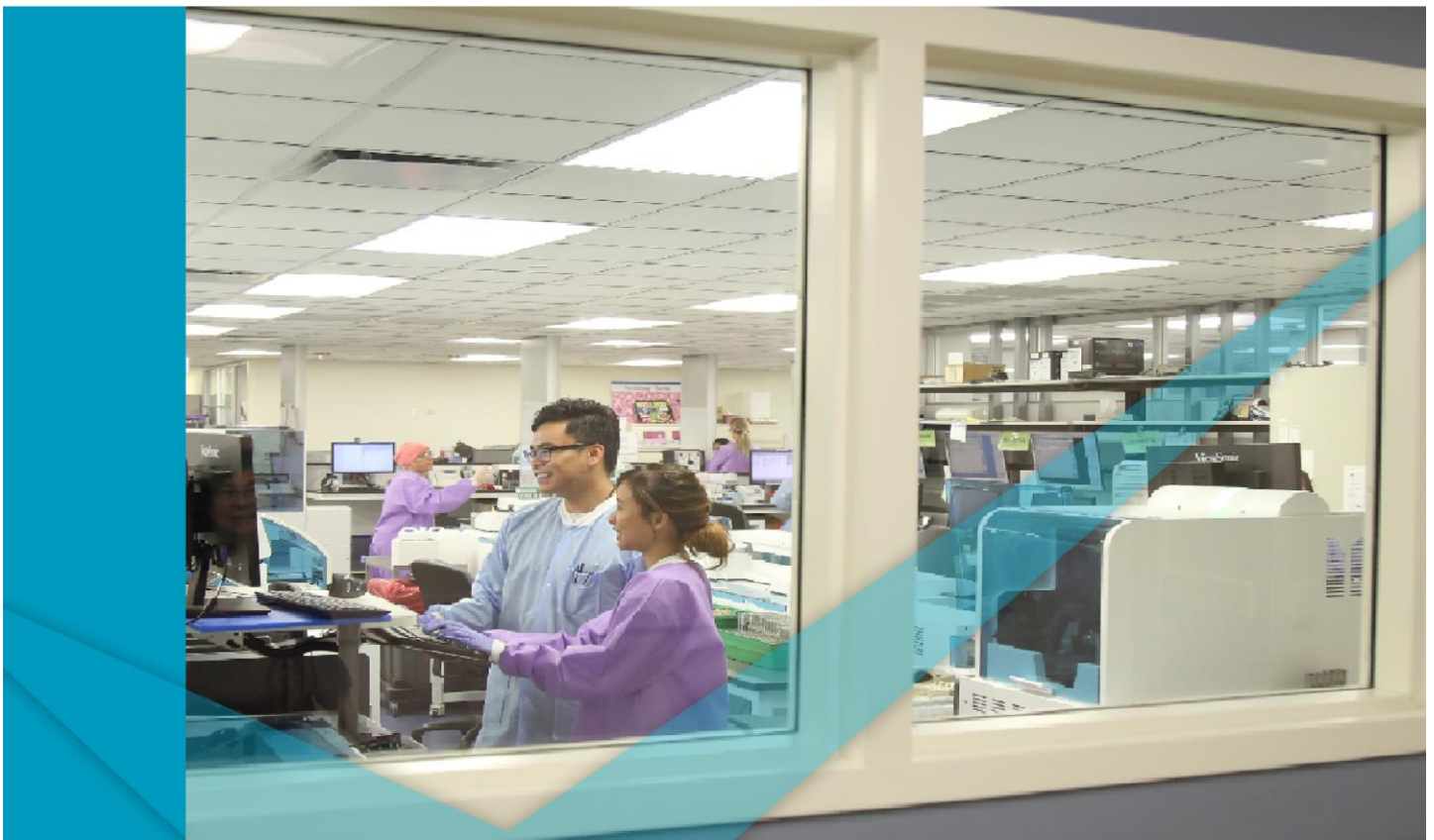




COLLEGE of AMERICAN
PATHOLOGISTS
Laboratory Quality Solutions

Guide to CAP Accreditation



ACCREDITATION PROGRAMS

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LABORATORY ACCREDITATION AND THE COLLEGE OF AMERICAN PATHOLOGISTS

About the CAP Laboratory Accreditation Program

The CAP's internationally recognized accreditation programs offer the most respected choice to achieve accreditation and maintain regulatory compliance.

