

**COLLEGE OF AMERICAN PATHOLOGISTS
FORENSIC URINE DRUG TESTING
ACCREDITATION PROGRAM**

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STANDARDS FOR ACCREDITATION

PREAMBLE

Urine drug testing is a critical component of efforts to combat drug abuse in our society because it can objectively identify drug users in a variety of settings. It can be used as a screening tool to determine a subject's prior use and is capable of detecting concentrations of drugs or their metabolites in occasional, recent, or chronic users. The laboratory should attempt to prevent misuse of its services for purposes that do not help combat drug abuse in our society.

Compared to most clinical laboratory testing, however, the legal consequences of a positive urine test for an illegal drug may be severe. It can be argued that even the suggestion that drug abuse has occurred can affect a subject's livelihood, freedom, or rights. Therefore, drug testing presents a heightened probability of legal challenges, and thus is considered "forensic testing."

Reliable discrimination between the presence or absence of specific drugs or their metabolites is critical, not only to achieve the goals of the testing program, but to protect the rights of subjects. Public interest is best served by setting standards that forensic urine drug testing laboratories must meet in order to achieve maximum acceptability of test results.

In response to the forensic nature of urine drug testing, the College of American Pathologists has established minimum requirements for accreditation of those laboratories that are engaged in urine drug testing for legal, regulatory, safety, employment, and other non-medical purposes. These requirements are detailed in the following pages.

Although accreditation is a reflection of standards expected of certified laboratories in drug testing procedures, it is not to be construed as a guarantee of test accuracy.

Appropriate interpretation of results depends upon a complete understanding of the total collection, analytical, and reporting processes.

STANDARD I

Laboratory Scientific Director

The laboratory scientific director shall be qualified to assume professional, scientific, consultative, organizational, educational, and administrative responsibilities for the laboratory. The director shall have sufficient authority to implement and maintain the Standards.

Interpretation

A. Qualifications, Responsibilities, and Role of the Scientific Director

The scientific director of the drug testing laboratory (who may be, but is not necessarily, the laboratory director) is an individual with documented scientific qualifications comparable to those persons certified by the American Board of Forensic Toxicology or a PhD degree with certification in toxicological chemistry by the American Board of Clinical Chemistry. Alternative acceptable qualifications include an MD degree with certification in clinical and/or forensic pathology and at least two years of active laboratory experience in analytical toxicology or a PhD degree in a biological or chemical discipline and at least two years of active laboratory experience in analytical toxicology. All alternative qualifications also require documented training and/or experience with the forensic applications of analytical toxicology (such as court testimony, research, participation in continuing education programs, and review of publications).

The standard for directors is designed to assure knowledge and experience in analytical toxicology with a wide variety of screening and confirmation methodologies. Since urine drug testing in the work place is a legal issue, the director should have knowledge of evidentiary rules that apply when toxicological data are submitted as part of a judicial or administrative procedure. The scientific director therefore should have the appropriate training and background to be able to discharge the following responsibilities:

1. **Significance, Interpretation, and Correlation of Data:** Provide consultations about the significance of the forensic laboratory data. Interpret, correlate, and communicate laboratory data to requestors.
2. **Consultations:** Provide consultations to clients regarding the scientific and legal significance of the laboratory findings as appropriate.
3. **Interactions with Others:** Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the medical and client community, the medical and scientific device industry, and the subject population being served through the client.

4. Standards of Performance: Define, implement, and monitor standards of performance in quality control, quality improvement, and cost-effectiveness of the forensic laboratory service(s).
5. Monitoring and Correlation of Forensic Data: Monitor all work performed in the forensic laboratory to determine that forensically reliable data are being generated; correlate laboratory results for client management.
6. Quality Improvement Responsibilities: Assume responsibility for implementation of the quality improvement plan. The scientific director should participate as a member of the various quality improvement committees of the institution or laboratory.
7. Personnel: Ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory.
8. Strategic Planning: Perform planning for setting goals and developing and allocating resources appropriate to the laboratory's environment.
9. Administrative and Management Responsibilities: Provide effective and efficient administration of the forensic laboratory's service including budget planning and control with responsible financial management, in accordance with institutional assignment of such responsibilities.
10. Educational Responsibilities: Provide educational programs for the laboratory staff, and participate in educational programs of the institution.
11. Research and Development Responsibilities: Plan and direct research and development appropriate to the facility and institution.
12. Reference Laboratories: Select and monitor all referral laboratories for quality of service.
13. Safety: Implement a safe laboratory environment in compliance with good practice and applicable regulations.

