



COLLEGE of AMERICAN
PATHOLOGISTS

Laboratory Quality Solutions

Standards for Laboratory Accreditation

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CAP Laboratory Accreditation Program Standards for Accreditation

Preamble

Pathology is the medical specialty that examines and analyzes human tissue, bodily fluids, and other clinical specimens in order to understand, prevent, diagnose, and treat disease. The pathology and clinical laboratory service provides, without limitation, examination of clinical specimens, interpretation of results, clinical consultation, biological products such as blood components whose use depends on the result of laboratory examinations, and scientific investigation and education related to disease prevention, diagnosis, monitoring, and treatment.

The four Standards in this document constitute the core principles of the College of American Pathologists (CAP) Laboratory Accreditation Program (LAP). The objective of the Standards is to ensure that accredited clinical laboratories meet the needs of patients, physicians, and other health care practitioners. The CAP accredits clinical 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 LAP is committed to helping laboratories comply with the Standards by setting forth detailed accreditation checklist items that amplify those Standards. 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

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 laboratory service. 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 and implementing the requirements of the Accreditation Checklists and documenting compliance. The director must have the authority to fulfill these responsibilities effectively.

The laboratory shall be staffed with a sufficient number of personnel to perform quality laboratory testing in a safe and efficient manner. The laboratory shall be organized to ensure that the 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, storage and waste disposal facilities, and public utilities.

Patients, laboratory personnel, 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 to advance the safety of patients and laboratory personnel. 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 appropriate communication to clinicians, patients, administration, and government entities.

Standard IV - Administrative Requirements

A laboratory accredited by the LAP must comply with the requirements specified in the LAP Terms of Accreditation and Accreditation Checklists. These requirements include, but are not limited to, on-site inspections, interim inspections, interim self-assessment, maintenance of appropriate records and documentation, cooperation with the LAP, and adherence to its policies.

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, Medical Significance, Interpretation, and Correlation of Data* - Provide consultations about the medical significance of clinical laboratory data for purposes of diagnosis and possible treatment, as appropriate (or ensure that such consultations are provided by a pathologist or other qualified physician). Interpret, correlate, and communicate laboratory data to clinicians, patients, and other authorized requestors (or ensure that such functions are carried out by a pathologist or other qualified physician).
 2. *Anatomic Pathology* – Perform anatomic pathology procedures, or ensure anatomic pathology services are provided by a qualified pathologist, if the laboratory offers such services.
 3. *Medical Staff Privileges* - Serve as an active or provisional member of the medical staff for those facilities served, as appropriate.
 4. *Interaction with Others* - Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, physicians and other members of the medical staff, the medical community, laboratory staff, the in vitro diagnostic industry, and the patient population served.
 5. *Standards of Performance* - Define, implement, and monitor standards of performance in quality control processes, quality improvement, and cost effectiveness of the pathology and clinical laboratory service(s).
 6. *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.

7. *Valid Methods and Procedures* - Ensure that test methods and procedures are scientifically valid and clinically relevant.
8. *Monitoring and Correlation of Laboratory Data* - Monitor all work performed in the laboratory to determine that timely and medically reliable data are being generated and appropriately reported; correlate laboratory data for diagnosis and patient management.
9. *Quality Management* - Assume responsibility for implementation of the quality management plan. The director and professional laboratory personnel must participate as members of the quality improvement committees of the institution, if applicable.
10. *Personnel* - Ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory, clinicians, and patients.
11. *Strategic Planning* - Perform planning for setting goals and developing and allocating resources appropriate to the medical environment.
12. *Administration and Management* - Provide effective and efficient administration of the pathology and clinical laboratory service, including budget planning and control with responsible financial management, in accordance with regulatory requirements and institutional assignment of such responsibilities.
13. *Education* - Provide educational programs for the medical and laboratory staff and participate in educational programs of the institution, if applicable.
14. *Research and Development* - Plan and direct research and development appropriate to the facility and focused upon the clinical needs of the facility.
15. *Reference Laboratories* - Select reference laboratories based on quality of service and monitor the performance of such reference laboratories.
16. *Safety* - Implement a safe laboratory environment in compliance with good practice and applicable regulations.
17. *Selection of Equipment, Methods, and Reagents* - Provide input into the selection of equipment, methods, and reagents appropriate to the needs of patients, the scope of testing, and the financial constraints on the laboratory or institution.
18. *Records* - Establish and implement an adequate system of record management and maintenance in the laboratory and monitor adequacy of and adherence to that system.

