Revised: 05/10/2007

COMMISSION ON LABORATORY ACCREDITATION

Laboratory Accreditation Program

FORENSIC DRUG TESTING CHECKLIST

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If a Checklist has been updated since receiving your packet, you will be inspected based upon the Checklists that were mailed. If you have any questions about the use of Checklists in the inspection process, please e-mail the CAP (accred@cap.org), or call (800) 323-4040, ext. 6065.

FORENSIC DRUG TESTING

OUTLINE

SUMMARY OF CHANGES
FORENSIC DRUG TESTING Checklist
5/10/2007 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

Question	Effective Date
FDT.00624	05/10/2007
FDT.00726	05/10/2007
FDT.00837	05/10/2007
FDT.00980	05/10/2007
FDT.01040	05/10/2007
FDT.02002	05/10/2007
FDT.05821	05/10/2007
FDT.05823	05/10/2007
FDT.05825	05/10/2007
FDT.05827	05/10/2007
FDT.05829	05/10/2007
FDT.05831	05/10/2007
FDT.05833	05/10/2007
FDT.05835	05/10/2007
FDT.05837	05/10/2007
FDT.05839	05/10/2007
FDT.05841	05/10/2007
FDT.05843	05/10/2007
FDT.07350	05/10/2007
FDT.17363	05/10/2007
FDT.17396	05/10/2007
FDT.20163	05/10/2007
FDT.20196	05/10/2007
FDT.20996	05/10/2007
FDT.21012	05/10/2007
FDT.25180	05/10/2007
FDT.25210	05/10/2007

REVISED Checklist Questions

Question	Effective Date
FDT.02720	05/10/2007
FDT.05809	05/10/2007

DELETED Checklist Questions

Question	Effective Date
FDT.00950	05/10/2007
FDT.05035	05/10/2007
FDT.20330	05/10/2007
FDT.22530	05/10/2007
FDT.23630	05/10/2007
FDT.28330	05/10/2007

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INSPECTION TECHNIQUES – KEY POINTS

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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 could not identify an obvious 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 results 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, 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

when reviewing these representative records, selecting data from the beginning, middle and end of the period since the last on-site inspection.

IV. Review correction of previous deficiencies: Review the list of deficiencies from the previous on-site inspection provided in the inspector's packet. Ensure that they have been appropriately addressed.

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EXTENT OF SERVICES PROVIDED

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FDT.00050 Phase II **N/A YES NO**

Does the laboratory perform both screening and confirmatory testing of forensic drug samples in the facility?

COMMENTARY:

N/A

FDT.00080 Phase II **N/A YES NO**

For testing represented by the laboratory as falling under CAP FDT accreditation, are only confirmed positive results reported as positive?

NOTE: All forensic drug testing must include confirmation of positive results before reporting. Pre-employment as well as employee (workplace) drug testing should be performed in a scientifically and legally defensible manner. Accredited FDT laboratories should encourage their clients to follow testing procedures that meet forensic requirements. If the laboratory is required by clients to report non-confirmed positive results for pre-employment samples, then the laboratory must have in place a system that differentiates this non-forensic drug testing service from its forensic drug testing service.

COMMENTARY:

N/A

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 drug test?

COMMENTARY:

N/A

FDT.00300 Phase II N/A YES NO

Are all positive screening results (excluding ethanol, see FDT.00350) confirmed using a well-defined and scientifically acceptable mass spectrometric method (*e.g.* GC/MS, LC/MS, GC/MS/MS, LC/MS/MS) 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. If the laboratory is required by clients to report non-confirmed positive results for pre-employment samples, then the laboratory must have in place a system that differentiates this non-forensic drug testing service from its forensic drug testing service.

COMMENTARY:

N/A

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:

N/A

FDT.00420 Phase II N/A YES NO

Does the laboratory use defined cutoff values for the screening and confirmation test for all drugs?

NOTE: The laboratory must use defined cutoff values for the screening and confirmation tests for all drugs and drug classes. Cutoff values may be defined by the laboratory or at the client's request. The laboratory, however, must be able to analyze challenges in the CAP/AACC UDC Forensic Urine Drug Testing (Confirmatory) Survey or a CAP approved alternative PT program at the reporting limits specified in the proficiency testing instructions.

COMMENTARY:

N/A

URINE DRUG TESTING, EXTENT OF SERVICES PROVIDED

The urine drug testing requirements include the questions in the GENERAL EXTENT OF SERVICES PROVIDED section above and the following:

FDT.00522 Phase II N/A YES NO

At a minimum, does the laboratory perform confirmation for: amphetamine, methamphetamine, benzoylecgonine, codeine, morphine, 6-monoacetylmorphine, phencyclidine, and delta-9-THC-COOH in urine?

NOTE: List on the Inspector's Summation Report any of the above analytes that the laboratory does not confirm.

COMMENTARY:

N/A

ORAL FLUID DRUG TESTING, EXTENT OF SERVICES

The oral fluid drug testing requirements include the questions in the GENERAL EXTENT OF SERVICES PROVIDED section above and the following:

*****NEW**** ***05/10/2007***

FDT.00624 Phase II N/A YES NO

At a minimum, does the laboratory perform confirmation for: amphetamine, methamphetamine, benzoylecgonine, cocaine, codeine, morphine, 6-monoacetylmorphine, phencyclidine, and delta-9-THC in oral-fluid?

NOTE: List on the Inspector's Summation Report any of the above analytes that the laboratory does not confirm.

COMMENTARY:

N/A

HAIR DRUG TESTING, EXTENT OF SERVICES PROVIDED

The hair drug testing requirements include the questions in the GENERAL EXTENT OF SERVICES PROVIDED section above and the following:

***NEW** 05/10/2007*

FDT.00726 Phase II N/A YES NO

At a minimum, does the laboratory perform confirmation for: amphetamine, methamphetamine, benzoylecgonine, cocaine, norcocaine, codeine, morphine, 6-monoacetylmorphine, phencyclidine, and delta-9-THC-COOH in hair?

NOTE: List on the Inspector's Summation Report any of the above analytes that the laboratory does not confirm.

COMMENTARY:

N/A

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LABORATORY SAFETY

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The inspector should review relevant questions from the Safety section of the Laboratory General checklist, to assure that the forensic drug testing laboratory is in compliance. Please elaborate upon the location and the details of each deficiency in the Inspector's Summation Report.

