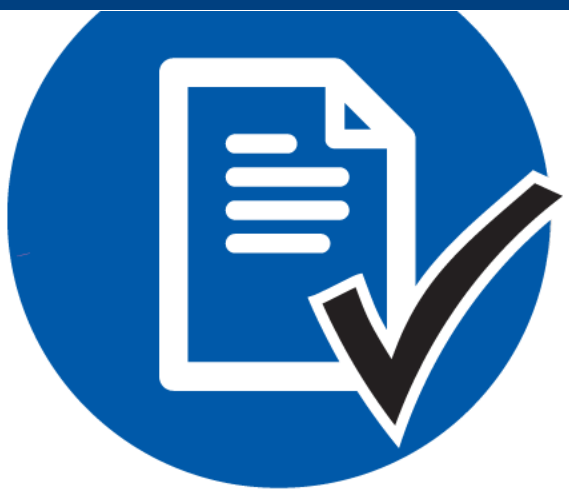
COLLEGE of AMERICAN PATHOLOGISTS

Master

Forensic Drug Testing Checklist

CAP Accreditation Program



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09.22.2021

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Forensic Drug Testing Checklist

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ON-LINE CHECKLIST AVAILABILITY AND RESOURCES

Participants of the CAP accreditation programs may download the checklists from the CAP website (cap.org) by logging into e-*LAB* Solutions Suite. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory's activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

A repository of questions and answers and other resources is also available in e-LAB Solutions Suite under Accreditation Resources, Checklist Requirement Q & A.

SUMMARY OF CHECKLIST EDITION CHANGES
Forensic Drug Testing Checklist
09/22/2021 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
   - Modifications that may require a change in policy, procedure, or process for continued compliance; or
   - A change to the Phase
3. Deleted/Moved/Merged:
   - Deleted
   - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
   - Merged — The combining of similar requirements

NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for on-site inspections and self-evaluations may not list all of these requirements.

NEW Checklist Requirements
None

REVISED Checklist Requirements

Requirement	Effective Date
FDT.05045	09/22/2021
FDT.05055	09/22/2021
FDT.05110	09/22/2021
FDT.05800	09/22/2021

DELETED/MOVED/MERGED Checklist Requirements

Requirement	Effective Date
FDT.05080	09/21/2021
FDT.05809	06/03/2020
FDT.05813	09/21/2021

FDT.05827	09/21/2021
FDT.05831	09/21/2021
FDT.05837	09/21/2021
FDT.05843	06/03/2020
FDT.05846	09/21/2021
FDT.05848	09/21/2021

INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a forensic drug testing laboratory.

Laboratories not subject to US regulations: *Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

EXTENT OF SERVICES PROVIDED

A specific menu of drugs tested is not required for accreditation. The test menu must be defined by the laboratory director, considering the needs of the laboratory's clients. The laboratory may offer different test menus to different clients based on client request.

The laboratory must comply with proficiency testing and other checklist requirements for all testing represented as accredited by the CAP FDT accreditation program. Proficiency testing requirements are found in the All Common Checklist.

Inspector Instructions:

	• Sampling of test referral policies and procedures • Sampling of screening and confirmatory test records (includes defined cut-off values)
	• What is your course of action when ethanol testing yields a positive result?

FDT.00300 Positive Result Confirmation **Phase II**

Positive screening results (excluding ethanol, see FDT.00350) are confirmed using a well-defined and scientifically acceptable mass spectrometric method (eg, GC/MS, LC/MS, GC/MS/MS, LC/MS/MS) that, when feasible, is analytically different from the screening method. Testing for screening and confirmatory phases are performed on two separate aliquots taken from the original specimen container.

NOTE: The CAP FDT program requires that all screen-positive drug tests be confirmed by a mass spectrometric method, but allows the confirmation to be performed at a CAP FDT-accredited or Substance Abuse and Mental Health Services Administration (SAMHSA) certified laboratory other than the original screening laboratory. 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.

Evidence of Compliance:

- ✓ Written procedure defining the method for confirmatory testing of all positive results for tests **AND**
- ✓ Records reflecting the confirmatory testing performed on positive results

FDT.00310 Laboratory Qualifications - Confirmatory Tests **Phase II**

All confirmatory tests are performed in-house or referred to a laboratory that is CAP FDT-accredited or SAMHSA-certified.

FDT.00320 Referral Process Procedures **Phase II**

If the laboratory refers any testing for re-screening and confirmation, there are written procedures that fully describe the referral process from initial screening, specimen aliquoting, chain-of-custody, receipt of referral laboratory results, and reporting of results.

NOTE: Deficiencies in the procedure should be identified for corrective action.

FDT.00330 Screen-Positive Drugs - Confirmation **Phase II**

The laboratory requires the confirming CAP FDT-accredited or SAMHSA-certified laboratory to both re-screen and confirm the presence of screen-positive drugs.

NOTE: If the laboratory performing the initial screening test (for "screen-only" laboratories) refers any confirmation testing, it must be able to demonstrate that the confirming laboratory re-screens and confirms the screen-positive specimen.

FDT.00350 Ethanol Confirmation **Phase II**

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

Evidence of Compliance:

- ✓ Written procedure defining the method for confirmatory testing of positive ethanol results **AND**
- ✓ Test reports and records with confirmatory results

REFERENCES

1) Clinical and Laboratory Standards Institute. *Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline.* 3rd ed. CLSI Document C52-ED3. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.
2) Wu AHB, McKay C. National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: Recommendations for the Use of Laboratory Tests to Support Poisoned Patients Who Present to the Emergency Department. *Clin Chem*. 2003;49(3):357-379.
3) Frederick DL, King DS. Lactate Dehydrogenase Can Cause False-Positive Ethanols. *Clinical and Forensic Toxicology News (Quarterly AACC/CAP)*. June 2012:4-7.

