable specimens are detected (e.g., color, odor, volume, foreign material, etc.)?

NOTE: This procedure should require at least the visual inspection of urine samples and assessment of the sample volume for acceptability for analysis.

COMMENTARY:

There must be a documented procedure for the determination of acceptability of sample quality for analysis that must include at least visual inspection, volume determination, and the course of action to be taken when unacceptable samples are identified.

FDT.05090 **Phase II** **N/A YES NO**

Is the aliquoting procedure followed by the staff?

NOTE: The inspector should observe the aliquoting process to determine whether the documented procedure is satisfactory and being followed.

COMMENTARY:

The aliquoting procedure must be satisfactory and followed by the staff to prevent cross-contamination and specimen mix-up.

FDT.05100 **Phase II** **N/A YES NO**

Is there a documented policy that no aliquot is ever returned to the original container?

COMMENTARY:

There must be a documented policy indicating that an aliquot is never returned to the original container.

FDT.05400 **Phase II** **N/A YES NO**

Do laboratory personnel consistently follow the policy of never returning an aliquot to the original container?

COMMENTARY:

Laboratory personnel must follow the documented policy of never returning an aliquot to the original container.

FDT.05700 **Phase II** **N/A YES NO**

Is there a documented policy that all positive specimens are retained frozen in their original containers for at least one year?

COMMENTARY:

There must be a documented policy that positive specimens are required to be retained frozen in their original container for a minimum of one year.

1. *Chain-of-custody documents*
2. *Results of calibrators*
3. *Results of quality controls*
4. *Identifications of specimens tested in each batch*
5. *Testing sequence of calibrators, controls, and unknowns*
6. *Results of specimens*
7. *Identity of analyst(s) performing the test*

COMMENTARY:

There must be a documented requirement that each of the following steps of the analytical screening and confirmatory procedures are reviewed and documented:

1. Chain-of-custody documents
2. Results of calibrators
3. Results of quality controls
4. Identifications of specimens tested in each batch
5. Testing sequence of calibrators, controls, and unknowns
6. Results of specimens
7. Identity of analyst(s) performing the test

FDT.05815**Phase II****N/A YES NO****Is the certification procedure followed?****COMMENTARY:**

The laboratory must certify all results according to the procedure before reporting.

FDT.05850**Phase II****N/A YES NO****Does the certifying review procedure require documented identification of the reviewer, and the date of the completed review?****COMMENTARY:**

The certifying review procedure must require identification of the reviewer, and the date review was performed.

- 8. Evidence of review of the completed data by a certifying official
- 9. Evidence of comparison of initial and confirmatory testing to ensure consistent results

COMMENTARY:

Data from all screening and confirmatory tests must be available, and contain the following:

- 1. Results of standards or calibrators
- 2. Results of controls
- 3. Results of patient/donor specimens tested
- 4. Laboratory identification and sequence of specimens tested
- 5. Evidence of any repeat injections, reanalysis, secondary screening or rescreening
- 6. Identity of the individual(s) performing and reviewing the tests
- 7. Evidence of potential carryover review
- 8. Evidence of review of the completed data by a certifying official
- 9. Evidence of comparison of initial and confirmatory testing to ensure consistent results

FDT.05886	Phase II	N/A YES NO
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Do the records permit valid review of the data?

COMMENTARY:

The records must be complete to permit valid review of the data.

REPORTING OF RESULTS

The inspection team should review the laboratory's reporting system to ensure that appropriate and accurate information is reported to clients, and that this reporting system maintains confidentiality. This should include review of printed reports, FAX reports with documentation of transmission to a "secured or confidential FAX," remotely printed reports with documentation of their transmission in a confidential fashion, and determination of the security and confidentiality of computer access if results are made available via computer terminals.

FDT.05900	Phase II	N/A YES NO
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Are there documented protocols for the reporting of results to clients or their representatives?