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PROFICIENCY TESTING

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Definitions:

Proficiency testing (PT) is defined as determination of laboratory testing performance by means of interlaboratory comparisons, in which a PT program periodically sends multiple specimens to members of a group of laboratories for analysis and/or identification; the program then compares each laboratory's results with those of other laboratories in the group and/or with an assigned value…(adapted from Clinical Laboratory Standards Institute Harmonized Terminology Database; available at http://www.nccls.org/).

Alternative assessment is defined as determination of laboratory testing performance by means other than PT--for example, split-sample testing, testing by a different method, *etc.*

The laboratory must participate in the College of American Pathologists/American Association for Clinical Chemistry (CAP/AACC) UDC Forensic Urine Drug Testing (Confirmatory) Survey or a CAP-accepted alternative proficiency testing program.

FDT.00830 Phase II N/A YES NO

Is the laboratory enrolled in the CAP/AACC UDC Forensic Urine Drug Testing (Confirmatory) Survey, or a CAP-accepted alternative proficiency testing program for the testing performed?

COMMENTARY:

N/A

REFERENCE: College of American Pathologists, Commission on Laboratory Accreditation. Standards for laboratory accreditation; Standard III. Northfield, IL: CAP, 1998.

FDT.00835 Phase II N/A YES NO

For analytes where graded proficiency testing is not available, are other procedures used to validate performance at least semi-annually?

NOTE: Other appropriate performance assessment procedures may include: participation in ungraded proficiency testing programs, split sample analysis with reference or other laboratories, split samples with an established in-house method, assayed material, regional pools, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the scientific director to define such alternative performance assessment procedures, as applicable, in accordance with good clinical and scientific laboratory practice.

COMMENTARY:

N/A

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):7184 [42CFR493.1709]; 2) Shahangian S, *et al*. A system to monitor a portion of the total testing process in medical clinics and laboratories. Feasibility of a split-specimen design. *Arch Pathol Lab Med*. 1998;122:503-511.

*****NEW***** ***05/10/2007***

FDT.00837 Phase II N/A YES NO

For specimen matrices where graded proficiency testing is not available, are other procedures used to validate performance at least semi-annually?

NOTE: Other appropriate performance assessment procedures may include: participation in ungraded proficiency testing programs, split sample analysis with reference or other laboratories, split samples with an established in-house method, assayed material, regional pools, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the scientific director to define such alternative performance assessment procedures, as applicable, in accordance with good clinical and scientific laboratory practice.

COMMENTARY:

N/A

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):7184 [42CFR493.1709]; 2) Shahangian S, *et al*. A system to monitor a portion of the total testing process in medical clinics and laboratories. Feasibility of a split-specimen design. *Arch Pathol Lab Med*. 1998;122:503-511.

FDT.00840 Phase II N/A YES NO

Is there a documented procedure for proper handling, analysis, review, and reporting of proficiency testing samples?

COMMENTARY:

N/A

FDT.00860 Phase II N/A YES NO

Does the laboratory integrate all proficiency testing samples within the routine laboratory workload, and are those samples analyzed by personnel who routinely test patient/client samples, using the same method systems as for patient/client samples?

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. 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:

N/A

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) -- including, but not limited to, results outside 2 SDI, false negative and false positive results -- and actions taken to reduce the likelihood of recurrence. The evaluation and corrective action must be completed 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. The laboratory's procedures for evaluation of proficiency testing results, including alternative performance assessment, must be documented in the SOP.

COMMENTARY:

N/A

REFERENCES: 1) Ehrmeyer SS, *et al*. Use of alternative rules (other than the 1-2s) for evaluating interlaboratory performance data. *Clin Chem.* 1988:34:250-256; 2) Klee GG, Forsman RW. A user's classification of problems identified by proficiency testing surveys. *Arch Pathol Lab Med.* 1988;112:371-373; 3) 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)(iv)]; 4) NCCLS. Using proficiency testing (PT) to improve the clinical laboratory; approved guideline GP27-A. Wayne, PA: NCCLS, 1998; 5) Shahangian S, *et al*. Toward optimal PT use. *Med Lab Observ.* 2000;32(4):32-43.

FDT.00890 Phase II N/A YES NO

Are records of all proficiency testing and alternative performance assessment since the last on-site inspection complete?

COMMENTARY:

N/A

FDT.00920 Phase II N/A YES NO

Is there evidence of review by the scientific director of proficiency testing and alternative performance assessment reports and of evaluation and appropriate corrective action in response to unacceptable results within one month of receipt of all Surveys since the last on-site inspection?

COMMENTARY:

N/A

REFERENCES: 1) Ehrmeyer SS, *et al.* Use of alternative rules (other than the 1-2s) for evaluating interlaboratory performance data. *Clin Chem.* 1988:34:250-2; 2) Klee GG, Forsman RW. A user's classification of problems identified by proficiency testing surveys. *Arch Pathol Lab Med.* 1988;112:371-3; 3) 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)(iv)].

*****NEW***** ***05/10/2007***

FDT.00980 Phase II N/A YES NO

Is there a policy that prohibits interlaboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider?

COMMENTARY:

N/A

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):7146 [42CFR493.801(b)(3)]; 2) Bierig JR. Comparing PT results can put a lab's CLIA license on the line. Northfield, IL: College of American Pathologists *CAP Today.* 2002;16(2):84-87.

***NEW** 05/10/2007*

FDT.01040 Phase II N/A YES NO

Is there a policy that prohibits referral of proficiency testing specimens to another laboratory?

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28): [42CFR493.801(b)(4)].

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QUALITY MANAGEMENT

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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 FDT 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 FDT laboratory?

COMMENTARY:

N/A

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, urea nitrogen, or creatinine.

COMMENTARY:

N/A

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:

N/A

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:

N/A

FDT.01666 Phase II N/A YES NO

Does the laboratory's QM program require completion of a "root-cause" analysis for any false positive result reported?

NOTE: The laboratory's documented QM plan must include procedures for analyzing and determining the root-cause of any false positive drug result reported by the laboratory on patient, donor, or proficiency testing specimens. This procedure also applies to falsely reported specimen adulteration or substitution. Elements of this procedure should include investigation of pre-analytical,

analytical, and post-analytical components. The results of the investigation must be documented and should include any necessary retraining and corrective action to prevent recurrence.

COMMENTARY:

N/A

FDT.01832 Phase II N/A YES NO

Is there evidence of review of the root-cause analysis by the scientific director for any false positive result reported by the laboratory within 30 days of discovery?