The programs are built on a unique, reciprocal, peer-based inspection method that benefits both the laboratories being inspected and the laboratories providing the inspection teams.

The accreditation programs guide laboratories to achieve the highest standard of excellence in patient care.

The requirements for accreditation are based on more than fifty years of insight and pathology expertise. The requirements comprise documents known as Checklists and are updated annually to reflect current practices and technologies. The Checklists are used by the laboratory to prepare for inspections and by the inspection team as a guide to assess the overall quality of the laboratory and the compliance with CAP Checklist requirements.

What to expect by participating in the CAP Laboratory Accreditation Program?

An on-site laboratory inspection occurs every two years. In the years when an on-site inspection does not occur, the laboratory performs a self-inspection using materials provided by the CAP.

Prior to an on-site inspection, the laboratory is provided with a customized checklists based on the laboratory's testing menu. The inspection team will use the same customized checklists during the on-site inspection.

Following the completion of an inspection, the inspector will provide the summary of inspection findings with the laboratory staff. The laboratory has 30 days to submit responses to identified deficiencies to the CAP. After successfully meeting all the requirements, the laboratory is awarded a "CAP Laboratory Accreditation" certificate and becomes part of an exclusive group of more than 8,000 laboratories worldwide that have met the highest standards of excellence.

TEN STEPS TO CAP LABORATORY ACCREDITATION

<p>1 Request Application</p>	<ul style="list-style-type: none"> ▪ Fill out and submit the Request for Application* form at cap.org. <p><i>*Note for International laboratories: you must be enrolled in CAP Proficiency Testing (PT)/External Quality Assurance (EQA) for a minimum of six months before requesting an application.</i></p>
<p>2 Review Welcome Kit</p>	<ul style="list-style-type: none"> ▪ Check your email to access the link to the online application (look for “CAP Accreditation Application Available” in the email subject line). ▪ Review additional information enclosed with the application link on how to get started with the accreditation process. ▪ Schedule an optional onboarding call with CAP staff who will guide you through the next steps in the accreditation process and answer questions.
<p>3 Complete Application</p>	<ul style="list-style-type: none"> ▪ Complete the accreditation application within 3 months from the day it becomes available online. ▪ Review the due date on the homepage after you log in. ▪ Monitor email reminders that the CAP will send out as the application due date approaches. ▪ Work with the CAP staff for any follow-up questions during application review.
<p>4 Receive Customized Checklists</p>	<ul style="list-style-type: none"> ▪ Receive customized checklists by mail and begin inspection preparation and/or ▪ Download customized checklists online by logging into your account if you prefer electronic checklists.
<p>5 Schedule Inspection Date</p>	<ul style="list-style-type: none"> ▪ Look for a letter in the mail (sent to the accreditation contact from your laboratory) announcing the inspection team leader’s name and the organization. ▪ Schedule** the inspection date with the inspection team leader (the team leader will contact the laboratory director to set the inspection date). ▪ Prepare for the initial on-site inspection that will take place within 6 months after the submission of online application. <p><i>**Note: After the first on-site inspection, all recurring inspections for the Laboratory Accreditation Program are unannounced.</i></p> <p><i>For international laboratories and specialty accreditation programs, subsequent inspections are announced.</i></p> <p><i>All inspections are performed within the 90-day period preceding the anniversary date.</i></p>
<p>6 Host Inspection Day</p>	<ul style="list-style-type: none"> ▪ Expect the arrival of the inspection team who will conduct the inspection with the same customized checklists that you received earlier. ▪ [Support the inspection team as needed or requested.] ▪ Receive a copy of the summary report from the inspection team leader (given to the laboratory director) during the summation conference.