NOTE: These protocols require that a forensic urine drug test report must include the following:

- 1. Date of specimen collection (when given)

2. *Date of specimen receipt by the laboratory*
3. *Donor and client identification information*
4. *Laboratory's unique specimen identification information*
5. *Drugs analyzed as part of the forensic urine drug test*
6. *Cutoff values per drug for both screening and confirmation tests*
7. *Positive and/or negative results*
8. *Date of report*

COMMENTARY:

There must be documented protocols for the reporting of results present. The reports of forensic urine drug tests must include the following elements:

1. Date of specimen collection (when given)
2. Date of specimen receipt by the laboratory
3. Donor and client identification information
4. Laboratory's unique specimen identification information
5. Drugs analyzed as part of the forensic urine drug test
6. Cutoff values per drug for both screening and confirmation tests
7. Positive and/or negative results
8. Date of report

FDT.06500**Phase II****N/A YES NO**

Are only confirmed positives reported as positive?

COMMENTARY:

For specimens under the CAP FUDT accreditation program, only confirmed positives can be reported as positive. Specimens that have only been screened are classified as not being part of the FUDT program.

FDT.06600**Phase II****N/A YES NO**

Are there documented protocols for reporting of results by telephone?

NOTE: The CAP FUDT Program does not prohibit results reporting by telephone; however, the laboratory must have a documented protocol for ensuring the reliability and confidentiality of telephone reports. A permanent report must follow the reporting of results by telephone.

COMMENTARY:

There must be a documented protocol for reporting results by telephone, ensuring the reliability and confidentiality of reports. A permanent report must follow the reporting of results by telephone.

FDT.06700 Phase II N/A YES NO

Are there documented protocols for the electronic reporting of results (e.g., computer, FAX)?

COMMENTARY:

There must be a documented protocol for procedures for reporting results by electronic techniques such as computer or FAX.

FDT.06800 Phase II N/A YES NO

Do documented protocols for reporting emphasize confidentiality of reports?

NOTE: The reporting of forensic drug testing results must be done in a confidential manner such that only authorized personnel can receive, review, or print these results, regardless of the methods used for reporting (telephone, FAX, remote printer, computer terminal, etc.).

COMMENTARY:

The documented protocols for reporting results must emphasize the confidentiality of reports. The reporting of forensic drug testing results should be done in a confidential manner such that only authorized personnel can receive, review, or print results regardless of the methods used for reporting (telephone, FAX, remote printer, computer terminal, etc.).

RECORDS

The laboratory must maintain various records to meet the requirements of the CAP FUDT Accreditation Program. The inspection team should review the laboratory's system of record maintenance and control to ensure that records are maintained in a secure manner. The inspection team should review the laboratory's records from: the previous on-site FUDT inspection; the previous on-site general CAP inspection, and the previous FUDT self-inspection.

The laboratory must maintain the following records for at least 2 years:

1. *Laboratory security access logs*
2. *Laboratory accessioning logs*
3. *Chain-of-custody documents and requisitions*
4. *Analytical data from screening and confirmation analyses*
5. *Specimen reports*
6. *QC program records*

7. *Instrument maintenance/service records*
8. *Instrument calibration records*
9. *Reagent/standard/calibrator/control preparation and verification records*
10. *Method performance validation records*
11. *Personnel files on all laboratory personnel involved with the forensic drug testing performed by the laboratory*
12. *Proficiency testing survey results, reports, and corrective actions*
13. *Previous CAP FUDT on-site inspection records and corrective actions*
14. *Previous CAP FUDT self-inspection records and corrective actions*
15. *Previous CAP general on-site inspection records and corrective actions appropriate to the FUDT laboratory*

FDT.07000**Phase II****N/A YES NO**

Is there a documented procedure that defines which records, and for what time periods, records must be maintained to meet client, legal, regulatory, and accreditation requirements?