COMMENTARY:

N/A

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QUALITY CONTROL/STANDARD OPERATING PROCEDURES (SOP)

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The scientific director must be responsible for the quality control (QC) program. There must be documentation of initial and annual review of the policy and approval of any changes by the scientific director. The overall QC program must be defined clearly, documented (paper or electronic), and readily available to the technical and supervisory staff. It should include delegation of responsibilities, general policies, protocols, and analytic details. The records should be organized 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 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. *Recording of QC results*
4. *Criteria for acceptance/rejection of QC results*
5. *Corrective actions taken for QC failures*
6. *Protocol used to document the recording and review of QC results and any corrective Actions taken for QC failures*
7. *Requirement and protocol for weekly and monthly QC review*
8. *Delegation of authority for weekly QC review*
9. *Monitoring precision of each confirmatory assay, at or near the cutoff(s)*
10. *Detection and correction of significant clerical and analytical errors before reporting the results*

COMMENTARY:

N/A

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)].

*****NEW***** ***05/10/2007***

FDT.02002 Phase II N/A YES NO

Are the results of controls verified for acceptability before reporting results?

NOTE: It is implicit in quality control that test results will not be reported when controls do not yield acceptable results.

COMMENTARY:

N/A

FDT.02005 Phase II N/A YES NO

Are appropriate controls used for all SCREENING tests?

NOTE: The following 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*

ELISA may require different controls around the cutoff and the laboratory must validate the appropriateness of their controls.

COMMENTARY:

N/A

FDT.02010 Phase II N/A YES NO

Are appropriate matrix-matched controls used for all CONFIRMATION tests using SINGLE POINT CALIBRATION?

NOTE: The following 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:

N/A

FDT.02015 Phase II **N/A YES NO**

Are appropriate matrix-matched controls used for all CONFIRMATION tests using MULTIPLE POINT CALIBRATION?

NOTE: The following 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:

N/A

FDT.02020 Phase I **N/A YES NO**

Are conjugated drug controls included in procedures where conjugates are hydrolyzed?

NOTE: This requirement may be satisfied with the use of purchased material or the use of pooled donor specimens.

COMMENTARY:

N/A

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 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:

N/A

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 above the cutoff gives a positive response to be acceptable, and the control below the cutoff 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 a pre-determined range of the established control mean. It is commonly accepted that this range be no more than ± 20% for urine assays and no more than ± 30% for other specimen matrices.

COMMENTARY:

N/A

FDT.02035 Phase II N/A YES NO

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

COMMENTARY:

N/A

FDT.02060 Phase II N/A YES NO

Does the QC procedure require documented review, at least weekly, by the scientific director or designee, of QC results to detect instrument malfunction or analytical system trends?

COMMENTARY:

N/A

FDT.02080 Phase II N/A YES NO

Does the QC procedure require documented review, at least monthly, by the scientific director, of QC and blind QC records or summarized QC data to detect trends, and review corrective actions taken by laboratory personnel?

NOTE: The scientific director must be responsible for the overall QC program, which should include monthly review of the proper performance of QC analysis, QC evaluation, corrective actions taken, and documentation by laboratory personnel.

COMMENTARY:

N/A

FDT.02150 Phase II N/A YES NO

Does the QC procedure require monitoring of the precision of each confirmation assay around the commonly accepted cutoffs?

NOTE: The laboratory must routinely monitor the precision of the assay at the cutoff. This may be accomplished by using the cutoff control to determine the assay's precision at the cutoff value.

COMMENTARY:

N/A

FDT.02166 Phase II N/A YES NO

Is there a documented procedure and system in operation to detect significant clerical and analytical errors before reporting the results?

NOTE: The detection of errors (e.g., wrong donor identification information, wrong client information, failure to report critical chain-of-custody errors, wrong tests performed, etc.) may have forensic implications, as may analytical errors. A documented procedure must be present that describes the laboratory's system to detect and prevent these clerical and analytical errors. This system may include the requirements for secondary or certifying review of both clerical and analytical data before release of results.

COMMENTARY:

N/A

FDT.02182 Phase II N/A YES NO

Are results of QUANTITATIVE controls conveniently recorded or plotted and analyzed routinely to detect trends in instrument or process failure?

COMMENTARY:

N/A

FDT.02600 Phase II N/A YES NO

Is there documented review (at least weekly) of QC records by the scientific director or designee?

COMMENTARY:

N/A

FDT.02650 Phase II N/A YES NO

Is there documented review (at least monthly) of QC records or summarized data, by the scientific director?

COMMENTARY:

N/A

FDT.02710 Phase II N/A YES NO

Are records of the internal QC program complete?

NOTE: The inspector must provide specific details of any deficiencies in Part B (Deficiency Summary) of the Inspector's Summation Report.

COMMENTARY:

N/A

FDT.02715 Phase II N/A YES NO

Is there documentation of corrective action when control results exceed defined tolerance limits?

NOTE: Patient/client test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

Even if patient samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected patient results.

COMMENTARY:

N/A

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 scientific 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.

*****REVISED** 05/10/2007***

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 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 this printed or electronic procedure must be detailed in the procedure manual. In all cases, appropriate reviews must occur.

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. However, procedures must be available to laboratory personnel when the electronic versions are inaccessible (e.g., during laboratory information system or network downtime); thus, the laboratory must maintain either paper copies or electronic copies on CD or other media that can be accessed via designated computers. All procedures, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection.

Electronic versions of procedures 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 annual review). Documentation of review of electronic procedures may be accomplished by including statements such as "reviewed by [name of reviewer] on [date of review]" in the electronic record. Alternatively, paper review sheets may be used to document review of electronic procedures. Documentation of review by a secure electronic signature is NOT required.

COMMENTARY:

N/A .

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) Clinical and Laboratory Standards Institute (CLSI). *Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition*. CLSI document GP2-A5 (ISBN 1-56238-600-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.

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:

N/A

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 scientific director 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.

COMMENTARY:

N/A

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):7164 [42CFR493.1211(f)].

FDT.03200 Phase II N/A YES NO

Are all changes dated and initialed by the scientific director?

COMMENTARY:

N/A

FDT.03250 Phase II N/A YES NO

Are all policies and procedures promptly reviewed and approved by the new scientific director if there is a change in directorship?

COMMENTARY:

N/A

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):7164 [42CFR493.1211(e)].

FDT.03300 Phase II **N/A YES NO**

Are copies of all procedures (paper or electronic) and the dates on which they were in effect maintained for reference?