FDT.00420 Cut-off Values **Phase II**

The laboratory uses defined cut-off values for the screening and confirmation tests for all drugs.

NOTE: The laboratory must use defined cut-off values for the screening and confirmation tests for all drugs and drug classes. Cut-off 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.

Evidence of Compliance:

- ✓ Records of defined cut-off values for all screening and confirmatory tests

LABORATORY SAFETY

The inspector should review relevant requirements 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.

QUALITY MANAGEMENT

Inspector Instructions:

	• Records of quality monitoring, including pre-analytic (correct collection, effects of excessive sample dilution or potential adulteration), analytic and post-analytic and corrective action when indicators do not meet threshold
	• What is your course of action when a false positive result is reported?
	• Further evaluate the responses and root-cause analysis for any false positive result reported

FDT.01200 Specimen Collection QM **Phase I**

There is 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. The laboratory must be able to perform ancillary tests that may aid in the detection of excessive dilute or potentially adulterated samples, eg, pH, specific gravity, or creatinine.

Evidence of Compliance:

✓ Records of collection monitoring with client communication or consultation

FDT.01400 Interpretive Consultations **Phase I**

There is evidence that the laboratory is actively involved in consultation with clients about interpretive problems.

Evidence of Compliance:

- ✓ Records of external communication such as memos, laboratory newsletters/communications or consultation log

FDT.01666 Root Cause Analysis for False Positives **Phase II**

The laboratory's QM program requires completion of a "root-cause" analysis with review by the laboratory director within 30 days of discovery for any false positive result reported.

NOTE: The laboratory's written QM plan must include procedures for analyzing and determining the root-cause of any false positive confirmed drug result reported by the laboratory on donor or proficiency testing specimens. (This does not apply to screening tests and those pending confirmation.) This procedure also applies to falsely reported specimen adulteration or substitution. Elements of this procedure must include investigation of pre-analytic, analytic, and post-analytic components. The results of the investigation must be recorded and include corrective action (eg, retraining) to prevent recurrence.

QUALITY CONTROL/STANDARD OPERATING PROCEDURES (SOP)

The laboratory director must be responsible for the quality control (QC) program. There must be records of initial and biennial review of the policy and approval of any changes by the laboratory director. The overall QC program must be defined clearly, recorded (paper or electronic), and readily available to the technical and supervisory staff. It should include delegation of responsibilities, general policies, procedures, and analytic details. The records should be organized with a defined system to permit regular review by appropriate supervisory personnel and the laboratory director.

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, laboratory director, or designee.

GENERAL QUALITY CONTROL

Inspector Instructions:

	• Sampling of QC policies and procedures • QC records for each analytic procedure for the past year (includes weekly and monthly review) • Sampling of internal blind QC records
	• How do you determine when quality control is unacceptable and when corrective actions are needed? • How does your laboratory verify or establish acceptable quality control ranges? • How do you monitor the precision of your confirmatory testing?

DISCOVER

- Review a sampling of QC data over the previous two-year period. Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action

FDT.02002 QC Confirmation of Acceptability **Phase II**

The results of controls are reviewed for acceptability before reporting results.

Evidence of Compliance:

✓ Written policy that controls are reviewed and acceptable prior to reporting results

FDT.02005 QC - Screening Tests **Phase II**

Appropriate controls are used for all SCREENING tests.

NOTE: The laboratory must include appropriate controls based upon the methodology/ technology used and the AMR of the test. The following controls should be used for all commonly used screening cutoffs to challenge the cutoffs:

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*

A control 25% below cutoff may not be practical for some drugs/matrices and some cutoffs, eg, cannabinoids at 20 ng/mL and some benzodiazepines at 100 ng/mL. The laboratory must have written criteria for the required controls for all screening tests and all matrices being tested. The blind controls may be internal blind controls, known by the analyst to be blind controls, but blind as to content.

FDT.02010 QC - Confirmation Tests - Single Point Calibration **Phase II**

Appropriate matrix-matched controls are 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 cut-offs in use:

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

FDT.02015 QC - Confirmation Tests - Multiple Point Calibration **Phase II**

Appropriate matrix-matched controls are 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 cut-offs 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*

FDT.02020 Conjugated Drug Controls **Phase I**

Conjugated drug controls are 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.

FDT.02025 Internal Blind QC **Phase II**

An internal blind QC program is an integral part of the laboratory's QC system.

NOTE: An internal blind quality control program is required. 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. Criteria for acceptance and rejection of internal blind controls must be defined. 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 and include challenges from among the 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 laboratory director. An internal or external double blind QC program, where the analyst does not know the identity or content of the blind control, is encouraged but not mandatory.

Evidence of Compliance:

- ✓ Written procedure defining the criteria for acceptable control limits **AND**
- ✓ Records of internal blind controls including review by laboratory personnel and laboratory director **AND**
- ✓ Records of certifying review including review of internal blind control records

REFERENCES

1) Clinical and Laboratory Standards Institute. *Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline.* 3rd ed. CLSI Document C52-ED3. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.

FDT.02030 QC Acceptance Criteria - Controls **Phase II**

Criteria for acceptance and rejection of controls are defined and appropriate.

NOTE: The criteria for qualitative screening assays must be such that the positive control above the cut-off gives a positive response to be acceptable, and the control below the cut-off 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.