COMMENTARY:

The laboratory must have a documented procedure that defines which records, or the time period for retention, that are required by clients, legal processes, regulatory or accrediting agencies. The CAP FUDT accreditation program requires retention of the following forensic records for at least two years:

1. Laboratory security access logs
2. Laboratory accessioning logs
3. Chain-of-custody documents and requisitions
4. Analytical data from screening and confirmation analyses
5. Specimen reports
6. QC program records
7. Instrument maintenance/service records
8. Instrument calibration records
9. Reagent/standard/calibrator/control preparation and verification records
10. Method performance validation records
11. Personnel files on all laboratory personnel involved with the forensic drug testing performed by the laboratory
12. Proficiency testing survey results, reports, and corrective actions
13. Previous CAP FUDT on-site inspection records and corrective actions
14. Previous CAP FUDT self-inspection records and corrective actions
15. Previous CAP general on-site inspection records and corrective actions appropriate to the FUDT laboratory

FDT.07100**Phase II****N/A YES NO**

Are the records maintained in a secured area that is only accessible to authorized personnel?

NOTE: Proper labeling should include, as applicable and appropriate, the following elements:

1. *Content and concentration, level, or titer*
2. *Date prepared or received*
3. *Expiration date*
4. *Storage requirements*
5. *Safety precautions or warnings*

The above elements may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so as to be traceable to the appropriate data in the log. While useful for inventory management, labeling with "date received" is not routinely required. There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc. The inspector will describe specific issues of non-compliance in the Inspector's Summation Report.

COMMENTARY:

N/A

FDT.17210

Phase II

N/A YES NO

Are outdated RSCC discarded and replaced routinely?

NOTE: Certain expensive reagents may warrant use after the labeled expiration date. In such cases, the laboratory must have a clearly defined, documented policy specifying such reagents, circumstances under which extended usage may exist, special control procedures to be implemented and specific person authorizing their use.

COMMENTARY:

Outdated reagents must be discarded and replaced. Certain expensive reagents may warrant use after the labeled expiration date. In such cases, the laboratory must have a clearly defined and documented policy specifying such reagents, circumstances under which extended usage may exist, special control procedures to be implemented and the specific person authorizing their use.

FDT.17220

Phase II

N/A YES NO

Are high quality drug calibration standards and control materials used whenever possible?

NOTE: Calibrators or calibration standards are test materials with defined values that establish the relationship between the response measurement and the output values. "Calibration standard" refers to a primary reference material that is of fixed or known composition. "Calibrators" are secondary

materials and are the test materials most often used by laboratories for calibration. Control materials should have known values, and be independent of the calibrators provided by the manufacturer of a method system, if possible.

COMMENTARY:

High quality standards must be used whenever possible. Calibrators or calibration standards are test materials with defined values that establish the relationship between the response measurement and the output values. "Calibration standards" refers to a primary reference material that is of fixed or known composition. Calibrators are secondary materials and are the test materials most often used by laboratories for calibration. Control materials should have known values, and be independent of the calibrators provided by the manufacturer of a method system, if possible.

FDT.17230 Phase II N/A YES NO

Are drug calibration standards documented as to quality?

NOTE: The laboratory may use manufacturer's certification data for the purity of the drug calibration standards, but must still independently document the quantitative accuracy of any calibrator solutions created from the calibration standard. If manufacturer's certification of purity is not available, then the laboratory must validate the purity by determining if any significant extraneous compounds are present, using the appropriate analytical methods. Minimum requirements would be the analysis of a pure drug standard solution using GC/MS (or the same method used for drug confirmation analysis) to demonstrate that no interfering compounds are present.

COMMENTARY:

There must be documentation of the quality of drug standards used by the laboratory. The laboratory may use manufacturer's certification data for the purity of the drug calibration standards, but must still independently document the quantitative accuracy of any calibrator solutions created from the calibration standard. If manufacturer's certification of purity is not available, then the laboratory must validate the purity by determining if any significant extraneous compounds are present, using the appropriate analytical methods. Minimum requirements would be the analysis of a pure drug standard solution using GC/MS (or the same method used for drug confirmation analysis) to demonstrate that no interfering compounds are present.