COMMENTARY:

N/A

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 scientific director.

COMMENTARY:

N/A

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:

N/A

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:

N/A

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.

.....

General Specimen Handling

.....

FDT.04800 Phase II N/A YES NO

Does the receiving and/or accessioning procedure require documentation of verification of specimen identity, integrity of the sealed or secured specimen container, and completeness of the external chain-of-custody documents?

COMMENTARY:

N/A

FDT.04816 Phase II N/A YES NO

Is there proper documentation of the condition of the specimen security seal upon receipt at the laboratory?

COMMENTARY:

N/A

FDT.04832 Phase II N/A YES NO

Is there proper documentation of the completeness of the external chain-of-custody form upon receipt at the laboratory?

COMMENTARY:

N/A

FDT.04850 Phase II N/A YES NO

Does the laboratory properly complete appropriate sections of external chain-of-custody documents?

COMMENTARY:

N/A

FDT.04890 Phase II N/A YES NO

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

COMMENTARY:

N/A

FDT.04910 Phase II N/A YES NO

Does the laboratory generate and properly complete internal chain-of-custody documents to 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:

N/A

FDT.04950 Phase II N/A YES NO

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

COMMENTARY:

N/A

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:

N/A

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, quantity, foreign material, *etc*.)?

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

COMMENTARY:

N/A

FDT.05080 Phase II N/A YES NO

Does the documented aliquoting procedure prevent cross-contamination and mix-up of the specimens and aliquots?

COMMENTARY:

N/A

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:

N/A

FDT.05800 Phase II N/A YES NO

Is there a documented policy on retaining negative specimens for a specific time?

NOTE: Negative specimens must be retained for sufficient time to complete the final reporting of all specimens within a batch, including confirmation testing, and for report receipt and review by clients.

COMMENTARY:

N/A

FDT.05805 Phase II N/A YES NO

Is disposal of positive and negative specimens documented on a chain-of-custody form?

COMMENTARY:

N/A

.....

Urine Specimen Handling

.....

The urine specimen handling requirements include the questions in the SPECIMEN HANDLING section above and the following:

FDT.05807 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:

N/A

*****REVISED** 05/10/2007***

FDT.05809 Phase II N/A YES NO

Is there a documented procedure for determining specimen validity?

NOTE: This may include measurements of creatinine, specific gravity, pH, etc. The laboratory is required to discuss the issue of excessively dilute specimens, and potential adulteration with its clients under its QM program.

COMMENTARY:

N/A

FDT.05811 Phase I **N/A YES NO**

Are all specimens tested for validity?

NOTE: At a minimum, this requires a test for creatinine.

COMMENTARY:

N/A

FDT.05813 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.05815 Phase II **N/A YES NO**

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

COMMENTARY:

N/A

FDT.05817 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:

N/A

FDT.05819 Phase II **N/A YES NO**

Is the policy that positive specimens are retained frozen in their original container for at least one year followed?

COMMENTARY:

N/A

.....

Oral Fluid Specimen Handling

.....

The oral fluid specimen handling requirements include the questions in the SPECIMEN HANDLING section above and the following:

*****NEW***** ***05/10/2007***

FDT.05821 Phase II **N/A YES NO**

Is the original collection device, its container and any fluid derived from the collection device always maintained 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:

N/A

*****NEW***** ***05/10/2007***

FDT.05823 Phase II **N/A YES NO**

Is there a documented procedure for determining specimen validity?

NOTE: This may include measurements of IgG, etc.

COMMENTARY:

N/A

*****NEW***** ***05/10/2007***

FDT.05825 Phase II N/A YES NO

Are all specimens tested for validity?

COMMENTARY:

N/A

*****NEW***** ***05/10/2007***

FDT.05827 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.

*****NEW***** ***05/10/2007***

FDT.05829 Phase II N/A YES NO

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

COMMENTARY:

N/A

*****NEW***** ***05/10/2007***

FDT.05831 Phase II N/A YES NO

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

COMMENTARY:

N/A

***NEW** 05/10/2007*

FDT.05833 Phase II N/A YES NO

Is the policy that all positive specimens are retained frozen and the original containers are retained for at least one year followed?

COMMENTARY:

N/A

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Hair Specimen Handling

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The hair specimen handling requirements include the questions in the SPECIMEN HANDLING section above and the following:

***NEW** 05/10/2007*

FDT.05835 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:

N/A

***NEW** 05/10/2007*

FDT.05837 Phase II N/A YES NO

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

COMMENTARY:

N/A

***NEW** 05/10/2007*

FDT.05839 Phase II N/A YES NO

Is the policy that all positive specimens and their original containers are retained for at least one year followed?

COMMENTARY:

N/A

***NEW** 05/10/2007*

FDT.05841 Phase II N/A YES NO

Does the laboratory have validated procedures to control for potential external contamination?

NOTE: This may include wash procedures and/or metabolite identification.

COMMENTARY:

N/A

***NEW** 05/10/2007*

FDT.05843 Phase II N/A YES NO

Are the procedures for controlling for potential external contamination followed?

COMMENTARY:

N/A

CERTIFICATION OF RESULTS

FDT.05845 Phase II N/A YES NO

Is there a documented procedure that requires review and documentation of each step of the process?

NOTE: The procedure must require review of the following elements for screening and confirmatory testing:

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:

N/A

FDT.05847 Phase II N/A YES NO

Is the certification procedure followed?

COMMENTARY:

N/A

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:

N/A

****

INSPECTION OF RECORDS

****

The inspection team should review laboratory records to ensure that the laboratory's procedures and policies are followed and to ensure that the laboratory maintains appropriate analytical and administrative documents. The Team Leader should request retrieval of specific records in advance of the inspection. Analytical records from the proficiency testing surveys and alternative performance assessments since the last inspection must be reviewed. The records reviewed must include internal and external chain-of-custody forms, analytical data, certifying review documents, and examples of the final reports. The following should be considered when selecting batches for review.:

1. *At least 20% of the batches should originate from the time interval between the last on-site inspection and 60 days prior to the current inspection*
2. *At least one batch should be reviewed for each drug in each matrix analyzed*
3. *Review of batches before and after proficiency testing failures may be of value to assess systematic analytical problems*

FDT.05862 Phase II **N/A YES NO**

Are the external and internal chain-of-custody documents available, and properly completed?

NOTE: The inspector should list problem areas on the Inspector's Summation Report.