<p>7 Respond to Deficiencies Within 30 Days</p>	<ul style="list-style-type: none"> ▪ Review the instructions for responding to deficiencies left by the inspection team. ▪ Send all deficiency responses at the same time. ▪ Submit all responses within 30 calendar days after the inspection date.
<p>8 Support CAP Review of Responses</p>	<ul style="list-style-type: none"> ▪ Collaborate with the CAP technical specialist for any follow-up questions regarding submitted responses. ▪ Look for an emailed letter from the technical specialist requesting additional documentation that may be needed to complete the review of deficiency responses. ▪ Anticipate accreditation decision within 75 days of the inspection date.
<p>9 Receive Certificate of Accreditation</p>	<ul style="list-style-type: none"> ▪ Look for the laboratory's Certificate of Accreditation by mail, to the attention of the laboratory director. ▪ Mark your calendar with the initial inspection date, which becomes the laboratory's anniversary date.
<p>10 Perform Self-Inspection and Maintain Continuous Compliance</p>	<ul style="list-style-type: none"> ▪ Receive materials from the CAP and conduct a self-inspection on the laboratory's anniversary date. ▪ Make changes in laboratory directorship, location, name/ownership, test menu, roles and personnel by logging into e-Lab Solutions Suite at any time. ▪ Enroll in or discontinue PT/EQA products when the test menu changes, if needed, by contacting the CAP Customer Contact Center or visiting our online store. ▪ Note that accreditation cycle repeats every two years starting with Step 3 on the laboratory's anniversary date.

THINGS TO KNOW FOR CAP LABORATORY ACCREDITATION

Eligibility	The laboratory must have a qualified laboratory director, successfully participate in the appropriate proficiency testing/external quality assurance, and be performing patient testing.
Director Qualifications	The CAP requires specific qualifications for the laboratory director, the person responsible for operation of the laboratory. Qualifications of the director may differ based on the type and complexity of the testing performed. A laboratory director must have an MD, DO, DPM, PhD, or must have commensurate education and experience necessary to meet personnel requirements as determined by the CAP.
Laboratory Personnel Qualifications	<p>CAP requires that all high complexity testing personnel have earned at least a minimum of an associate degree in a laboratory science or medical technology from an accredited institution. Personnel performing moderately complex testing must have earned a high school diploma or equivalent.</p> <p>The laboratory must retain documentation that all testing personnel have satisfactorily completed initial training on all instruments/methods applicable to their designated job.</p>
Proficiency Testing (PT)/External Quality Assurance (EQA)	<p>Proficiency Testing (PT)/External Quality Assurance (EQA) is an interlaboratory peer program that compares a laboratory's test results using unknown specimens to results from other laboratories using the same or similar methods. Laboratories subject to US regulations must enroll and participate in a CAP-accepted PT program for all required analytes (see the Master Activity Menu to determine which analytes require enrollment in PT).</p> <p>For international laboratories, the laboratory must enroll in all available CAP PT/EQA a minimum of six months prior to requesting CAP application.</p> <p>This time frame enables the international laboratory to become familiar with the requirements necessary to obtain permits and any other documents needed to receive PT/EQA shipments.</p>
Key Components	<p>To meet CAP Laboratory Accreditation requirements, the laboratory must have the following key documents/processes:</p> <ul style="list-style-type: none">• Quality Management Program• Chemical Hygiene Plan• Document Control Process• Competency Assessment Program• Test Method Validation Documentation• Laboratory Director Oversight Documentation• Laboratory Information System (LIS) – if applicable

Additional Resources

The following products and documents are available from the CAP to assist laboratories in the process of preparing for accreditation *as part of the non-refundable accreditation application fee*:

- Audioconferences/Webinars
- Online Inspector Training
- CAP Accreditation Checklists
- Laboratory Accreditation Manual
- PT Toolbox
- Standards for Laboratory Accreditation*
- CAP Accreditation Resources Library

**The following items are available for an additional fee:*

- CAP Accreditation Readiness Assessment (CARA)
- Online Competency Assessment Program
- Q-Probes and Q-Tracks

Cost of Accreditation

Annual accreditation fees are based on the institution's laboratory sections, list of testing performed (activity menu), organization structure and complexity.