FDT.17330 Phase II N/A YES NO

If the laboratory prepares calibrators and controls in-house, does it use different sources or lot numbers of drug calibration standards (when possible) for the creation of calibrators and controls, or at least prepare these materials separately?

COMMENTARY:

.....
 Glassware

FDT.17830

Phase II

N/A YES NO

Are glass volumetric pipettes of certified accuracy (Class A, National Institute of Standards and Technology (NIST) standard or equivalent) or, if not certified, are they checked by gravimetric, colorimetric, or some other verification procedure before initial use?

NOTE: The following table shows the American Society for Testing and Materials' calibration (accuracy) specifications for Class A volumetric pipettes:

Nominal Capacity (mL)	Variation (\pm mL)
0.5 - 2	0.006
3 - 7	0.01
8 - 10	0.02
15 - 30	0.03
40 - 50	0.05
100	0.08

COMMENTARY:

Glass volumetric pipettes must either be of certified accuracy (Class A, National Institute of Standards and Technology (NIST) standard or equivalent) or be calibrated before initial use. Reconstitution of lyophilized calibrators, controls or proficiency testing materials, or any other tasks requiring accurate volumetric measurement, must be performed only with measuring devices of class A accuracy, or those for which accuracy has been defined and deemed acceptable for the intended use. The following table shows the American Society for Testing and Materials' calibration (accuracy) specifications for class A volumetric pipettes:

NOMINAL CAPACITY (mL)	VARIATION (\pm mL)
0.5 - 2	0.006
3 - 7	0.01
8 - 10	0.02
15 - 30	0.03
40 - 50	0.05
100	0.08

REFERENCES: 1) Curtis RH. Performance verification of manual action pipets. Part I. *Am Clin Lab.* 1994;12(7):8-; 2) Curtis RH. Performance verification of manual action pipets. Part II. *Am Clin Lab.* 1994;12(9):16-1; 3) Perrier S, *et al.* Micro-pipette calibration using a ratiometric photometer-reagent system as compared to the gravimetric method. *Clin Chem.* 1995;41:S18; 4) American Society for

calibration accuracy either by volumetric, colorimetric, gravimetric, or other means. Results of such checks must be documented.

REFERENCES: 1) Curtis RH. Performance verification of manual action pipets. Part I. *Am Clin Lab.* 1994;12(7):8-; 2) Curtis RH. Performance verification of manual action pipets. Part II. *Am Clin Lab.* 1994;12(9):16-1; 3) Perrier S, *et al.* Micro-pipette calibration using a ratiometric photometer-reagent system as compared to the gravimetric method. *Clin Chem.* 1995;41:S18; 4) Bray W. Software for the gravimetric calibration testing of pipets. *Am Clin Lab.* Oct 1995 (available on the internet at http://www.labtronics.com/pt_art.htm; 5) Kroll MH, *et al* (eds). Laboratory instrument evaluation, verification & maintenance manual, 5th edition. Northfield, IL: College of American Pathologists, 1999:126-12; 6) Johnson B. Calibration to dye for: Artel's new pipette calibration system. *Scientist.* 1999;13(12):1; 7) Connors M, Curtis R. Pipetting error: a real problem with a simple solution. Parts I and II. *Am Lab News.* 1999;31(13):20-2; 8) Skeen GA, Ashwood ER. Using spectrophotometry to evaluate volumetric devices. *Lab Med.* 2000;31:478-479.

FDT.18230

Phase II

N/A YES NO

Are automatic pipettes that are used for quantitative dispensing checked for accuracy and reproducibility at specified intervals, and results documented?

NOTE: For analytic instruments with integral automatic pipettors, it may not be practical for the end-user laboratory to conduct its own tests of pipetting accuracy and precision. Manufacturers' recommendations should be followed.

COMMENTARY:

Automatic pipettes used for quantitative dispensing must be checked for accuracy and reproducibility at specified periodic intervals. Results of such checks must be documented. For analytic instruments with integral automatic pipettors, it may not be practical for the end-user laboratory to conduct its own tests of pipetting accuracy and precision. Manufacturers' recommendations should be followed.