Evidence of Compliance:

- ✓ Written procedure defining the criteria for acceptable control limits

FDT.02035 QC Acceptance Criteria - Internal Blind Controls **Phase II**

Criteria for acceptance and rejection of internal blind controls are defined and appropriate.

Evidence of Compliance:
- ✓ Written procedure defining the criteria for acceptable control limits

FDT.02045 Alternative Control Procedures **Phase II**

If the laboratory performs test procedures for which control materials are not commercially available, there are written procedures for an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be recorded.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. Examples of alternative procedures may include split sample testing with another method or with another laboratory, the testing of previously tested specimens in duplicate, testing of specimens in duplicate, or other defined processes approved by the laboratory director.

Evidence of Compliance:
- ✓ Written procedures for alternative quality control **AND**
- ✓ Records of alternative control procedures

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): [42CFR493.1256(h)].

FDT.02060 Weekly QC Review **Phase II**

Quality control data are reviewed and assessed at least weekly by the laboratory director or designee to detect instrument malfunction or analytical system trends.

Evidence of Compliance:
- ✓ Records of QC review with follow-up for outliers, trends, or omissions

FDT.02080 Monthly QC Review **Phase II**

Quality control data are reviewed and assessed at least monthly by the laboratory director, including QC and blind QC records or summarized QC data to detect trends, and review of corrective actions taken by laboratory personnel.

NOTE: The laboratory director must be responsible for the overall QC program, which must include review at least monthly of QC analysis, QC evaluation and corrective actions taken, including appropriate records by laboratory personnel. The review of the quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month should be reviewed when the tests are performed.

Evidence of Compliance:
- ✓ Records of QC review and follow-up for outliers, trends, or omissions

FDT.02150 Confirmation Assay Precision **Phase II**

The QC procedure requires monitoring of the precision of each confirmation assay around the commonly accepted cut-offs.

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

Evidence of Compliance:
- ✓ Records of precision monitoring

FDT.02166 Unusual Laboratory Results **Phase II**

There is a documented procedure and system in operation to detect significant clerical and analytical errors before reporting the results.

NOTE: The detection of errors (eg, 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.

One common method is review of results by a qualified person (technologist, supervisor, pathologist, section director) before release from the laboratory, but there is no requirement for supervisory review of all reported data for single analyte tests that do not include interpretation. All tests that include an interpretation must be reviewed by the section director or qualified designee before release from the laboratory. In computerized laboratories, there should be automatic "traps" for improbable results. The system for detecting clerical errors, significant analytical errors, and unusual laboratory results must provide for timely correction of errors, ie, before results become available for decision making. For confirmed errors detected after reporting, corrections must be promptly made and reported to the ordering physician or referring laboratory, as applicable.

Each procedure must include a listing of common situations that may cause analytically inaccurate results, together with a defined protocol for dealing with such analytic errors or interferences. This may require alternate testing methods; in some situations, it may not be possible to report results for some or all of the tests requested.

The intent of this requirement is NOT to require verification of all results outside the reference (normal) range.

Evidence of Compliance:

- ✓ Records of review of results **OR** records of consistent implementation of the error detection system(s) defined in the procedure **AND**
- ✓ Records of timely corrective action of identified errors

FDT.02182 QC Data **Phase II**

Results of quantitative controls are conveniently recorded or plotted and analyzed routinely to detect trends in instrument or process failure.

FDT.02715 QC Corrective Action **Phase II**

There is a record of corrective action when control results exceed defined acceptability limits.

NOTE: 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 test results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

Even if donor 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 test results.

PROCEDURE MANUAL

Inspector Instructions:

	• Representative sample of procedures for completeness, organization (can retrieve information easily) and laboratory director review. Current practice must match contents of policies and procedures.
	• What previously used procedures are available for reference purposes?

FDT.03200 Procedure Revision Review **Phase II**

All changes are dated and initialed by the laboratory director.

FDT.03300 Retained Procedures **Phase II**

Copies of all procedures (paper or electronic) and the dates on which they were in effect are retained for reference.

FDT.03400 Procedure Manual **Phase II**

There is 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 (ie, 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 (ie, 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*

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). Quality Management System: Development and Management of Laboratory Documents; Approved Guideline - Sixth Edition. CLSI document QMS02-A6 (ISBN 1-56238-869-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2013.

FDT.04700 Procedure Manual Index **Phase II**

The procedure manual has an index or it is organized in a fashion that allows for quick retrieval of information.

SPECIMEN HANDLING

Review the written 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, recording of exceptions, aliquoting, placing into batches, storing, and completion of records.

Inspector Instructions:

	• Sampling of specimen handling policies and procedures for completeness (includes collection, accessioning, specimen retention/storage, record retention) • Sampling of records/logs for completeness (includes specimen rejection, security seal records, specimen validity, collection monitoring) • Sampling of external and internal chain-of-custody records for completeness (includes specimen disposition) • Sampling of specimen rejection records/log
	• Sampling of specimens (unique labeling) • Locked limited-access secured area (contains original specimen/containers) • Locked limited-access secured area (contains forensic records)
	• What is your course of action when unacceptable specimens are received? • What procedure does your laboratory follow when dilutions are made from the primary specimen? • What process does your laboratory follow for retention of positive specimens? • How do you ensure the validity of all specimen types? • Who has access to the secure area where the original specimens are stored?
	• If problems are identified during the review of specimen handling processes, or when asking questions, further evaluate the laboratory's responses, corrective actions and resolutions

FDT.04800 Receiving/Accessioning Procedure **Phase II**

The receiving and/or accessioning procedure requires a record of verification of:

1. **Specimen identification adequacy**
2. **Specimen security seal condition or secured specimen container integrity**
3. **External chain-of-custody completeness upon receipt**

FDT.04850 Chain-of-Custody Records **Phase II**

The laboratory properly completes appropriate sections of external and internal chain-of-custody records to include the following:

- **Type of specimen collected**
- **Verification of donor and/or specimen identity**
- **Identification of laboratory-generated aliquots**
- **Verification of the integrity (tamper-evident) of the specimen container**
- **Identity of individuals handling the specimens**
- **Storage location when not in the possession of an authorized individual, including aliquots**
- **Reason for the transfer of custody and date of transfer**

Evidence of Compliance:
- ✓ Written procedure for chain-of-custody requirements **AND**
- ✓ Completed chain-of-custody records following written procedure

FDT.04890 Unique Specimen Labeling **Phase II**

The written accessioning procedure requires unique labeling of each specimen by the laboratory.

FDT.04950 Restricted Access **Phase II**

Access to specimens, aliquots and any extracts thereof is restricted to authorized laboratory personnel.

Evidence of Compliance:
- ✓ Written procedure limiting access to the laboratory by authorized personnel only

FDT.05000 Accessioning Procedure **Phase II**

The accessioning procedure has defined criteria for determining the acceptability of specimens for analysis, and there is a written procedure 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 defined in the accessioning procedure, along with the required actions that laboratory personnel must take in reporting these problems to the client.

FDT.05020 Specimen Acceptability **Phase II**

There is a documented procedure for determining the quality of specimens received for analysis, and course of action to take when unacceptable specimens are detected (eg, 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.

Evidence of Compliance:
- ✓ Records of specimen evaluation

REFERENCES

1) Clinical and Laboratory Standards Institute. *Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline.* 3rd ed. CLSI Document C52-ED3. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.

*****REVISED** 09/22/2021***

FDT.05045 Specimen Validity - Urine **Phase II**

All urine specimens are tested for validity.

NOTE: At a minimum, this requires a test for creatinine. but may also include measurements of specific gravity, pH, etc. The laboratory is required to discuss the issue of excessively dilute specimens and potential adulteration with its clients.

Evidence of Compliance:

- ✓ Written procedure for determining specimen validity **AND**
- ✓ Records of specimen validity testing

REFERENCES

1) Clinical and Laboratory Standards Institute. *Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline.* 3rd ed. CLSI Document C52-ED3. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.

***REVISED** 09/22/2021*

FDT.05055 External Contamination - Hair and Nails **Phase II**

The laboratory follows validated procedures to control for potential external contamination of hair and nail specimens.

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

FDT.05095 Secured Specimen Storage **Phase II**

The original specimen (in the original container) and appropriately labeled aliquots are maintained in an appropriate manner when not in the possession of an authorized individual.

NOTE: The original specimens must always be maintained either in the direct custody of an authorized individual or be in a locked secured area accessible only to authorized individuals.

This locked and limited access area may be a refrigerator, freezer, or storage room within the laboratory.

Aliquots or extracts in the laboratory for testing must be in the possession of an authorized individual or be maintained with "line of sight" custody. If the laboratory is a secure, limited-access facility, custody of the aliquot may be assigned to an instrument or temporary storage area, as long as records of individual access and egress from the area are recorded

An authorized individual is considered a person with specific training and work responsibilities for chain-of-custody specimens. General personnel, such as custodians, or technologists not assigned to the chain-of-custody work, must not have unescorted access to secure areas.

Evidence of Compliance:

- ✓ Written policy defining criteria for storage of and access to specimens collected by chain-of-custody procedure **AND**
- ✓ Records for internal chain-of-custody reflecting limited-access storage **OR** record of direct custody of the specimen by an authorized person at all times

***REVISED** 09/22/2021*

FDT.05110 Positive Specimen Retention **Phase II**

All positive specimens are retained frozen in their original containers as defined in the specimen retention policy and for at least:

- **One year - all specimen types except blood**
- **30 days or longer at the discretion of the laboratory director - blood specimens**

NOTE: For hair, umbilical cord tissue, and nails, both the original specimen container and any residual sample, processed or not, must be retained.

Evidence of Compliance:
- ✓ Retention policy for positive specimens **AND**
- ✓ Records of specimen disposition consistent with retention policy

***REVISED** 09/22/2021*

FDT.05800 Negative Specimen Retention **Phase II**

Negative specimens are retained as defined in the specimen retention policy.

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.

Evidence of Compliance:
- ✓ Records of specimen disposition consistent with retention policy

FDT.05805 Specimen Disposal **Phase II**

Disposal of positive and negative specimens is recorded on a chain-of-custody form.

CERTIFICATION OF RESULTS

Inspector Instructions:

- Sampling of certifying review of analytical and forensic records

FDT.05849 Results Certification **Phase II**

There is a written procedure that requires a record of review of each step of the certification process.

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

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

FDT.05850 Certifying Review **Phase II**

The certifying review procedure requires a record that includes the identification of the reviewer, and the date of the completed review.

INSPECTION OF RECORDS

Inspector Instructions:

READ

- Sampling of laboratory records using the following guidelines:
  - At least 20% of batches originating from the time between the last on-site inspection and 60 days prior to the current inspection
  - At least one batch for each drug in each matrix
  - Review of batches before and after proficiency testing failures to assess systematic analytical problems
- Sampling of external and internal chain-of-custody records for completeness (includes specimen disposition)

FDT.05862 Chain-of-Custody Documents **Phase II**

The external and internal chain-of-custody records are available, and properly completed.