COMMENTARY:

N/A

FDT.05874 Phase II **N/A YES NO**

Are the data from all screening and confirmatory tests available?

NOTE: The data must include:

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*

COMMENTARY:

N/A

FDT.05886 Phase II N/A YES NO

Do the records permit valid review of the data?

COMMENTARY:

N/A

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

Are there documented protocols for the reporting of results to clients or their representatives?

NOTE: These protocols require that a forensic 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. *Specimen matrix tested and, if hair, site of collection*
6. *Drugs analyzed as part of the forensic drug test*
7. *Cutoff values per drug for both screening and confirmation tests*
8. *Positive and/or negative results*
9. *Date of report*

COMMENTARY:

N/A

FDT.06500 Phase II N/A YES NO

Are only confirmed positives reported as positive?

NOTE: If the laboratory is required by clients to report non-confirmed positive results for pre-employment samples, then the laboratory must have in place a system that differentiates this non-forensic drug testing service from its forensic drug testing service.

COMMENTARY:

N/A

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

Are there documented protocols for reporting of results by telephone?

NOTE: The CAP FDT 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:

N/A

FDT.06700 Phase II **N/A YES NO**

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

COMMENTARY:

N/A

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:

N/A

RECORDS

The laboratory must maintain various records to meet the requirements of the CAP FDT 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 FDT inspection; the previous on-site general CAP inspection, and the previous FDT self-inspection.

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?

NOTE: 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 (at least 2 years after retirement of procedure)*
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 FDT on-site inspection records and corrective actions*
14. *Previous CAP FDT self-inspection records and corrective actions*
15. *Previous CAP general on-site inspection records and corrective actions appropriate to the FDT laboratory*

COMMENTARY:

N/A

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

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

COMMENTARY:

N/A

FDT.07200 Phase I N/A YES NO

Are the records for the last two years easily accessible?

COMMENTARY:

N/A

FDT.07300 Phase II N/A YES NO

On review of the previous CAP self-inspection performance records, has the laboratory taken the corrective actions required to correct all cited Phase II deficiencies?

NOTE: The inspector must list any uncorrected deficiencies in the Inspector's Summation Report.

COMMENTARY:

N/A

*****NEW***** ***05/10/2007***

FDT.07350 Phase II N/A YES NO

On review of the previous CAP on-site inspection performance records, has the laboratory taken the corrective actions required to correct all cited Phase II deficiencies?

NOTE: The inspector must list any uncorrected deficiencies in the Inspector's Summation Report.

COMMENTARY:

N/A

FDT.07500 Phase II N/A YES NO

Are all technical, legal, and administrative records available for review that are required for the laboratory to maintain accreditation in the CAP FDT Program?

NOTE: The inspector must identify any missing documents in the Inspector's Summation Report.

COMMENTARY:

N/A

REAGENTS/STANDARDS/CALIBRATORS/CONTROLS

The verification of reagents/standards/calibrators/controls (RSCC) is required and must be documented. Several methods are acceptable, such as direct analysis with reference materials, other standards, or checking against previously validated controls. The intent is for new RSCC to be verified by an appropriate method and this process be recorded before the RSCC is placed in service.

FDT.07600 Phase II **N/A YES NO**

Is there a documented procedure that describes the system for monitoring of RSCC preparation or receipt by the laboratory and the verification of same before they are placed into service?

COMMENTARY:

N/A

FDT.17170 Phase II **N/A YES NO**

Does this documented procedure require that new RSCC are verified against previously validated RSCC before being placed into service?

COMMENTARY:

N/A

FDT.17180 Phase II **N/A YES NO**

Are results of RSCC validation recorded?

COMMENTARY:

N/A

FDT.17190 Phase II N/A YES NO

Are RSCC properly labeled, as applicable and appropriate, with the following elements?

1. **Content and quantity, concentration or titer**
2. **Storage requirements**
3. **Date prepared or reconstituted by laboratory**
4. **Expiration date**
5. **Safety precautions or warnings**

NOTE: 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

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7164 [42CFR493.1252(c)]; 2) Gonzales Y, Kampa IS. The effect of various storage environments on reagent strips. *Lab Med.* 1997;28:135-137; 3) NCCLS. Clinical laboratory technical procedure manuals - fourth edition; approved guideline GP2-A4. Wayne, PA: NCCLS, 2002.

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:

N/A

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:

N/A

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:

N/A

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:

N/A

*****NEW**** ***05/10/2007***

FDT.17363 Phase II N/A YES NO

Is control material matrix-matched or validated against the matrix by the laboratory?

NOTE:

1. *Urine: Urine based matrix*
2. *Oral-Fluid: Buffer/preservative solution from the collection device or purified saliva as appropriate*
3. *Hair: Digest of negative hair*
4. *Other materials may be used if validated by the laboratory and shown to be equivalent to the above*

COMMENTARY:

N/A

*****NEW***** ***05/10/2007***

FDT.17396 Phase II **N/A YES NO**

Is calibration material matrix-matched or validated against the matrix by the laboratory?

NOTE:

1. *Urine: Urine based matrix*
2. *Oral-Fluid: Buffer/preservative solution from the collection device or purified saliva as appropriate*
3. *Hair: Digest of negative hair*
4. *Other materials may be used if validated by the laboratory and shown to be equivalent to the above*

COMMENTARY:

N/A

FDT.17430 Phase II **N/A YES NO**

For quantitative tests, has a statistically valid target range been established for each lot of control material by repetitive analysis in runs that include previously tested control materials?

COMMENTARY:

N/A

FDT.17530 Phase II N/A YES NO

If the laboratory uses drugs covered by the Controlled Substances Act, does it maintain appropriate Drug Enforcement Administration (DEA) and State licenses?

NOTE: For U.S. laboratories, a DEA license, and in some states a State license, is required for controlled substances. A DEA license is not required for certain commercial solutions of controlled substances. The intent is to be compliant with Federal and State laws.

COMMENTARY:

N/A

INSTRUMENTS AND EQUIPMENT

A variety of instruments and equipment are used to support the performance of analytical procedures in a laboratory. All instruments and equipment should be properly operated, maintained, serviced, and monitored to ensure that malfunctions do not adversely affect analytical results. The inspection team should review the procedures for instrument-equipment operations, maintenance, and monitoring records to ensure that these devices are properly used. The procedures and schedules for instrument maintenance must be as thorough and as frequent as specified by the manufacturer.