REFERENCES: 1) Curtis RH. Performance verification of manual action pipets. Part I. *Am Clin Lab.* 1994;12(7):8-; 2) Curtis RH. Performance verification of manual action pipets. Part II. *Am Clin Lab.* 1994;12(9):16-1; 3) Perrier S, *et al.* Micro-pipette calibration using a ratiometric photometer-reagent system as compared to the gravimetric method. *Clin Chem.* 1995;41:S18; 4) Bray W. Software for the gravimetric calibration testing of pipets. *Am Clin Lab.* Oct 1995 (available on the internet at http://www.labtronics.com/pt_art.htm; 5) Kroll MH, *et al* (eds). Laboratory instrument evaluation, verification & maintenance manual, 5th edition. Northfield, IL: College of American Pathologists, 1999:126-12; 6) Johnson B. Calibration to dye for: Artel's new pipette calibration system. *Scientist.* 1999;13(12):1; 7) Connors M, Curtis R. Pipetting error: a real problem with a simple solution. Parts I and II. *Am Lab News.* 1999;31(13):20-2; 8) Skeen GA, Ashwood ER. Using spectrophotometry to evaluate volumetric devices. *Lab Med.* 2000;31:478-479.

FDT.19530 **Phase II** **N/A YES NO**

Is there a documented procedure for the proper use of analytical balances, and does that procedure require that balances are mounted on a vibration-free stand?

COMMENTARY:

The laboratory must have a documented procedure for the proper use of analytic balances, and require that the balance is mounted on a vibration-free base.

FDT.19630 **Phase II** **N/A YES NO**

Are balances cleaned, serviced, and checked periodically by qualified service personnel?

COMMENTARY:

Balances must be cleaned, serviced, and recalibrated by experienced personnel.

FDT.19730 **Phase II** **N/A YES NO**

Are standard weights (of appropriate ANSI/ASTM class) available and used for checking accuracy, and are results documented?

NOTE: The verification of accuracy of the analytical balance must be performed each time it is used for the creation of analytical calibrators and/or assayed controls from standard materials, as well as when gravimetrically checking the accuracy of pipettes. The use of a comparable ANSI/ASTM Class weight should be used to check the accuracy of the balance, and this check must be recorded.

COMMENTARY:

Standard weights must be available to check balances for accuracy, and results must be documented. Appropriate ANSI/ASTM class weights must be used to verify balance accuracy when weighing standard materials to prepare analytical calibrators or assayed controls, as well as when gravimetrically checking the accuracy of pipettes. The verification of accuracy of the analytical balance must be performed each time it is used for the creation of analytical calibrators and/or weighed-in controls from standard materials. Weights with a class tolerance factor greater than the readability of the balance should be used. ASTM Class 1 weights are appropriate for calibrating high precision analytical balances (0.01 to 0.1 mg). ASTM Class 2 weights are appropriate for calibrating high precision top-loading balances with readabilities from 0.001 to 0.01 g. ASTM Class 3 weights are appropriate for calibrating moderate precision balances, from 0.01 to 0.1 g. Verification of accuracy need not be performed more than once per shift.

For assay modifications such as dilution or enrichments, there must be validation data to support that the modification produces reliable results.

FDT.20980**Phase II****N/A YES NO**

If automatic pipetting is used, has the laboratory evaluated the testing system for carryover effects?

NOTE: The laboratory must have a procedure in place for evaluating whether carryover effects are present. One suggested method is to run known high samples (calibrators, standards, reference material, assayed controls), followed by known low samples to see if the results of the low-level material are affected. If carryover is detected, the laboratory must determine the level beyond which low-level samples are affected and this must be defined in the procedure. Results of each analytical run must be reviewed to ensure that no results exceed this level. If results that exceed the defined level are detected, then the appropriate course of action must be defined (repeat subsequent samples, for example).