FDT.05874 Screening/Confirmatory Tests **Phase II**

The data from all screening and confirmatory tests are available.

NOTE: The data must include:

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

FDT.05886 Records **Phase II**

The records permit valid review of the data.

REPORTING OF RESULTS

Inspector Instructions:

	• Sampling of reporting policies and procedures (includes telephone and electronic reporting) • Sampling of test reports as applicable (printed, FAX with record of transmission to a "secure or confidential FAX", remotely printed, computer access)
	• How do you ensure confidentiality of donor reports? • How does your laboratory differentiate non-forensic drug testing from forensic drug testing services?
	• Examine the laboratory's reporting system. Ensure that the process provides appropriate, accurate and confidential reporting.

FDT.05900 Result Reporting **Phase II**

There are written procedures for the reporting of results to clients or their representatives.

NOTE: These procedures 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*

FDT.06500 Confirmed Positives **Phase II**

Only confirmed positives are 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. If the laboratory refers some or all confirmatory testing, the laboratory's screening results must be withheld pending the receipt of the confirmatory laboratory's results.

Evidence of Compliance:

✓ Records reflecting confirmatory testing performed on positive results **OR** policy defining situations where unconfirmed positive results may be reported **AND**

- ✓ Test reports with confirmed positive results **OR** patient reports with a statement that clearly differentiates the non-forensic testing result from the forensic drug testing service

FDT.06600 Telephone Reporting **Phase II**

There are written procedures for reporting of results by telephone.

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

FDT.06700 Electronic Reporting **Phase II**

There are written procedures for the electronic reporting of results (eg, computer, FAX).

FDT.06800 Confidential Reporting **Phase II**

Written procedures for reporting emphasize the 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.).

RECORDS

Inspector Instructions:

- Record retention policy

FDT.07000 Record Retention - Forensic Drug Testing **Phase II**

There is a written policy that defines which records, and for what time periods, records are retained to meet client, legal, regulatory, and accreditation requirements.

NOTE: The laboratory must retain the following records for at least two years:

1. *Laboratory security access logs*
2. *Laboratory accessioning logs*
3. *Chain-of-custody records 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 two 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*

FDT.07100 Secured Storage **Phase II**

The records are stored in a secured area that is only accessible to authorized personnel.

Evidence of Compliance:

✓ Written procedure for secure storage of records

FDT.07200 Record Availability **Phase II**

The records for the last two years are available at the time of the inspection.

REAGENTS/STANDARDS/CALIBRATORS/CONTROLS

The verification of reagents/standards/calibrators/controls (RSCC) is required and must be recorded. 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 recorded before the RSCC is placed in service.

Inspector Instructions:

	• Sampling of verification of reagents/standards/calibrators/controls policies and procedures • Sampling of RSCC verification records (includes certification/verification of calibrator purity) • Sampling of control range verification records • Current DEA license (for US laboratories that handle pure controlled substances)
	• Sampling of RSCC materials (labeling, storage, quality of calibration standards)
	• What is your course of action if calibration is unacceptable? • What is your course of action when preparing calibrators/controls in-house? • How does your laboratory matrix match calibrator/control materials? • What is your course of action if using expired RSCC materials? • When was the last time you performed a calibration procedure and how did you verify calibration?

FDT.07600 RSCC Validation **Phase II**

There is a written procedure that describes the system for monitoring of RSCC preparation or receipt by the laboratory and the verification of same against previously verified RSCC before they are placed into service.

FDT.17190 RSCC Labeling **Phase II**

RSCC are 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.

Evidence of Compliance:

✓ Written policy defining elements required for reagent labeling

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) Clinical and Laboratory Standards Institute (CLSI). Quality Management System: Development and Management of Laboratory Documents; Approved Guideline - Sixth Edition. CLSI document QMS02-A6 (ISBN 1-56238-869-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2013.

FDT.17210 RSCC Expiration **Phase II**

Outdated RSCC are discarded and replaced routinely.

NOTE: Certain reagents may warrant use after the labeled expiration date. In such cases, the laboratory must have a clearly defined, written policy specifying such reagents, the circumstances under which extended usage is permitted, the control procedures for such usage, and the persons authorized to extend the usage of the RSCC.

FDT.17220 Calibration/Control Materials **Phase II**

High quality drug calibration standards and control materials are 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.

Evidence of Compliance:

✓ Written procedure defining the use of appropriate calibration/control materials

FDT.17230 Quality of Calibration Standards **Phase II**

The quality of drug calibration standards is recorded.

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

FDT.17330 Calibrator Preparation **Phase II**

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

Evidence of Compliance:

✓ Written procedure for in-house preparation of calibrators and controls

FDT.17363 Control Matrix **Phase II**

Control material is 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: Negative hair digest or extract*
4. *Blood: Whole blood, plasma, or serum based matrix, as appropriate*
5. *Other materials may be used if validated by the laboratory and shown to be equivalent to the above*

Evidence of Compliance:

✓ Written procedure defining use of matrix-matched controls **OR** records of validation when differing matrices are used

FDT.17396 Calibrator Matrix **Phase II**

Calibration material is 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: Negative hair digest or extract*
4. *Blood: Aqueous calibrators when appropriate*
5. *Other materials may be used if validated by the laboratory and shown to be equivalent to the above*

Evidence of Compliance:

✓ Written procedure defining use of matrix-matched calibrators **OR** records of validation when differing matrices are used

FDT.17430 QC Range Verification **Phase II**

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

Evidence of Compliance:

- ✓ Written procedure defining methods used to establish control ranges **AND**
- ✓ Records of control range verification for each lot

FDT.17530 Pure Controlled Substances **Phase II**

If the laboratory procedures require the use of chemicals (for standards, controls, etc.) covered by the Controlled Substances Act, the laboratory maintains appropriate licenses.