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Glassware

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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 (± 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:

N/A

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 Testing and Materials. Standard specification for glass volumetric (transfer) pipets, designation E 969-95. Philadelphia, PA: ASTM, 199; 5) Johnson B. Calibration to dye for: Artel's new pipette calibration system. *Scientist.* 1999;13(12):1; 6) 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; 7) Skeen GA, Ashwood ER. Using spectrophotometry to evaluate volumetric devices. *Lab Med.* 2000;31:478-479.

FDT.17930 Phase I N/A YES NO

Is the use of less precise measuring devices such as serological plastic pipettes and graduated cylinders limited to situations where the accuracy and precision of calibrated glass pipettes are not required?

NOTE: In contrast with the more stringent accuracy requirements of glass pipettes, ASTM requirements for plastic pipettes are ± 3% of the stated volume.

COMMENTARY:

N/A

REFERENCE: American Society for Testing and Materials. Standard specification for serological pipet, disposable plastic, designation E 934-88, In 1993 annual book of ASTM standards, section 14 (general methods and instrumentation). Philadelphia, PA: ASTM, 1993;14.02:485-486.

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Automatic Pipettes

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Fixed volume adjustable and/or micropipettes. Automatic pipettes and diluting devices of all types must be checked for accuracy and reproducibility initially and periodically thereafter.

FDT.18130 Phase II N/A YES NO

Is there a documented procedure defining how pipettes are checked for accuracy of calibration (gravimetric, colorimetric, or other verification procedure) initially and on a periodic basis thereafter, and how these results are documented?

COMMENTARY:

N/A

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:

N/A

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.

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Instrument/Equipment Operation and Maintenance

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FDT.18330 Phase II N/A YES NO

Are there documented standard procedures for set-up and operation of all instruments and equipment used in the laboratory?

NOTE: The laboratory should have an organized system for monitoring and maintaining all instruments. Function checks should be designed to check the critical operating characteristics to detect drift, instability or malfunction before the problem is allowed to affect test results. All servicing and repairs should be documented. Procedures for the operation of instrument systems must be documented and available to the operator.

COMMENTARY:

N/A

FDT.18430 Phase II N/A YES NO

Is there a documented procedure describing the laboratory's schedule or system for regular checking of the critical operating characteristics for all instruments and equipment in use, and for the performance of routine or special instrument maintenance?

COMMENTARY:

N/A

FDT.18530 Phase II N/A YES NO

Are function checks documented and readily available to detect trends or malfunctions?

COMMENTARY:

N/A

FDT.18630 Phase II N/A YES NO

Are tolerance limits for acceptable function defined and documented for specific instruments, whenever appropriate?

COMMENTARY:

N/A

FDT.18730 Phase II N/A YES NO

Are instructions provided for major troubleshooting and repair of instruments?

COMMENTARY:

N/A

FDT.18830 Phase II N/A YES NO

Are instrument maintenance, service, and repair records (or copies) easily available to and usable by the technical staff operating the instruments and equipment?

NOTE: The effective utilization of instruments by the technical staff depends upon the prompt availability of maintenance, repair, and service documentation (copies are acceptable). Laboratory personnel are responsible for the reliability and proper function of their instruments and must have access to this information. Off-site storage, such as with centralized medical maintenance or computer files, is not precluded if the inspector is satisfied that the records can be promptly retrieved.

COMMENTARY:

N/A

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Thermometers

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FDT.18930 Phase II N/A YES NO

Is an appropriate thermometric standard device of known accuracy (NIST-certified or guaranteed by manufacturer to meet NIST Standards) available?

NOTE: Thermometers should be present on all temperature-controlled instruments and environments and checked daily. Thermometric standard devices should be recalibrated or recertified prior to the date of expiration of the guarantee of calibration.

COMMENTARY:

N/A

FDT.19030 Phase II N/A YES NO

Are all non-certified thermometers initially checked against the thermometric standard device before being placed in service?

COMMENTARY:

N/A

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Temperature-Dependent Equipment

.....

FDT.19130 Phase II N/A YES NO

Are there documented procedures that define the requirements for daily temperature checks of equipment when used?

NOTE: Such equipment includes:

1. *Dry baths (heating blocks)*
2. *Incubators and ovens (when used for analytical procedures)*

3. Refrigerators and freezers? (daily temperatures required if used for storage reagents/standards/calibrators/controls)

The inspector must provide specific details of any deficiencies in Part B (Deficiency Summary) of the Inspector's Summation Report.

COMMENTARY:

N/A

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Centrifuges

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FDT.19230 Phase II N/A YES NO

Are all centrifuges clean and properly maintained?

COMMENTARY:

N/A

FDT.19330 Phase II N/A YES NO

Is there a documented protocol and schedule for maintenance of all centrifuges?

COMMENTARY:

N/A

FDT.19430 Phase II N/A YES NO

Are the operating speeds of all centrifuges checked periodically as needed for the intended use, and is this done in a safe manner?

NOTE: The operating speed of all centrifuges must be checked periodically (when indicated), and this must be done in a safe manner. For centrifuges having a safety mechanism preventing the opening of the lid while in operation, the checks of rpm should be performed only by an authorized service representative of the manufacturer or an appropriately trained clinical engineer.

COMMENTARY:

N/A

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Analytical Balances

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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:

N/A

FDT.19630 Phase II N/A YES NO

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

COMMENTARY:

N/A

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. 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.

COMMENTARY:

N/A

FDT.19830 Phase II N/A YES NO

Are weights well-maintained (clean, in a covered container, not corroded)?

COMMENTARY:

N/A

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PROCEDURES AND TEST SYSTEMS

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The inspection team should critically review all the SOPs related to the analytical systems used for screening and confirmation testing. Specific attention should be paid to documentation of each method's performance specifications. The inspection team should critically review the maintenance and monitoring records for each analytical system to ensure that the documented SOPs are followed and that the analytical system is used in a scientifically valid manner.

METHOD PERFORMANCE VALIDATION

The laboratory must initially validate all analytical methods. All current screening and confirmatory analytical methods for drugs must have documented method performance validation data on file and available for review. The inspection team should review all forensic drug testing analytical methods to ensure that the proper validation studies have been done.

FDT.19930 Phase II N/A YES NO

Is there a documented procedure or protocol that is used to define how new analytical methods are initially validated?

COMMENTARY:

N/A

FDT.20030 Phase II N/A YES NO

Does the documented method validation procedure or protocol require that method performance specifications are evaluated and documented?

