



COLLEGE of AMERICAN
PATHOLOGISTS
Laboratory Quality Solutions

Laboratory Accreditation Manual



PATIENT SAFETY
COMPLIANCE
CONSISTENCY
CONFIDENCE
ACCURACY
QUALITY

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Editor

Contacting the CAP Accreditation Programs

Laboratories may contact the LAP with questions on accreditation-related topics by:

- **Email:** accred@cap.org.
- **Phone:** **800-323-4040 or 847-832-7000**. CAP Accreditation business hours are 7:00 AM–5:30 PM Central Time, Monday through Friday, excluding holidays.
- **Mail:**

CAP Accreditation Programs
College of American Pathologists
325 Waukegan Road
Northfield, IL 60093
- **Chat:** via CAP.ORG for simple questions. Chat hours are 9:00 AM-4:30 PM Central Time, Monday through Friday, excluding holidays.

For specific accreditation topics, laboratories can submit questions to accred@cap.org or contact the CAP accreditation staff by phone (800-323-4040 or 847-832-7000) at the extensions listed below.

Topic	Extension
<ul style="list-style-type: none"> • Interpretation of checklist items • Responding to deficiencies • Technical review of deficiencies 	6065
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ACCREDITATION RESOURCES

CAP accredited laboratories have access to additional checklist accreditation tools and resources found on the CAP website (cap.org) by logging into **e-LAB Solutions Suite - Accreditation Resources**. Content found in Accreditation Resources includes:

- A library of past Focus on Compliance webinars and laboratory inspection preparation videos
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification, quality management)
- Proficiency testing (PT) frequently asked questions, forms, and troubleshooting guides
- IQCP eligibility, frequently asked questions, forms, templates, and examples
- Laboratory director education and resources
- Quality management resources
- Inspector training and inspection tip sheets
- Self and post inspection toolbox

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INTRODUCTION

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Purpose of this Manual

The Laboratory Accreditation Manual provides laboratories and inspectors with a basic overview of the CAP's accreditation programs and accreditation processes.

Overview of Accreditation Programs

The College of American Pathologists accreditation programs provide an engaging, dynamic, and collaborative process that fosters an environment of continuous improvement. A description of each of these programs is included in the [Accreditation Program Types](#) section.

The accreditation programs were created with the primary objective of improving the quality of clinical laboratory services through voluntary participation, professional peer review, year-round education, and compliance with established performance standards. Since their creation, these programs have become widely acknowledged for excellence. In total, the CAP accredits more than 8,000 laboratories worldwide with more than 600 outside the US in 60 countries.

The accreditation programs are based on rigorous standards translated into detailed checklist requirements that provide a clear roadmap to demonstrate compliance, achieve accreditation, and run a high-quality laboratory. CAP inspection teams use the checklists as a guide to assess the laboratory's overall management and operation. Inspectors examine the preanalytic, analytic, and postanalytic aspects of quality management (QM), such as:

- General quality control (QC) performance and monitoring
- Test methodologies and specifications
- Reagents, controls, and media
- Equipment
- Specimen handling
- Test reporting
- Internal performance assessment
- External proficiency testing.

In addition, personnel requirements, safety, document management, and other administrative practices are evaluated in the inspection process.

The programs are internationally recognized and are the only ones that utilize teams of practicing laboratory professionals as inspectors for all laboratory disciplines. Designed to go beyond regulatory compliance, the programs help laboratories use best practices while achieving the highest standards of excellence to positively impact patient care.

CAP Accreditation Program Organization

Following the CAP vision and the CAP Board of Governors, the Council on Accreditation (CoA) sets the strategic direction for the CAP accreditation programs. The CoA establishes CAP policy and monitors overall program effectiveness in ensuring that participating laboratories meet regulatory and CAP requirements. The CoA is responsible for the following:

- Advancement of the CAP's accreditation programs as the prime exemplar for the inspection and accreditation of clinical laboratories and biorepositories
- Administration of the programs through the principles of peer review and education
- Furthering the goal of laboratory improvement to ensure that quality laboratory services are provided to patients and clients
- Continuation of the programs' ability to meet the scientific, service, and regulatory needs of participants
- Overseeing the activities of the programs' regional and state commissioners
- Recognition of the pathologist laboratory director's role in clinical decision making and consultation.

To fulfill these roles, the CoA oversees and coordinates the activities of nine accreditation program committees to align priorities and activities with the overall goals and strategies supporting the CAP's accreditation programs. The CoA uses the expertise of more than 30 CAP scientific committees to keep the programs and their requirements up to date with the latest best practices as new advances and technology become part of the modern laboratory workflow. These committees are composed of volunteer CAP member experts, assisted, and coordinated by CAP staff.