NOTE: The intent is to be compliant with national, federal, state (or provincial), and local laws and regulations.

For US 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.

PROCEDURES AND TEST SYSTEMS

Inspector Instructions:

	• If problems are identified during the review of the methods and instrument systems, or when asking questions, further evaluate the laboratory's responses, corrective actions and resolutions • Select a representative assay and follow the entire process from specimen receipt to final result reporting

METHOD PERFORMANCE VALIDATION

The laboratory must validate all analytical methods. All current screening and confirmatory analytical methods for drugs must have method performance validation data on file and available for review.

Inspector Instructions:

	• Initial validation and method validation evaluation policy and procedure • Method validation records
	• If problems are identified during the review of method validation studies, or when asking questions, further evaluate the laboratory's responses, corrective actions and resolutions • Select a recent method validation and review all records

FDT.19930 Initial Validation **Phase II**

There is a written procedure for method validation.

FDT.20030 Method Validation Evaluation **Phase II**

The method validation procedure requires that method performance specifications are evaluated and the review is recorded.

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 (ie, relevant interferences)*
5. *Linearity for quantitative methods including LOQ, which must be determined*
6. *Carryover potential*

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 Method Validation Records **Phase II**

The records for method performance validation are complete for all forensic drug testing analytical methods and sample types.

FDT.20163 Method Performance Annual Verification **Phase II**

There is a procedure for verification of confirmation method performance at least annually and results are recorded.

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*

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]

IMMUNOASSAYS

Inspector Instructions:

	• Sampling of immunoassay policies and procedures (includes re-analysis and secondary screening information) • Validation data for modifications, if applicable • Sampling of calibration data
	• Multi-well plate procedure
	• How are you assured your automatic pipetting systems exhibit no carryover effects?

FDT.20980 Pipette Carryover **Phase II**

The laboratory has evaluated its automatic pipetting systems for carryover.

NOTE: The laboratory must have written procedures 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).

Evidence of Compliance:

✓ Records of reassessment of samples with potential carryover

REFERENCES

1) Clinical and Laboratory Standards Institute. *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline.* CLSI Document GP31-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2009.

FDT.20996 Multi-Well Plate **Phase II**

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

NOTE: The laboratory must have a written procedure to prevent contamination into or between wells of multi-well plates.

FDT.21030 Calibration Materials **Phase II**

Appropriate calibrators are 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 must have validated the stability of the calibration, and have a record of the validation.

Evidence of Compliance:
- ✓ Written procedure defining use of appropriate calibrators **AND**
- ✓ Records of calibration

FDT.21130 Analytical Data **Phase II**

The analytical data is presented to permit scientific review of the data for calibrators, controls and unknowns by the analyst.

FDT.21430 Spectrophotometer Calibration **Phase II**

Spectrophotometers, if part of an immunoanalyzer, are calibrated at the frequency and as directed by the instrument manufacturer, and results recorded.

Evidence of Compliance:
- ✓ Written procedure for spectrophotometer calibration **AND**
- ✓ Records of calibration at defined frequency

FDT.21680 Reanalysis/Secondary Screening **Phase II**

There is a written policy defining situations when reanalysis and secondary screening are indicated.

LIQUID CHROMATOGRAPHY (LC)

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

Inspector Instructions:

	• Sampling of LC policies and procedures • Sampling of LC control, calibration/standards records • Sampling of column verification records
	• How does your laboratory ensure appropriate extracted calibrator(s) are analyzed? • How does your laboratory evaluate potential carryover? • When are reinjection or reanalysis procedures required?

FDT.22130 Instrument Operation **Phase II**

There are written procedures for calibration and operation of LC equipment.

FDT.22150 Calibration and Calibration Verification **Phase II**

Appropriate calibration or calibration verification is performed on each day of testing or following the manufacturer's instructions.

NOTE: For qualitative assays, an appropriate calibrator should be run at normal and abnormal levels. For quantitative assays, a multipoint calibration may be required if the measurement has a non-linear response. For some assays, a level near the assay's limit of detection (LOD) or at critical decision point(s) is needed. For measurement systems that have a linear response verified by periodic multipoint calibration verification and AMR verification protocols, a calibration procedure that uses a single calibrator at an appropriate concentration is acceptable. Analyses based on a single point calibration must be controlled by appropriate quality control samples. In addition, inclusion of a negative control (reagent blank) is good laboratory practice.

Evidence of Compliance:
- ✓ Written procedure for calibration/calibration verification **AND**
- ✓ Records of calibration/calibration verification

FDT.22230 Column Performance **Phase II**

The procedure requires monitoring the performance of the column on each day of use.

NOTE: 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. 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. Records must be retained.

FDT.22280 Extracted Calibrators **Phase II**

The written procedure requires that an appropriate extracted calibrator(s) is analyzed with each batch of samples.

NOTE: At least one extracted calibrator at the commonly accepted cut-off for single-point calibration, or multiple calibrators above and below the commonly accepted cut-off 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 must have a record of the validation of the stability of the calibration.

FDT.22330 Daily QC **Phase II**

The written procedure requires that appropriate controls are extracted and analyzed with each batch of specimens.

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

FDT.22430 Internal Standard **Phase II**

Internal standards are used as appropriate.

NOTE: An internal standard is not required for FDA-cleared/approved kits where an internal standard is not used. For a qualitative assay, the use of an internal standard is appropriate if sample preparation includes an extraction step(s), there is low or variable analyte recovery, and/or an accurate sample injection volume is important.

