



CAP Forensic Drug Testing Accreditation Program Standards for Accreditation

Preamble

Forensic drug testing is a laboratory specialty concerned with the testing of urine, oral fluid, hair, and other specimens for drugs of abuse and alcohol. It is performed for non-medical purposes, including employment-related screening and law enforcement. The laboratory may be freestanding or a section of a medical or forensic laboratory. The forensic drug-testing laboratory may also provide testing for medical purposes. However, the College of American Pathologists (CAP) Forensic Drug Testing (FDT) Program does not accredit non-forensic testing. Such accreditation may be obtained through the CAP Laboratory Accreditation Program (LAP) or other accreditation programs.

The four Standards in this document constitute the core principles of the CAP FDT Program. The objective of the Standards is to ensure that accredited laboratories meet the needs of employers, legal and regulatory authorities, and those tested. The CAP accredits forensic drug testing laboratories that conform to the Standards. The specifics of how the Standards are applied to laboratories are found in the CAP Accreditation Checklists and Terms of Accreditation.

The CAP is committed to helping laboratories comply with the Standards through the publication of detailed checklist items. However, the ultimate responsibility for compliance rests with the laboratory director and the laboratory organization as well as the governing body of the organization.

Standard I - Director and Personnel

The Laboratory Director/Scientific Director must meet the qualifications, and have authority, to direct the laboratory. A board-certified pathologist or other qualified physician or scientist with doctoral-level or commensurate qualifications that meet or exceed requirements or applicable law shall direct the forensic drug testing laboratory. The director must have two years of active laboratory experience in analytical toxicology. Certification by the American Board of Forensic Toxicology or certification in toxicological chemistry by the American Board of Clinical Chemistry satisfies the experience requirement. The director must be qualified to assume professional, scientific, consultative, organizational, administrative, and educational responsibilities for the services provided. The director is responsible for maintaining the Standards, implementing the requirements of the Accreditation Checklists, and documenting compliance. The director must have the authority to fulfill these responsibilities effectively. The laboratory must be staffed with a sufficient number of personnel to perform quality laboratory testing. The laboratory must be organized to ensure that the laboratory director's responsibilities are fulfilled, lines of authority within the laboratory are defined, and individuals who work within the laboratory fulfill their responsibilities and interact effectively with one another.



Standard II - Physical Resources

There shall be sufficient resources to support the activities of the laboratory. Such resources include but are not limited to physical space, testing instruments, reagents, information processing and communication systems, ventilation, public utilities, refrigerated and freezer storage space, and storage and waste disposal facilities. There must be restricted access to all specimens, data, records and reports. Laboratory personnel, those tested, and visitors shall be protected from hazardous conditions. Reasonable accommodation shall be made for disabled persons.

Standard III - Quality Management

The laboratory shall have policies and procedures to ensure quality laboratory testing and chain-of-custody documentation. These requirements include, but are not limited to, validation of test systems, analytic quality control, quality management of pre- and post-analytic processes, proficiency testing (or periodic alternative assessments of laboratory test performance), human resource management, information management, on-going quality improvement, and client communication.

Standard IV - Administrative Requirements

FDT Program laboratories accredited by the CAP must comply with the requirements specified in the Terms of Accreditation and Accreditation Checklists. These requirements include, but are not limited to, periodic on-site inspection, possible interim inspection, interim self-assessment, participation in proficiency testing, payment of accreditation fees, and cooperation with the Commission on Laboratory Accreditation.

Interpretation of Standards

Standard I - Director and Personnel

- A. The director must have the appropriate training and background to be able to discharge the following responsibilities:
 1. *Consultation, Significance, Interpretation, and Correlation of Data* - Provide consultations to authorized individuals about the significance of laboratory data, as appropriate. Interpret, correlate, and communicate laboratory data to authorized individuals.
 2. *Interaction with Others* - Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, clients, laboratory staff, and those tested.
 3. *Valid Methods and Procedures* - Ensure that test methods and procedures are scientifically valid.



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4. *Standards of Performance* - Define, implement, and monitor standards of performance in quality control processes, quality improvement, and cost effectiveness of the forensic laboratory service(s).
5. *Proficiency Testing* - Ensure that the proficiency testing (PT) system covers the extent and complexity of the testing performed in the laboratory and develop a mechanism for determining the reliability of tests for which CAP does not require PT. Monitor the results of all PT, ensure that such testing is properly performed, and document corrective action.
6. *Certifying Review* - Ensure appropriate review and certification of all chain of custody and laboratory data prior to reporting to determine that reliable data are being generated and reported.
7. *Quality Management* - Assume responsibility for implementation of the quality management plan. The director and professional laboratory personnel must participate as members of the various quality improvement committees of the institution, if applicable.
8. *Personnel* - Ensure that there are sufficient qualified personnel with adequate training and experience to meet the needs of the laboratory.
9. *Strategic Planning* - Perform planning for setting goals and developing and allocating resources appropriate to the forensic drug testing environment.
10. *Administration and Management* - Provide effective and efficient administration of the service, including budget planning and control with responsible financial management, in accordance with institutional assignment of such responsibilities.
11. *Education* - Provide educational programs for the laboratory staff and participate in educational programs.
12. *Research and Development* - Plan and direct research and development appropriate to the facility and focused upon the needs of the facility.
13. *Reference Laboratories* - Select reference laboratories based on quality of service and monitor the performance of such reference laboratories.
14. *Safety* - Implement a safe laboratory environment in compliance with good practice and applicable regulations.
15. *Selection of Equipment, Methods, and Reagents* - Provide input into the selection of equipment, methods, and reagents appropriate to the needs of those tested, the scope of testing, and the financial constraints on the laboratory.
16. *Records* - Establish and implement an adequate system of record management and maintenance in the laboratory and monitor adequacy and adherence to that system.