All laboratory personnel must be in compliance with applicable federal, state, and local laws and regulations. Each physician shall 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. Administrative functions may be delegated to qualified laboratory managers and supervisors. Medical and technical functions may be delegated to qualified physicians and other qualified laboratory personnel as appropriate. The director, however, remains responsible for the overall operation and administration of the laboratory to assure that quality patient services are provided.

Delegation of responsibility must be documented in writing and be specific as to task and position or individual.

If the director is not qualified to direct any of the individual sections of the laboratory, a qualified individual must be retained to direct those sections.

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 medical reliability of results reported by the laboratory and the safety of laboratory personnel.

D. Anatomic Pathologist

Anatomic pathology services must be provided by a qualified pathologist. If the director is not so qualified, a laboratory which offers anatomic pathology services must retain the services of a qualified pathologist(s). Anatomic pathology services related to Mohs surgery may be provided by a qualified dermatologist.

E. Technical Consultant

For laboratories subject to CLIA-88 performing moderately complex tests and not directed by a physician or doctoral scientist meeting CLIA requirements for director of a high complexity laboratory (refer to TLC.10100), a qualified technical consultant must be retained. The technical consultant is responsible for the technical and scientific oversight of the laboratory. The laboratory and technical consultant must have a written agreement defining the responsibilities of the technical consultant.

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. The environment within the laboratory should permit 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 patients, laboratory personnel, and visitors. The laboratory should be a safe working place. It should comply with all applicable safety codes. The safe collection, handling, and (where appropriate) disposal of patient samples and of chemicals should be an integral part of the

laboratory safety program. 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. Performance Improvement

The director must monitor and evaluate the quality and appropriateness of the laboratory's contribution to patient care. When problems are identified (whether systematic or localized), the director must address them, both within the pathology department and with other hospital departments, as appropriate. The director must ensure that the pathology service participates in the institutional quality management plans that deal with relevant areas and outcomes of patient care. The quality management plan should be developed in accordance with the requirements of applicable laws, regulations, and external review organizations. The program should be directed toward continuing improvement in quality, including identifying actions that can anticipate and prevent problems.

B. 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 program should be directed toward continuing improvement in quality, including identifying actions that can anticipate and prevent laboratory errors and problems. The director must define goals, policies, procedures, delegation of functions, and regular review by appropriate levels of personnel. The program must include limits of acceptability and corrective action procedures to use when limits are exceeded.

C. 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.

D. Proficiency Testing

The director must ensure that the proficiency testing (PT) system covers the extent and complexity of the testing performed in the laboratory. PT is designed to assure test reliability through an interlaboratory comparison program. The 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 all proficiency testing, ensure that such testing is properly performed, and document corrective actions.

E. Clinical Relevance

The director is responsible for ensuring that the tests offered by the laboratory and ordered by physicians or others are clinically relevant and based upon sound science. A test is

deemed clinically relevant if its use is well established in clinical practice, described in medical textbooks, or supported by medical guidelines or peer-reviewed literature.

Standard IV - Administrative Requirements

Eligibility for participation in the LAP 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 expertise of the LAP 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 pathology and clinical laboratory service must submit to a complete periodic on-site inspection and any interim inspections that the LAP determines to conduct. The Commission on Laboratory Accreditation will not inspect or accredit a portion of a single cohesive laboratory except under special and/or unusual circumstances, and then only by prior arrangement. 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 so notify the commission and are subject to inspection and reevaluation in accordance with applicable policy.

Laboratories enrolled in the LAP 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. Recurrence of the same deficiencies in consecutive inspections is considered a serious problem and is subject to review by the commission.

The laboratory director and the laboratory must cooperate with the commission. Each accredited laboratory must comply with the Terms of Accreditation listed in the official notice of accreditation sent to the laboratory by the CAP.

Revision History

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