Evidence of Compliance:
- ✓ Written policy defining the use of the internal standard **OR**

✓ Written justification for not using an internal standard in assay

FDT.22830 LC Records **Phase II**

Specimen run order, chromatographic peak shape and retention time for calibrators, controls and unknowns are recorded and maintained for review.

FDT.22930 Analytical Data **Phase I**

The analytical data are presented to permit scientific review by the analyst of the data for calibrators, controls, and unknowns.

FDT.23030 Carryover Detection **Phase II**

There is a procedure for detection and evaluation of potential carryover.

NOTE: No matter what type of injection is used, the procedure must address criteria for the evaluation of potential carryover from a preceding elevated (high concentration) sample to the following sample in each analytical batch analysis.

Evidence of Compliance:

✓ Records for reassessment of samples with potential carryover

FDT.23080 Reinjection/Reanalysis **Phase II**

There is a written policy defining situations when reinjection or reanalysis are indicated.

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.

Inspector Instructions:

	• Sampling of GC policies and procedures • Sampling of GC control, calibration/standards records • Sampling of column verification records
	• How does your laboratory evaluate potential carryover? • When are reinjection or reanalysis procedures required?

FDT.23230 Instrument Operation **Phase II**

There are written procedures for calibration and operation of GC equipment.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline - Second Edition.* CLSI Document C43-A2. (ISBN 1-56238-720-0). Clinical and Laboratory Standards Institute, 940 West Valley Road, Wayne, PA 19087-1898, USA, 2010.

FDT.23250 Calibration and Calibration Verification **Phase II**

Appropriate calibration or calibration verification is performed on each day of testing or following the manufacturer's instructions.

NOTE: For qualitative assays, an appropriate calibrator should be run at normal and abnormal levels. For quantitative assays, a multipoint calibration may be required if the measurement has a non-linear response. For some assays, a level near the assay's limit of detection (LOD) or at critical decision point(s) is needed. For measurement systems that have a linear response verified by periodic multipoint calibration verification and AMR verification protocols, a calibration procedure that uses a single calibrator at an appropriate concentration is acceptable. Analyses based on a single point calibration must be controlled by appropriate quality control samples. In addition, inclusion of a negative control (reagent blank) is good laboratory practice.

Evidence of Compliance:

- ✓ Written procedure for calibration/calibration verification **AND**
- ✓ Records of calibration/calibration verification

FDT.23330 Column Performance **Phase I**

The procedure requires monitoring the performance of the column on each day of use.

NOTE: Good laboratory practice dictates the use of a system to monitor 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. 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. Records must be retained.

FDT.23380 Extracted Calibrators **Phase II**

The procedure requires that appropriate extracted calibrator(s) be 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 must have a record of the validation of the stability of the calibration.

FDT.23430 Daily QC **Phase II**

The written procedure requires that appropriate controls be extracted and analyzed with each batch of samples.

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

FDT.23530 Internal Standard **Phase II**

Internal standards are used as appropriate.

NOTE: An internal standard is not required for FDA-cleared/approved kits where an internal standard is not used. For a qualitative assay, the use of an internal standard is appropriate if sample preparation includes an extraction step(s), there is low or variable analyte recovery, and/or an accurate sample injection volume is important.

Evidence of Compliance:
- ✓ Written policy defining the use of the internal standard **OR**
- ✓ Written justification for not using an internal standard in assay

FDT.23730 Test Records **Phase II**

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

Evidence of Compliance:
- ✓ Records of evaluation of instrument performance **AND**
- ✓ Records of instrument maintenance when performance exceeds defined limits

FDT.23930 Gas Leakage **Phase I**

A written procedure specifies the checking of gas lines and connections for leaks every time tubing or a connection has been manipulated.

Evidence of Compliance:
- ✓ Records of gas line checks

FDT.24130 GC Records **Phase II**

Specimen run order, chromatographic peak shape, and retention time for calibrators, controls and unknowns are recorded and maintained for review.

FDT.24230 Analytical Data **Phase I**

The analytical data are presented to permit scientific review by the analyst of the data for calibrators, controls and unknowns.

FDT.24330 Carryover Detection **Phase II**

There is a procedure for detection and evaluation of potential carryover.

NOTE: No matter what type of injection is used, the procedure must address criteria for the evaluation of potential carryover from a preceding elevated (high concentration) sample to the following sample in each analytical batch analysis.

Evidence of Compliance:
- ✓ Written procedure defining carryover evaluation **AND**
- ✓ Records for reassessment of samples with potential carryover

FDT.24380 Reinjection/Reanalysis **Phase II**

There is a written policy defining situations when reinjection or reanalysis are indicated.

MASS SPECTROMETRY (MS)

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

Inspector Instructions:

READ	• Sampling of MS policies and procedures • Identification criteria compliance
ASK	• How does your laboratory identify possible ion-suppression? • How does your laboratory ensure appropriate extracted calibrator(s) are analyzed? • When are reinjection or reanalysis procedures required?

FDT.24430 Instrument Operation **Phase II**

There are written procedures for calibration and operation of MS equipment.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline - Second Edition.* CLSI Document C43-A2. (ISBN 1-56238-720-0). Clinical and Laboratory Standards Institute, 940 West Valley Road, Wayne, PA 19087-1898, USA, 2010.

FDT.24530 Instrument Maintenance **Phase II**

The procedure requires that the mass spectrometer be maintained at intervals as defined by the manufacturer.

FDT.24630 Mass Spectrometer Tuning **Phase II**

The mass spectrometers are tuned each day of testing, or according to manufacturer's recommendations, and tune records are retained.