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All laboratory personnel must be in compliance with applicable federal, state, and local laws and regulations. All physicians must maintain a current medical license issued by the state in which the laboratory is located.

B. Delegation of Functions

The director need not perform all functions personally. Certain administrative functions may be delegated to qualified laboratory managers and supervisors. Forensic and technical functions may be delegated to qualified laboratory personnel as appropriate. The director, however, remains responsible for the overall operation and administration of the laboratory to assure that quality testing services are provided. Delegation of responsibility must be documented in writing and be specific as to task and position or individual.

C. Director Involvement

The director must demonstrate adequate involvement in, and oversight of, laboratory activities to ensure that all applicable responsibilities listed in section A, above, are properly fulfilled through onsite or remote consultation. If director involvement is routinely conducted remotely, onsite visits must occur at a frequency that is set forth in writing, is periodically reviewed, and is appropriate to the complexity of the laboratory and volume of testing performed.

The director must perform onsite assessments of the adequacy of staffing and of the physical and environmental conditions of the laboratory sufficiently often to ensure the timeliness and reliability of results reported by the laboratory and the safety of laboratory personnel.

Standard II - Physical Resources

The resources of the facility include space, instrumentation, furnishings, communication and data processing systems, supplies, ventilation, piped gases and water, public utilities, and storage and waste disposal facilities. There should be limited access to specimens, data, records, and reports. The environment within the laboratory should be favorable for the effective performance of its personnel. Bench and storage space for the proper handling of specimens and housing of equipment and supplies should be adequate and convenient. Special work areas should be provided for testing systems that require a controlled environment. Work areas should be arranged for ease of communication and smooth workflow. Reasonable accommodation should be made for disabled lab personnel. The laboratory should be a safe working place for lab personnel, visitors, and those tested. It should comply with the safety codes of applicable jurisdictional authorities. The safe collection and handling of samples and of chemicals should be an integral part of the laboratory



safety program. All waste materials should be properly disposed. Solid, liquid, and gaseous wastes should be discharged or disposed of consistent with regulatory requirements and environmental responsibility. Provision should be made for all reasonably foreseeable emergencies.

Standard III - Quality Management

A. Quality Control

The director must define and oversee the overall quality control program for the laboratory. The purpose of the quality control (QC) system is to prevent, detect and remedy errors in the analytic testing process. The director must define goals, policies, procedures, delegation of functions, and regular review by appropriate levels of personnel. The program must include acceptability limits and corrective action procedures to use when limits are exceeded.

B. Instrument Performance

The director must define and oversee a program that monitors, evaluates, and documents the proper calibration, function, and maintenance of instruments and laboratory equipment.

C. Performance Improvement

The director must systematically monitor and evaluate the quality and appropriateness of the laboratory's service. When systematic problems are identified, the director must address them, both within the department and with other departments, if applicable.

D. Proficiency Testing

The director must ensure that the proficiency testing (PT) system covers the extent and complexity of analytical procedures. PT is designed to assure test reliability through an interlaboratory comparison program. CAP-accepted proficiency testing programs serve this purpose wherever applicable. With respect to tests for which CAP does not require PT, the director must develop a mechanism for determining their reliability. The director must monitor the results of proficiency testing and participate in the documentation of corrective actions.

E. Scientific Relevance

The director is responsible for ensuring that the tests offered by the laboratory are relevant and based upon sound science. A test is deemed relevant if its use is well established in practice, described in textbooks, or supported by relevant guidelines or peer-reviewed literature.

Standard IV - Administrative Requirements

Eligibility for participation in the FDT Program will be determined in accordance with the policies of the CAP. The laboratory test menu must consist of testing methods and analytes that are within the



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expertise of the FDT program and the experience of the inspecting personnel. Laboratories will be evaluated in accordance with the Standards for Laboratory Accreditation of the CAP and the applicable version of the Accreditation Checklists.

The forensic laboratory service must submit to a complete periodic on-site inspection and any interim inspections that the commission determines to conduct. The conduct of inspections and evaluation of results shall be in accordance with the policies and procedures of the Commission.

Laboratories undergoing a change in directorship, location, ownership, or scope of service must notify the commission. They are subject to re-inspection and reevaluation.

Laboratories enrolled in the FDT Program are required to perform periodic self-evaluations. When deficiencies are noted, the laboratory shall take appropriate corrective action that shall be documented and subject to review by the commission.

Laboratories must comply with the Terms of Accreditation listed in the official notice of accreditation sent to the laboratory by the CAP.

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