B. Delegation of Responsibilities

The scientific director need not perform all responsibilities personally. Administrative functions may be delegated to qualified laboratory managers and supervisors. Scientific and technical responsibilities may be delegated to other qualified laboratory scientists or personnel as appropriate. The scientific director, however, remains responsible for the overall operation and administration of the laboratory to assure that quality laboratory services are provided.

Standard II Resources and Facilities

The laboratory shall have sufficient and appropriate space, equipment, facilities, and supplies for the performance of the required volume of work with accuracy, precision, efficiency, and safety. In addition, the laboratory shall have effective methods for

communication to ensure prompt and reliable reporting. There shall be appropriate record storage and retrieval.

Interpretation

The scope of the responsibilities and activities of the laboratory must be delineated. Once this determination has been made, sufficient and appropriate space and equipment must be provided.

The environment within the laboratory shall be conducive to effective performance of personnel and equipment. There should be sufficient, conveniently located bench and storage space for the proper handling of specimens and housing of equipment and reagents. Special areas for tests requiring a controlled environment shall be provided. Work areas shall be arranged to minimize transportation and should be adequately lighted.

Communication systems should be appropriate for the size and complexity of the organization and institution.

Facilities, equipment, and instruments shall be appropriate for the services performed.

The laboratory must be a safe working place for the personnel and individuals it serves. It must comply with the safety codes of regulatory authorities. The safe collection and handling of specimens and reagents shall be an integral part of the laboratory safety program. Proper disposal of hazardous wastes shall be provided.

The laboratory must be secure, not only in the traditional sense of resisting illegal breaking and entering, but also in the sense of limiting access to areas where specimens are being processed and records are stored. Access to these secure areas should be limited to specifically authorized individuals whose authorization is approved and documented.

Standard III Quality Assurance and Quality Control

There shall be an ongoing quality assurance program designed to monitor and evaluate objectively and systematically the quality and appropriateness of services, to pursue opportunities to improve services, and to identify and resolve problems. Each laboratory shall have a quality control system that demonstrates the reliability and medical and forensic usefulness of laboratory data.

Interpretation

Urine drug laboratories shall have a quality assurance program that encompasses all aspects of the testing process: specimen acquisition, chain-of-custody, security, screening,

confirmation of analytical procedures, and reporting of results. Quality control procedures will be designed, implemented, and reviewed to monitor the conduct of each step of the process. Documentation of the process shall be required and available for review at any time.

When specimens are delivered to the laboratory, the external chain-of-custody documents must be included and completed by the collection site and by the receiving laboratory. Within the laboratory, each specimen must have an internal chain-of-custody document that indicates the date and the purpose each time the specimen is handled or transferred, and that identifies every individual in the chain who has removed, aliquoted, or performed an analysis. Finally, all positive specimens should be retained in original containers in secure storage at freezing temperature (-20 C or lower) for at least one year. The laboratory should be prepared to maintain storage on any specimen under legal challenge for an indefinite period.

Procedure manuals must follow a standard format and indicate sources, dates of adoption, and evidence of periodic review, as described in the National Committee on Clinical Laboratory Standards' (NCCLS) *Clinical Laboratory Procedures Manuals, Approved Guidelines* GP2-A2, 1992.

Control urine specimens containing no drug and specimens fortified with known standards are to be analyzed with each batch of specimens screened. Controls with added drug or metabolite at or near the threshold (cutoff) will be included. Controls will be analyzed in parallel with confirmation tests. Implementation of procedures to ensure that carry-over does not contaminate the testing of a subject's specimen must be documented.