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

FDT.24880 Extracted Calibrators **Phase II**

The procedure requires that appropriate extracted calibrator(s) be 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.

FDT.25130 Identification Criteria - Single Stage Mass Spectrometry **Phase II**

The identification criteria for single stage mass spectrometry (ie, GC/MS, LC/MS) are defined.

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 (eg, 20% of those of calibrators). This limit should be supported by either literature references (eg, CLSI C43-A2 for GC/MS) or through experimental means. Such ion ratio tolerance limits may differ based on the technique applied (eg, GC/MS versus LC/MS) as well as the analyte(s) being determined (eg, 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 two ion ratios. However, one ion ratio of two characteristic ions may be acceptable if there are only a few characteristic ratios AND if there are other identifying characteristics, eg, 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.

Evidence of Compliance:

✓ QC and test records

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline - Second Edition.* CLSI Document C43-A2. (ISBN 1-56238-720-0). Clinical and Laboratory Standards Institute, 940 West Valley Road, Wayne, PA 19087-1898, USA, 2010.
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)

FDT.25180 Identification Criteria - Tandem Mass Spectrometry — Phase II

The identification criteria for tandem mass spectrometry (MS/MS) are defined.

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, eg, 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 CLSI C43-A2).

An alternative approach for GC/MS/MS and LC/MS/MS utilizes a criteria of ion-ratio data whereby tolerances for at least three 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).

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

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

Evidence of Compliance:

✓ QC and test records

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline - Second Edition.* CLSI Document C43-A2. (ISBN 1-56238-720-0). Clinical and Laboratory Standards Institute, 940 West Valley Road, Wayne, PA 19087-1898, USA, 2010.
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)

FDT.25210 Matrix Effect Evaluation — Phase II

The LC-MS assay procedure includes an evaluation for possible ion-suppression or enhancement in donor samples during routine testing.

NOTE: Ion suppression (or less frequently, ion enhancement) is a recognized analytical anomaly in LC-MS assays. Such suppression can lead to false negative results or poor quantitative analyses (especially near assay limit of quantitation). While difficult to predict and observe from specimen to specimen, certain precautions should be used to try to recognize when ion suppression or enhancement occurs. Routine monitoring of the signal intensity of internal standard(s) is an effective way to recognize signal suppression/enhancement in a single patient sample, due to unexpected interfering components of the matrix. Internal standards to be used are those that cover the areas of the elution profile where matrix effects are most pronounced, and that the suitability of these internal standards has been determined (ie, with acceptance limits) during assay development and validation. Internal standard abundance acceptance criteria may be based on signal to noise ratio or may be compared to internal standard abundance in QC samples. As an example, for isotopically-labeled internal standards, if there is poor recovery of the internal standard, a signal to noise ratio greater than 3:1 should still suffice for acceptance of the specimen in question. If recovery of the isotopically-labeled internal standard is considered poor, then an alternate analysis should be considered, eg, the method of standard addition. For analogue-type internal standards, internal standard recovery may be used as a guide for identification of ion suppression/enhancement, although another option, such as the method of standard addition, would be a reasonable alternative. It should be noted that even isotopically-labeled internal standards do not always readily identify ion suppression or enhancement.

Evidence of Compliance:

- ✓ Written procedure requiring monitoring of internal standards **OR** records for alternative methods used

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)
3) Scientific Working Group for Forensic Toxicology (SWGTOX). Standard Practices for Method Validation in Forensic Toxicology. *J Anal Tox* 2013;37:452-474

FDT.25280 Reinjection/Reanalysis **Phase II**

There is a written policy defining situations when reinjection or reanalysis is required.

PERSONNEL

The laboratory should be staffed by appropriately qualified and trained personnel under the guidance of the laboratory director. Records of the qualifications and training must 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 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 (ie, 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.

LABORATORY DIRECTOR

Inspector Instructions:

	• Records of laboratory director education and experience
	• Interaction of laboratory director with laboratory supervisory personnel and laboratory staff
	• How does your laboratory choose the individual(s) who perform certifying scientist responsibilities?

FDT.26830 Laboratory Director Qualifications **Phase II**

The laboratory director meets at least one of the following qualifications.

1. **MD certified in clinical and/or forensic pathology with at least two years' experience in analytic toxicology**
2. **PhD in a chemical and/or biological discipline with at least two years' experience in analytic toxicology**
3. **Scientific director of a CAP FDT accredited laboratory on January 1, 1997 or before**

NOTE: The experience requirement is deemed to be satisfied if the individual is board certified by the American Board of Forensic Toxicology or the American Board of Clinical Chemistry in Toxicological Chemistry.

Evidence of Compliance:

✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field

FDT.27030 Laboratory Director Experience **Phase II**

The laboratory director has 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.

Evidence of Compliance:

✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field

FDT.27230 Laboratory Director Consultations **Phase II**

The laboratory director is available for consultation concerning interpretation of results.

Evidence of Compliance:
- ✓ Records of consultation

FDT.27330 Certifying Scientist Appointment **Phase II**

The certifying scientists are appointed by the laboratory director.

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

COMPUTER OPERATIONS

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.

Inspector Instructions:

	• Report confidentiality policy • Sampling of employee access records
	• How does your laboratory ensure the electronic confidentiality of donor reports?

FDT.27930 Confidential Results **Phase II**

The computer system maintains 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 laboratory director. The access level granted must be appropriate for the job responsibilities.

Evidence of Compliance:
- ✓ Written policy addressing confidentiality of FDT results **AND**
- ✓ Records of employees with access