To receive an estimate of annual accreditation fees, complete and return the Accreditation Fee Estimate Form available at cap.org.

International laboratories are required to pay for roundtrip, business-class airfare for intercontinental travel by inspector(s). The number of inspectors sent will be based on the volume and/or testing type in the laboratory. The CAP will pay for all hotel accommodations, meals, ground transportation and in-country air travel. Inspections typically occur once every two years.

Please note that accreditation fees do not include the cost of proficiency testing/external quality assurance.

APPLICATION PROCESS

Overview	The application process involves two steps: 1) Request for application; and 2) Completion of the online Organizational Profile and application by logging into e-LAB Solutions Suite on cap.org
Request for Application	<p>Download the Accreditation Request for Application form at cap.org.</p> <ul style="list-style-type: none">• Complete the form• Submit via email, mail or fax (information provided on form)• Include the one time, nonrefundable application fee<ul style="list-style-type: none">- Credit card- Wire transfer- Check
What's Next?	After the Request for Application is processed by the CAP, the laboratory will receive an email notification with instructions for accessing the online Organization Profile through the CAP's online resource (e-LAB Solutions Suite).
Online Application	<p>Once all tasks are completed in the laboratory's Organization Profile, click on the "application complete" button.</p> <p>For assistance, contact the Customer Contact Center at 001-847-832-7000 or email accreditationonline@cap.org.</p> <p>The applications must be completed within three months of receipt by the laboratory.</p>

DIRECTOR RESPONSIBILITIES

What are the Director's Responsibilities?

The director of a CAP-accredited laboratory is responsible for ensuring ongoing compliance with the Standards for Laboratory Accreditation and implementing the requirements of the accreditation checklists. The director must have the qualifications and authority to fulfill these responsibilities effectively.

Key Components

An effective director ensures:

- The following components are defined, implemented, and monitored:
 - An effective quality management program.
 - An adequate number of appropriately trained and qualified personnel.
 - A safe laboratory environment.
- Availability of consultations for ordering appropriate tests and the interpretation of laboratory findings of medical significance.
- Anatomic pathology services are provided by a qualified anatomic pathologist.
- The ability to function effectively with applicable accrediting and regulatory agencies, the medical community, patients, and administrative officials.
- Educational programs, strategic planning, research, and development appropriate for the laboratory and institution. If delegating activities to others, documentation specifying which individuals are authorized to act on his/her behalf.
- If not present full-time, a written agreement defining the frequency of, and responsibilities for, on-site visits. Activities performed during visits must be documented.

Who Is Responsible?

The director of a CAP-accredited laboratory is responsible for ensuring ongoing compliance with the Standards for Laboratory Accreditation and implementing the requirements of the accreditation checklists.

Outcome of an Effective Director

Laboratory benefits include:

1. A culture committed to continuous improvement.
2. An involved director who serves as a mentor and promotes a culture of quality.
3. A safe environment.
4. Ongoing compliance with the CAP requirements.
5. A testing environment always prepared for an inspection.