The laboratory quality control system shall contain the following components: (1) The selection of appropriate test methods; (2) an internal quality control program that monitors accuracy and precision of laboratory performance on a daily basis — such a program should be clearly defined in writing, provide established limits of control, prescribe appropriate actions required before acceptance or rejection of batches or analytic “runs,” and be documented with evidence of understanding and implementation by laboratory personnel; (3) an interlaboratory comparison system (proficiency testing) designed to compare laboratory performance with other laboratories; (4) an instrument maintenance program that monitors and demonstrates the proper calibration and function of equipment/instruments; (5) appropriate feedback mechanisms to assure clinical usefulness and relevance of laboratory data; (6) an educational program for the entire laboratory staff designed to maintain or improve the quality of personnel performance; (7) an external audit or accreditation process; and (8) appropriate documentation for the foregoing.

Participation in the appropriate College of American Pathologists' proficiency testing program for drugs of abuse or in a CAP-approved alternative proficiency testing program is mandatory. Acceptable performance of this proficiency testing program is one of the

criteria that must be met before a laboratory becomes eligible to apply for accreditation by the College of American Pathologists.

If any proficiency test results are unsatisfactory according to pre-established criteria, the cause of the unsatisfactory result must be investigated and corrected. A report of the investigation findings, together with subsequent corrective actions, should be recorded, dated, and signed by the responsible supervisor and laboratory (scientific) director. Unsatisfactory performance on CAP-recognized proficiency test samples may be sufficient cause to lead to loss of CAP accreditation by the laboratory.

Many laboratories have applied computer technology to various aspects of laboratory operations. All laboratory systems, including data processing and automation systems, must be validated and tested periodically to provide documented evidence of proper function. Specific requirements will be detailed in the CAP checklist and commentary for these laboratories.

Documentation of all aspects of the testing process must be available. This documentation will be maintained for at least two years, and will include the following: personnel files of analysts, supervisors, directors, and all individuals authorized to have access to specimens; chain-of-custody documents; quality assurance/quality control records; all test data; reports; performance records on proficiency testing; details of accreditation inspections; and hard copies of computer-generated data. The laboratory should be prepared to maintain documents for any specimen under challenge for an indefinite period.

All test results, including screening, confirmation, and quality control data must be reviewed by a qualified, responsible official (certifying scientist) before being certified as accurate. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the threshold (or cutoff) concentration for each (when appropriate).

Both the initial (screening) and confirmation testing must be performed within the facilities of a CAP-accredited forensic urine drug testing-accredited laboratory.

STANDARD IV

Inspection Requirements

All laboratories accredited in this program shall undergo periodic inspections and evaluations as determined by the Commission on Laboratory Accreditation of the College of American Pathologists.

Interpretation

The application process will be initiated by submission of a completed application containing the necessary information, evidence of enrollment in the appropriate proficiency testing programs, and payment of fees. Laboratories will be evaluated in

accordance with the *Standards for Accreditation – Forensic Urine Drug Testing Accreditation Program* of the College of American Pathologists.

The laboratory must submit to a complete periodic on-site inspection. The conduct of inspections and evaluations of results shall be in accordance with the policies and procedures of the Commission on Laboratory Accreditation of the College of American Pathologists.

Laboratories undergoing a change in directorship, location, or ownership are subject to inspection and evaluation in accordance with applicable policy.

Laboratories enrolled in this accreditation program are required to perform periodic self-evaluations. When deficiencies are noted, the laboratory shall take appropriate corrective action which shall be documented and subject to review by the Commission on Laboratory Accreditation. Uncorrected deficiencies at the next on-site inspection shall be considered recurrent. The commissioner(s) will review deficiencies detected during self-evaluation. Corrective action responses from the laboratory director may be required.

Occurrence of “critical deficiencies” and unresolved deficiencies is considered a serious problem and may be sufficient cause to lead to loss of CAP accreditation.