COMMENTARY:

When automatic pipetting is used, the laboratory must have a procedure in place for evaluating whether carryover effects are present. One suggested method is to run known high samples (calibrators, standards, reference material, assayed controls), followed by known low samples to see if the results of the low-level material are affected. If carryover is detected, the laboratory must determine the level beyond which low-level samples are affected and this must be defined in the procedure. Results of each analytical run must be reviewed to ensure that no results exceed this level. If results that exceed the defined level are detected, then the appropriate course of action must be defined (repeat subsequent samples, for example).

FDT.21030**Phase II****N/A YES NO**

Are appropriate calibrators used?

NOTE: Appropriate calibrators for screening assays should consist of at least one positive calibrator. If only one calibrator is used, it must be at the declared cutoff value(s).

Laboratories may use historical calibrations; however, controls must be run with each batch to verify the calibration. In addition, the laboratory should have validated the stability of the calibration, and documented the validation.

COMMENTARY:

Specified appropriate calibrators must be used in each run or batch of samples. Appropriate calibrators for screening assays should consist of at least one positive calibrator or calibration standard in each

COMMENTARY:

The background radioactivity, including the background in each well of a multi-well counter, must be determined each day of use.

FDT.21680 Phase II

N/A YES NO

Is there a documented procedure or policy defining situations when reanalysis and secondary screening are allowed or required?

COMMENTARY:

There must be a documented procedure or policy defining situations when reanalysis and secondary screening are allowed or required.

HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

FDT.22130 Phase II

N/A YES NO

Are there documented procedures for calibration, operation, and maintenance of HPLC equipment?

COMMENTARY:

Procedures must be documented for operation, calibration, and maintenance of HPLC equipment.

FDT.22230 Phase II

N/A YES NO

Does the documented HPLC procedure require monitoring the performance of the column and detector on each day of use?

NOTE: There must be a system that monitors the performance of the HPLC column and detector. Unextracted standards, extracted calibrators or controls, typically containing the target compound(s) may be analyzed each day of use to monitor critical aspects of HPLC performance. Appropriate criteria for evaluating such parameters as retention time, relative retention time, separation of closely eluting compounds of interest, plates, chromatography quality and detector response should be established and monitored. These records must be maintained.

COMMENTARY:

There must be a system that monitors the performance of the HPLC column and detector. Unextracted standards, extracted calibrators or controls, typically containing the target compound(s) may be analyzed each day of use to monitor critical aspects of HPLC performance. Appropriate criteria for evaluating such parameters as retention time, relative retention time, separation of closely eluting compounds of interest, plates, chromatography quality and detector response should be established and monitored. These records must be maintained.

FDT.22280 **Phase II** **N/A** **YES** **NO**

Does the documented procedure require that appropriate extracted calibrator(s) are analyzed with each batch of samples?

NOTE: At least one extracted calibrator at the commonly accepted cutoff for single-point calibration, or multiple calibrators above and below the commonly accepted cutoff for multipoint calibration, must be analyzed with each run.

COMMENTARY:

The documented procedure must require that appropriate extracted calibrator(s) are analyzed with each batch of samples. At least one extracted calibrator at the commonly accepted cutoff for single-point calibration, or multiple calibrators above and below the commonly accepted cutoff for multipoint calibration, must be analyzed with each run.

FDT.22330 **Phase II** **N/A** **YES** **NO**

Does the documented procedure require that appropriate blanks and controls are extracted and analyzed with each batch of specimens?

NOTE: See General Quality Control section for specific controls required.

COMMENTARY:

The documented procedure must require that appropriate blanks and controls are extracted and analyzed with each batch of specimens.

FDT.22430 **Phase II** **N/A** **YES** **NO**

Are internal standards used?

COMMENTARY:

Internal standards must be used.

FDT.22530 **Phase II** **N/A YES NO**

Are new columns verified for acceptable performance before use?

COMMENTARY:

New columns must be verified for acceptable performance before use.