LABORATORY DIRECTOR QUALIFICATIONS

Laboratories subject to US regulations	
High Complexity Testing	<ol style="list-style-type: none"> 1. MD, DO, or DPM licensed to practice (if required) in the jurisdiction where the laboratory is located, and have one of the following: <ul style="list-style-type: none"> - Certification in anatomic or clinical pathology, or both, by the American Board of Pathology or American Osteopathic Board of Pathology, or possess qualifications equivalent to those required for certification; or - Have at least one year of laboratory training during residency/fellowship; or - Have at least two years of experience supervising high complexity testing; <p style="text-align: center;">OR</p> <ol style="list-style-type: none"> 2. Doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution, and have current certification by a board approved by HHS**
Moderate Complexity Testing	<ol style="list-style-type: none"> 1. Qualified as in (1) above <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> - MD, DO, or DPM, licensed to practice in the jurisdiction where the laboratory is located (if required) and have one of the following: <ul style="list-style-type: none"> - At least 20 hours of continuing medical education credit hours in laboratory medicine; or - Equivalent training during medical residency/fellowship; or - At least one year of experience supervising non-waived laboratory testing <ol style="list-style-type: none"> 2. OR 3. Doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution with one of the following: <ul style="list-style-type: none"> - At least one year of experience supervising non-waived laboratory testing; or - Certified by a board approved by HHS**
Provider Performed Microscopy Testing	<ol style="list-style-type: none"> 1. MD or DO, or DPM, licensed to practice in the jurisdiction in which the laboratory is located, if required
Waived Testing	<ol style="list-style-type: none"> 1. MD or DO, or DPM, licensed to practice in the jurisdiction in which the laboratory is located, if required OR 2. Doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution
Laboratories not subject to US regulations	
All Testing Complexities	<ol style="list-style-type: none"> 1. MD, DO, PhD or have commensurate education and experience necessary to meet personnel requirements as determined by the CAP

Notes:

- i. For laboratories subject to US regulations, additional qualifications for grandfathered individuals and for the subspecialty of oral pathology may be found in the CLIA regulation 42CFR493.1443(b)(6).
- ii. Qualifications for histocompatibility laboratory directors, including continuing clinical laboratory education requirements, can be found in the Histocompatibility Checklist.
- iii. For laboratories participating in the Reproductive Laboratory Accreditation Program, directors of laboratories performing andrology testing must meet the requirements described above for high complexity testing and have at least two years of experience in a laboratory performing andrology procedures. This experience must include quality management, quality control, inspection, accreditation, and licensing procedures, as well as andrology procedures. Requirements for embryology laboratory directors are found in the Reproductive Laboratory Checklist in RLM.10166.
- iv. For laboratories participating in the Forensic Drug Testing Accreditation Program, specific requirements for laboratory director/scientific director are in the Forensic Drug Testing Checklist.
- v. **A list of boards approved by CMS for doctoral scientists may be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certification_Boards_Laboratory_Directors.html

DOCUMENT CONTROL SYSTEM

What Is Document Control?

Document control is the management of all paper or electronic documents, including policies, procedures, and forms. A written document control system outlines how all documents are initiated or revised, approved, utilized, reviewed, retained, and discontinued.

Every document within the laboratory must be:

- Current – have up-to-date review and reflect current practices.
- Accurate – only authorized revisions are made to documents, substantial revisions are reviewed and approved before implementation, and revisions are reflected on all copies of documents.
- Available – readily accessible to all staff utilizing them.

Key Components

A laboratory's document control system must ensure:

- All copies of policies, procedures, and forms are current.
- Personnel have read the policies and procedures relevant to their job activities.
- Personnel are knowledgeable about the contents of procedure manuals (including changes) and demonstrate proficiency relevant to the scope of their testing activities.
- All policies and procedures have been authorized by the laboratory director before implementation.
- Policies and procedures are reviewed at least every two years by the laboratory director or designee.
- Discontinued policies and procedures are quarantined in a separate file for a minimum of two years from the date of discontinuation (five years for transfusion medicine).

Who Is Responsible?

The laboratory director who meets CAP director qualifications is responsible for implementing and maintaining an effective document control program.

Outcome of an Effective System

The laboratory will benefit by:

- Ensuring on any given day practice matches policies and procedures.
- Promoting the use of only approved policies, procedures, and forms.
- Organizing procedures for ease of accessibility by testing personnel.
- Tracking the status of approvals and reviews to ensure they occur in a timely manner in accordance with CAP requirements.
- Maintaining ongoing compliance with CAP requirements.

CHEMICAL HYGIENE PLAN

What Is A Chemical Hygiene Plan?

A Chemical Hygiene Plan (CHP) includes procedures to protect employees from the health hazards of chemicals and keep exposures below specified limits. All personnel involved in the laboratory must receive training on the CHP and understand how it applies to their role.