NOTE: The specifications must include the following elements:

1. *Accuracy (comparison to reference methods or reference standards)*
2. *Precision (determined at the cutoff value(s))*
3. *Analytical sensitivity (LOD) must be determined for confirmation procedures*
4. *Analytical specificity (i.e., relevant interferences)*
5. *Linearity for quantitative methods including LOQ, which must be determined*
6. *Carryover potential*

COMMENTARY:

N/A

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(Feb28):7164 [42CFR493.1213; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register.* 1993(Jan 19):5230-5231 [42CFR493.1202, 493.1203, 493.1213].

FDT.20130 Phase II N/A YES NO

Are the records for method performance validation appropriate and complete for all forensic drug testing analytical methods?

NOTE: The inspector must provide specific details of any deficiencies in Part B (Deficiency Summary) of the Inspector's Summation Report.

COMMENTARY:

N/A

*****NEW***** ***05/10/2007***

FDT.20163 Phase II N/A YES NO

Is there a procedure or protocol for, at least, annual verification of confirmation method performance?

NOTE: The verifications must, at least, include the following elements:

1. *Precision (determined at the cutoff value(s))*
2. *Analytical sensitivity (LOD)*
3. *Linearity including LOQ*
4. *Carryover potential*

COMMENTARY:

N/A

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(Feb28):7164 [42CFR493.1213; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register.* 1993(Jan 19):5230-5231 [42CFR493.1202, 493.1203, 493.1213].

*****NEW***** ***05/10/2007***

FDT.20196 Phase II **N/A YES NO**

Are the records for confirmation method performance verification appropriate and complete?

NOTE: The inspector must provide specific details of any deficiencies in Part B (Deficiency Summary) of the Inspector's Summation Report.

COMMENTARY:

N/A

FDT.20230 Phase I **N/A YES NO**

Does the laboratory have a policy to make its list of current test methods, including performance specifications, available to clients upon request?

COMMENTARY:

N/A

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):7162-7164 [42CFR493.1109(g), 493.1213].

IMMUNOASSAYS

FDT.20930 Phase II N/A YES NO

Are immunoassay reagents used according to instrument and/or kit manufacturer's instructions or, if modified, is there validation data to support that the modification produces reliable results?

COMMENTARY:

N/A

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:

N/A

*****NEW**** ***05/10/2007***

FDT.20996 Phase II N/A YES NO

If a multi-well plate procedure is used, has the laboratory taken appropriate steps to prevent cross-contamination?

NOTE: The laboratory must have a procedure and/or appropriate engineering in place to prevent contamination into or between wells of multi-well.

COMMENTARY:

N/A

***NEW** 05/10/2007*

FDT.21012 Phase II N/A YES NO

If a multi-well plate procedure is used, is the procedure to prevent cross-contamination followed?

NOTE: This can only be assessed by direct observation.

COMMENTARY:

N/A

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:

N/A

FDT.21130 Phase II N/A YES NO

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

COMMENTARY:

N/A

FDT.21430 Phase II N/A YES NO

Are spectrophotometers, if part of an immunoanalyzer, calibrated appropriately (as directed by the instrument manufacturer), and results documented?

COMMENTARY:

N/A

FDT.21530 Phase II N/A YES NO

Are gamma counters and/or scintillation counters calibrated, results recorded and compared to previous values on each day of use?

COMMENTARY:

N/A

FDT.21630 Phase II N/A YES NO

Is background radioactivity, including the background in each well of a multi-well counter, determined on each day of use?

COMMENTARY:

N/A

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:

N/A

LIQUID CHROMATOGRAPHY (LC)

This section covers the LC inlet system of LC/MS and LC/MS/MS instruments.

FDT.22130 Phase II N/A YES NO

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

COMMENTARY:

N/A

FDT.22230 Phase II N/A YES NO

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

NOTE: Good laboratory practice dictates that there be a system that monitors the performance of the LC column. Unextracted standards, extracted calibrators or controls, typically containing the target compound(s) may be analyzed each day of use to monitor critical aspects of LC 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:

N/A

FDT.22280 Phase II N/A YES NO

Does the documented procedure require that appropriate extracted calibrator(s) is 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:

N/A

FDT.22330 Phase II N/A YES NO

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

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

COMMENTARY:

N/A

FDT.22430 Phase II N/A YES NO

Are internal standards used?

COMMENTARY:

N/A

FDT.22830 Phase II N/A YES NO

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

COMMENTARY:

N/A

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:

N/A

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:

N/A

FDT.23080 Phase II N/A YES NO

Is there a documented procedure or policy defining situations when reinjection or reanalysis are required?

COMMENTARY:

N/A

GAS CHROMATOGRAPHY (GC)

This section covers GC instruments with various detectors, including mass spectrometers. The program allows the use of flame ionization detection for testing of ethanol only. All other drugs must be confirmed by mass spectrometric methods.

FDT.23230 Phase II N/A YES NO

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

COMMENTARY:

N/A

FDT.23330 Phase I N/A YES NO

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

NOTE: Good laboratory practice dictates that there be a system that monitors the performance of the GC column. 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, and chromatography quality should be established and monitored. These records must be maintained.

COMMENTARY:

N/A

FDT.23380 Phase II **N/A YES NO**

Does the documented procedure require that appropriate extracted calibrator(s) is 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.

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:

N/A

FDT.23430 Phase II **N/A YES NO**

Does the documented procedure require that appropriate controls be extracted and analyzed with each batch of samples?

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

COMMENTARY:

N/A

FDT.23530 Phase II **N/A YES NO**

Are internal standards used?

COMMENTARY:

N/A

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:

N/A

FDT.23930 Phase II N/A YES NO

Are gas lines checked regularly for leaks?

COMMENTARY:

N/A

FDT.24130 Phase II N/A YES NO

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

COMMENTARY:

N/A

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:

N/A

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:

N/A

FDT.24380 Phase II N/A YES NO

Is there a documented procedure or policy defining situations when reinjection or reanalysis are required?

COMMENTARY:

N/A

MASS SPECTROMETRY (MS)

For questions on inlet system coupled to the mass spectrometer, see the LC and GC sections

FDT.24430 Phase II N/A YES NO

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

COMMENTARY:

N/A

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:

N/A

FDT.24630 Phase II N/A YES NO

Are the mass spectrometers tuned each day of testing, or according to manufacturer's recommendations, and are tune records maintained?