FDT.22830 **Phase II** **N/A YES NO**

Are specimen run order, chromatographic peak shape, retention time, detector response for calibrators, controls and unknowns recorded and maintained for review?

COMMENTARY:

The specimen run order, chromatographic peak shape, retention time, and detector response for calibrators, controls, and unknowns must be recorded and maintained for review.

FDT.22930 **Phase I** **N/A YES NO**

Are the analytical data presented to permit valid scientific review by the analyst of the data for calibrators, controls, and unknowns?

COMMENTARY:

The analytical data should be presented in a fashion to permit valid scientific review of the data for calibrators, controls, and unknowns by the analyst.

FDT.23030 **Phase II** **N/A YES NO**

Whether an automatic sampler or manual injection is used, are there criteria for the detection of potential carryover in each analytical batch run?

COMMENTARY:

No matter what type of injection is used, the procedure must discuss criteria for the evaluation of potential carryover from a preceding high concentration specimen to the following specimen in each analytical batch analysis.

FDT.23080**Phase II****N/A YES NO**

Is there a documented procedure or policy defining situations when reanalysis and secondary screening are allowed or required?

COMMENTARY:

There must be a documented procedure or policy defining situations when reanalysis and secondary screening are allowed or required.

GAS CHROMATOGRAPHY (GC)

This section covers GC instruments with various detectors, including mass spectrometers.

FDT.23230**Phase II****N/A YES NO**

Are procedures documented for calibration, operation, and maintenance of GC equipment?

COMMENTARY:

Procedures must be documented for operation, calibration, and maintenance of GC equipment.

FDT.23330**Phase II****N/A YES NO**

Does the documented procedure require monitoring the performance of the column and detector on each day of use?

NOTE: There must be a system that monitors the performance of the GC column and detector. Unextracted standards, extracted calibrators or controls, typically containing the target compound(s), may be analyzed on each day of use to monitor critical aspects of GC performance. Appropriate criteria for evaluating such parameters as retention time, relative retention time, separation of closely eluting compounds of interest, plates, chromatography quality and detector response should be established and monitored. These records must be maintained.

COMMENTARY:

The laboratory must have a system in place that monitors the performance of the GC column and detector. Unextracted standards, extracted standards or controls, typically containing the target compound(s), may be analyzed on each day of use to monitor critical aspects of GC performance. Appropriate criteria for evaluating such parameters as retention time, relative retention time, separation

COMMENTARY:

Internal standards must be used.

FDT.23630 **Phase II**

N/A **YES** **NO**

Are new columns verified for performance before use?

COMMENTARY:

New columns must be verified for performance before use.

FDT.23730 **Phase II**

N/A **YES** **NO**

Is there evidence of daily evaluation of the performance of GC columns, auto-injectors, detectors, and records of maintenance such as septum changes, column clipping, flow rates, etc., including corrective action if performance does not meet requirements?

COMMENTARY:

There must be evidence of daily evaluation of GC columns, auto-injectors, detectors, and records of maintenance such as septum changes, column clipping, flow rates, etc.), as well as records of corrective action taken.

FDT.23930 **Phase II**

N/A **YES** **NO**

Are gas lines checked regularly for leaks?

COMMENTARY:

Gas lines should be checked regularly for leaks.

FDT.24130 **Phase II**

N/A **YES** **NO**

Are specimen run order, chromatographic peak shape, retention time, detector response for calibrators, controls and unknowns recorded and maintained for review?

COMMENTARY:

The specimen run order, chromatographic peak shape, retention time, and detector response for calibrators, controls, and unknowns must be recorded and maintained for review.

FDT.24230 **Phase I** **N/A YES NO**

Are the analytical data presented to permit valid scientific review by the analyst of the data for calibrators, controls, and unknowns?

COMMENTARY:

The analytical data should be presented in a fashion to permit valid scientific review of the data for calibrators, controls, and unknowns by the analyst.