Key Components

An effective CHP includes:

- Defined laboratory director responsibilities and the designation of a chemical hygiene officer.
- Safety data sheets (SDS) for all hazardous chemicals used in the facility. The SDS must be accessible for review by all laboratory employees during every work shift.
- A training program on interpreting chemical labels and SDS, and the use of proper protection for chemical handling and disposal.
- Proper labeling on all chemical containers.
- Informing all laboratory employees of the right to know the hazards associated with their job.
- Evaluation of every chemical used in the laboratory for carcinogenic potential, reproductive toxicity, and acute toxicity.
- Annual review of the effectiveness of the CHP to include review of all incidents and occurrences of the past year.

Who Is Responsible?

The laboratory director is responsible for the CHP.

Outcome of an Effective System

The laboratory will benefit by:

- Increased employee safety and awareness.
- Reduction in laboratory accidents and improved spill responses.
- Safe and efficient organization for chemical storage.
- Ongoing compliance with CAP requirements.

LABORATORY INFORMATION SYSTEMS

What Is A Laboratory Information System? Laboratory information systems (LIS) provide a database serving the information needs of the laboratory by linking patient test results to the ordering clinician/client, and to the patient's medical record.

Overview Multiple LIS are available, including:

- Systems with a local host database (computer hardware and software on site) where the laboratory is the only user.
- Systems with a host physically removed from the laboratory, where multiple user laboratories may share the same database.

The Laboratory Accreditation Program does not consider the following types of devices as LIS:

- Small programmable technical computers or dedicated microprocessors that are an integral part of an analytic instrument.
- Purchased software services used for quality assurance and data analysis.
- Microcomputers used for word processing, spreadsheets, or other similar single-user functions.

Key Components The laboratory must provide the following:

- Computer facility and equipment with appropriate environmental controls and safety elements.
- Written LIS policies and procedures with instructions for daily operations appropriate to the level of use.
- Software validation for new installation and software updates, including staff training.
- System security policies and practices for user authorization confidentiality of patient data and protection against unauthorized alterations.
- Error detection and timely communication of patient data to the ordering clinician/client.
- Auto-verification is a process where the laboratory information system has defined parameters that allow results to flow from an interfaced instrument to the medical record without technical intervention or review. Defined system logic prevents the release of test results not meeting the defined parameters or criteria.
- Accurate transmission of data across instrument interfaces and interfaces with other computer systems (e.g., middleware, hospital information systems, and other output devices).
- Data retrieval and preservation for the required regulatory retention period available, within a time frame consistent with patient care needs.

Who Is Responsible? The laboratory director is responsible for ensuring communication of laboratory data.

The director may delegate some LIS-related functions to others and is responsible for determining the qualifications of these individuals. It is the director's overall responsibility to ensure these functions are properly carried out.

Outcome of an Effective System

The laboratory benefits include:

- Accurate and timely transmission of patient data.
- Effective presentation of patient data.
- Retention and retrieval of patient data consistent with regulatory requirements.
- Improved efficiency and productivity in the laboratory.
- Ongoing compliance with CAP requirements.

TEST METHOD VALIDATION

What Is Test Method Validation? Test method validation verifies or establishes test method performance specifications. These include analytic accuracy, precision, sensitivity, interferences (specificity), reportable range, and reference intervals (normal values), as applicable.

Overview The test method validation process must include:

- Written procedures describing the validation process for new instruments and methods.
- Documentation of data collected in the testing environment where the method will be implemented.
- Data obtained from studies performed by the manufacturer and from published literature, as applicable.
- Summary statement documenting approval of the validation studies by the laboratory director or qualified designee prior to initiation of patient testing.

Key Components

- The type of method validation required is dependent on the type of testing as defined by the CAP.
- Unmodified Commercial Assays requires verification of manufacturer claims for each aspect listed below, as applicable:
 - Analytic accuracy – closeness of agreement between a test result and an accepted reference value.
 - Analytic precision – reproducibility of a test result.
 - Analytic interferences– ability of an analytic method to detect only the analyte it was designed to measure.
 - Reportable range – interval of test results that the laboratory can establish or verify accuracy.
 - Reference intervals – range of test values expected for a designated population.
 - All other characteristics required for test performance.
- Laboratory-developed tests and modified commercial assays requires the laboratory to establish all aspects listed above, as applicable. Additionally, analytic sensitivity, specificity and clinical claims must be validated.