NOTE: Acceptable tolerance limits for tune parameters must be defined, and tune records maintained.

COMMENTARY:

N/A

FDT.24880 Phase II N/A YES NO

Does the documented procedure require that appropriate extracted calibrator(s) is 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:

N/A

FDT.25130 Phase II N/A YES NO

Are the identification criteria for single stage mass spectrometry (*i.e.*, GC/MS, LC/MS) satisfactory?

NOTE: One acceptable criterion for compound identification by GC/MS using ion ratios is that the unknown result must have ion ratios within a prescribed acceptance or tolerance limit (e.g., ± 20% of those of calibrators). This limit should be supported by either literature references (e.g., NCCLS 43-A for GC/MS) or through experimental means. Such ion ratio tolerance limits may differ based on the technique applied (e.g., GC/MS versus LC/MS) as well as the analyte(s) being determined (e.g., compounds with mainly ions of low abundance); thus, a defined limit to cover all methods and analytes cannot be given. In general, for LC/MS, ion ratios of ≤30% are practical and attainable.

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 AND if there are other identifying characteristics, e.g., retention time. The internal standard's identification should be monitored with at least one ion ratio. If total ion spectra are collected, identification must be based on ion ratios determined from total spectra analysis, and should fulfill the same criteria as given above for ion ratio identification.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. Gas chromatography/mass spectrometry (GC/MS) confirmation of drugs; approved guideline C43-A. Wayne, PA: NCCLS, 2002; 2) Official Journal of the European Communities. Commission Decision implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (17.8.2002).

***NEW** 05/10/2007*

FDT.25180 Phase II N/A YES NO

Are the identification criteria for tandem mass spectrometry (MS/MS) satisfactory?

NOTE: An acceptable tolerance criterion for compound identification using ion ratios is mandatory in addition to a defined number of ion ratios. Tolerance limits should accurately reflect the limitations of the method employed and should be supported by references from the literature or experimental data. Identification using selected reaction monitoring (SRM) typically requires the use of at least one ion ratio. Where only a single ion ratio is used, other assay characteristics should be considered to strengthen the identification, e.g., retention time, control for interferences, etc. If enough ions of sufficient abundance exist, two or more ion ratios should be monitored. Identification is strengthened with a greater number of ion ratios. The internal standard's identification should be monitored with at least one ion ratio. For example, in GC/MS/MS, the unknown result may have prescribed ion ratio tolerances within ± 25% of the extracted calibrator(s) (see NCCLS 43-A).

An alternative approach for GC/MS/MS and LC/MS/MS utilizes a criteria of ion-ratio data whereby tolerances for at least 3 ion ratios based on relative ion intensity (see table below) and a scoring system based on relative intensity of the product ions must be within prescribed limits (see 96/23/EC 17.8.2002 for details).

Relative intensity (% of base peak)	Maximum Tolerance for MS-MS
>50%	± 20%
>20-50%	± 25%
>10-20%	± 30%
≤ 10%	± 50%

Importantly, other procedures may exist. Again, each laboratory should have a method in place that is generally accepted and validated by the laboratory.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. Gas chromatography/mass spectrometry (GC/MS) confirmation of drugs; approved guideline C43-A. Wayne, PA: NCCLS, 2002; 2) Official Journal of the European Communities. Commission Decision implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (17.8.2002).

*****NEW***** ***05/10/2007***

FDT.25210 Phase II **N/A YES NO**

For LC/MS, does the laboratory's assay procedure include an evaluation in each specimen for possible ion-suppression?

NOTE: Ion suppression is a recognized analytical anomaly in LC/MS experiments. Such suppression can lead to false negative results or poor quantitative analyses. While difficult to predict and observe from specimen to specimen, certain precautions should be used to try to recognize when ion suppression occurs. As an example, there may be poor recovery of deuterated internal standards due to ion-suppression.

COMMENTARY:

N/A

REFERENCES: 1) Annesley, T.M. Ion Suppression in Mass Spectrometry. *Clin. Chem.*, 49, pp. 1041-1044 (2003); 2) Krull, I. and Swartz, M. Quantitation in Method Validation. LC-GC, 16, pp. 1084-1090 (1998).

FDT.25280 Phase II **N/A YES NO**

Is there a documented procedure or policy defining situations when reinjection or reanalysis is required?

COMMENTARY:

N/A

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PERSONNEL

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The laboratory should be staffed by appropriately qualified and trained personnel under the guidance of the director or scientific director. Records of the qualifications and training should be kept and be available for review. Minimum personnel qualifications for analytical testing in the FDT laboratory should be equivalent to those required under CLIA 1988 guidelines.

The laboratory should have an organizational chart, personnel policies, and job descriptions that define qualifications and duties for all positions. Personnel files should contain qualifications, and continuing education records for each employee.

Ideally, these files should be located in the laboratory. However, they may be kept in the personnel office or health clinic if the laboratory has ready access to them (i.e., easily available to the inspector).

Please consult the Laboratory General Checklist for additional details relating to personnel that are not covered in this FDT Checklist.

SCIENTIFIC DIRECTOR

FDT.26830 Phase II **N/A YES NO**

Does the director or scientific director meet at least one of the following qualifications?

1. **Certified as a Diplomate by the American Board of Forensic Toxicology**
2. **Certified by the American Board of Clinical Chemistry in Toxicological Chemistry**
3. **MD certified in clinical and/or forensic pathology with at least two years' experience in analytic toxicology**
4. **PhD in a chemical and/or biological discipline with at least two years' experience in analytic toxicology**
5. **Scientific director of a CAP FDT accredited laboratory on January 1, 1997**

COMMENTARY:

N/A

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:

N/A

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:

N/A

FDT.27230 Phase II N/A YES NO

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

COMMENTARY:

N/A

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:

N/A

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COMPUTER OPERATIONS

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The FDT laboratory will also be inspected with the CAP Laboratory General Checklist. This Checklist has detailed requirements for the proper operation and maintenance of laboratory computer systems, and it is the expectation of the CAP FDT Accreditation Program that any computer operations used for FDT services must follow these requirements. The inspection team should pay particular attention to computer operations in regard to confidentiality and access of data and reports.

FDT.27930 Phase II N/A YES NO

Does the computer system maintain FDT results in a confidential manner?

NOTE: Access to FDT records that are stored electronically must be restricted to FDT laboratory personnel authorized by the scientific director. The access level granted must be appropriate for the job responsibilities.

COMMENTARY:

N/A