FDT.24330 **Phase II** **N/A YES NO**

Whether an automatic sampler or manual injection is used, are there criteria for the detection of potential carryover in each analytical batch run?

COMMENTARY:

No matter what type of injection is used, the procedure must discuss criteria for the evaluation of potential carryover from a preceding high concentration specimen to the following sample in each analytical batch analysis.

FDT.24380 **Phase II** **N/A YES NO**

Is there a documented procedure or policy defining situations when reanalysis and reinjections are allowed or required?

COMMENTARY:

There must be a documented procedure or policy defining situations when reanalysis and reinjections are allowed or required.

MASS SPECTROMETRY (MS)

FDT.24430 **Phase II** **N/A YES NO**

Are procedures documented for operation, calibration, and maintenance of MS equipment?

COMMENTARY:

Procedures must be documented for operation, calibration, and maintenance of MS equipment.

FDT.24530 **Phase II** **N/A YES NO**

Does the documented procedure require that the mass spectrometer be maintained at regular intervals as suggested by the manufacturer?

COMMENTARY:

Mass spectrometers must be maintained as suggested by the manufacturer at regular intervals.

FDT.24630 **Phase II** **N/A YES NO**

Are the mass spectrometers tuned each day of use, are there defined tolerance limits for evaluating the acceptability of the tune data, and are tune records maintained?

COMMENTARY:

Mass spectrometers must be tuned either manually or automatically for each day of use. Tolerance limits for tune acceptance must be defined, and a record of that tune must be available for review.

FDT.25130 **Phase II** **N/A YES NO**

Are the identification criteria using either ion ratios or total spectra in compliance with recommendations?

NOTE: An acceptable criterion for compound identification using ion ratios is that the unknown result must have ion ratios within $\pm 20\%$ of the extracted calibrator(s). Identification using ion ratios typically requires the use of at least 2 ion ratios; however, one ion ratio of 2 characteristic ions may be acceptable if there are only a few characteristic ratios. The internal standard's identification should be monitored with at least one ion ratio. An acceptable criterion for compound identification using total spectra is that the unknown result must have a "spectral match" quality or fit that is within the defined limits that the laboratory has set and validated. Ion ratios determined from total spectra analysis is an acceptable identification method and should fulfill the same criteria as given above for ion ratio identifications.

COMMENTARY:

The mass spectral identification criteria must comply with recommendations. An acceptable criterion for compound identification using ion ratios is that the unknown result must have ion ratios within $\pm 20\%$ of the extracted calibrator(s). Identification using ion ratios typically requires the use of at least 2 ion ratios; however, one ion ratio of 2 characteristic ions may be acceptable if there are only a few

FDT.27030 **Phase II** **N/A YES NO**

Does the director or scientific director have appropriate experience in forensic applications of analytical toxicology, such as in-court testimony, attendance at relevant continuing education programs, research, and publications in analytical toxicology?

COMMENTARY:

The director (or scientific director) must have appropriate experience in forensic applications of analytical toxicology. This may include activities such as in-court testimony, attendance at relevant continuing education programs, research, and publications in analytical toxicology.

FDT.27130 **Phase II** **N/A YES NO**

Is the scientific director a full-time member of the laboratory, or does he/she spend a sufficient amount of actively involved time in the laboratory for the testing volume?

COMMENTARY:

The scientific director must be a full-time member of the laboratory, or the amount of actively involved time in the laboratory must be sufficient for the testing volume.

FDT.27230 **Phase II** **N/A YES NO**

Is the scientific director available for consultation concerning interpretation of results?

COMMENTARY:

The director must be available for consultation concerning interpretation of patient/client test results.

FDT.27330 **Phase II** **N/A YES NO**

Are the certifying scientists appointed by the scientific director?

NOTE: The certifying scientist is an individual who reviews and verifies analytical and other data, and reports results.

COMMENTARY:

The certifying scientist must be appointed by the scientific director. The certifying scientist is an individual who reviews and verifies analytical and other data, and reports results.