Who Is Responsible? The laboratory director or designee who meets CAP director qualifications is responsible for ensuring each method performed is of sufficient scope and scientifically valid. The director or designee documents final approval of the validation prior to the initiation of patient testing.

Outcome of an Effective System The laboratory benefits include:

- Organized and clear evidence of method validation.
- Accurate patient test results when the new method is implemented.
- Ongoing compliance with CAP requirements.

COMPETENCY ASSESSMENT PROGRAM

What Is Competency Assessment? A competency assessment program appraises an individual's knowledge and mastery of skills needed to properly perform a specific job.

Key Components

Six Elements of Competency Assessment

- Direct observations of test performance.
- Monitoring of test result reporting.
- Review of quality control records, proficiency testing results, and preventive maintenance records.
- Direct observation of instrument maintenance and function checks.
- Assessment of test performance by external proficiency testing or internal blind testing samples.
- Evaluation of problem-solving skills.

System Components A laboratory must have a process ensuring:

- Employees' competency assessments are completed semiannually for the first year of patient testing, and annually thereafter.
- All test systems are defined.
- All six elements of competency assessment for each test system are addressed.
- Records of employee competencies

Who Is Responsible? The laboratory director is responsible for implementing and maintaining an effective competency assessment program.

Outcome of an Effective System

The laboratory will benefit by:

- Organizing and scheduling staff competencies for all testing personnel in a manner that assures annual completion. For employees in their first year of patient testing, competency must be assessed semiannually.
- Incorporating the six required elements into routine review processes conducted throughout the year.
- Ensuring employees are performing and documenting laboratory tests and associated functions according to the laboratory procedures.
- Retraining and reassessing if performance problems are identified
- Maintaining ongoing compliance with CAP requirements.

QUALITY MANAGEMENT PROGRAM

What Is Quality Management?	A dynamic quality management program (QMP) enhances any and all activities that impact patient care, promoting quality and patient safety through risk reductions and continuous improvement.
Overview	<p>A laboratory must have a written and implemented QMP plan specific to the laboratory that includes:</p> <ul style="list-style-type: none">▪ All disciplines of the laboratory.▪ All inherent processes, including quality control, assurance, and improvement, operating on a continuous basis to provide quality patient care.
Key Components	<p>A QMP requires:</p> <ul style="list-style-type: none">▪ A system for monitoring processes which must include:<ul style="list-style-type: none">- A set of metrics or key indicators for preanalytic, analytic, postanalytic phases of testing and patient safety. For each key indicator, the laboratory must specify:<ul style="list-style-type: none">• Criteria of acceptance• Data collection, analysis, and evaluation• Frequency of review- Annual evaluation of effectiveness- Measurement of patient and/or physician satisfaction.- A documented quality control system and evidence quality control has been reviewed.- Internal and external communication of quality management outcomes.▪ A process improvement system, which must include:<ul style="list-style-type: none">- Review of errors, complaints, and incidents.- Identification and implementation of corrective action.▪ An infrastructure for the quality management system, including aspects such as a document control system.
Who Is Responsible?	<p>The laboratory director is responsible for the implementation of the QMP with assistance and involvement from the:</p> <ul style="list-style-type: none">▪ Manager▪ Supervisor▪ Laboratory staff▪ Non-laboratory staff (e.g., hospital quality assurance coordinator or safety and regulatory personnel)
Outcome of an Effective System	<p>The laboratory benefits include:</p> <ul style="list-style-type: none">▪ Continually ensuring that practice matches policies and procedures.▪ Providing opportunities for quality improvement.▪ Improving patient and/or clinician satisfaction.▪ Maintaining ongoing compliance with CAP requirements.