The nine accreditation program committees are:

- **Accreditation Committee:** responsible for ensuring objectivity and consistency in CAP accreditation decisions and accreditation status decisions, including accreditation suspension and probation, based on recommendations from reviewing commissioners, technical specialists, and other CAP committees.
- **Accreditation Education Committee:** oversees the continual development and implementation of all educational activities that support the CAP accreditation programs.
- **Biorepository Accreditation Program Committee:** promotes high standards for the procurement, processing, storage, and distribution of biospecimens that align with quality best practices in the biorepository field to support scientific research.

- **CAP ISO 15189:** charged with ensuring objectivity and consistency in CAP ISO 15189 accreditation decision making and overseeing the development of supporting guidance documents and quality management system education and tools.
- **Checklists Committee:** ensures that the accreditation requirements of the CAP accreditation programs are a practical tool to promote high standards in pathology and laboratory medicine and are equal to or exceed regulatory requirements.
- **Complaints and Investigations Committee:** oversees and adjudicates complaints, investigations, and validation inspections.
- **Continuous Compliance Committee:** ensures that accredited laboratories maintain continuous compliance with CAP and other regulatory requirements through oversight and education of proficiency testing (PT) and other mandated quality activities.
- **Inspection Process Committee:** oversees pre-inspection and inspection processes to improve the timeliness and quality of inspections.
- **International Accreditation Committee:** oversees the development, support, and growth of the accreditation programs outside of the United States.

Commissioners

Regional commissioners are responsible for the accreditation activities of a specified group of laboratories, which may include the timely assignment of inspectors, review of inspection findings, and presentation of accreditation issues to the Accreditation Committee. Following an inspection (in-person or virtual), the regional commissioner and CAP technical staff review the inspection findings and the laboratory's corrective action and contribute to any follow-up necessary to reach an accreditation decision.

State and deputy state commissioners assist the regional commissioners. These individuals are responsible for validating proposed inspector matches for the laboratories in their geographic regions. They are assisted by CAP staff to ensure inspections are timely and adhere to accreditation program policy. They are also responsible for providing feedback and mentoring to volunteer inspectors.

Inspectors and CAP Staff

CAP inspection teams are trained, practicing laboratory professionals who manage the same workflows and undergo the same challenges that all inspected laboratories encounter. The inspection team leader is typically a board-certified pathologist who has received training and has participated in several inspections as a team member. The inspection team comprises pathologists, doctoral scientists, supervisory-level medical technologists, pathology residents and fellows, and others who have been trained in CAP inspection requirements and have expertise in the laboratory section they inspect.

The CAP accreditation program staff at the CAP headquarters in Northfield, Illinois, comprises technical and administrative personnel who carry out the CoA's policies and procedures and are responsible for the management and operation of the program. They also include a limited number of full-time inspectors who conduct inspections meeting defined criteria.

Accreditation Documents

In addition to the Laboratory Accreditation Manual (LAM), three other documents are fundamental to the inspection process:

- 1) *Standards for Laboratory Accreditation* (the *Standards*)
- 2) *Accreditation Checklists*
- 3) Inspector's Summation Report (ISR).

Through peer review, the inspector uses the checklists to determine if the laboratory meets the criteria set out in the *Standards*. The inspector collects and records information on the ISR, which is the basis for the regional commissioner's accreditation recommendation. In addition to verifying compliance with accreditation requirements, the inspection team typically shares ideas for laboratory improvement. In return, the inspection team members often take new ideas or processes back to their own laboratories.

Standards for CAP Accreditation Programs

The *Standards* constitute the core principles of the CAP's accreditation programs. The objective of the *Standards* is to ensure that accredited laboratories meet the needs of patients, physicians, and other health care practitioners. The CAP accredits laboratories that conform to the *Standards*. Each of the accreditation programs has its own *Standards for Accreditation*. The CAP Board of Governors approves these standards, which have evolved through years of study and continuous review by the CoA. The inspector must be familiar with each standard and its interpretation. A copy of the *Standards* is included with each inspection packet and must be reviewed before the inspection of the laboratory. The inspection team leader is considered the authority for interpreting these standards.

Standard I identifies the **laboratory director's** qualifications, responsibilities, and role. It discusses which duties may be delegated and the role of a consulting pathologist.

Standard II addresses the **physical resources of the laboratory**, including space and instrumentation; furnishings; communication and data processing systems; reagents and other supplies; ventilation; piped gases and water; public utilities; storage and waste disposal; and protection of patients, laboratory personnel, and visitors from hazardous conditions.

Standard III encompasses **quality management**. This includes discussions of test system validations, QC of preanalytic, analytic and postanalytic processes, proficiency testing (or periodic alternative assessments of laboratory test performance), and ongoing performance improvement.

Standard IV includes the **administrative requirements** of the program. Laboratories must comply with the requirements specified in the *Standards*, the terms of accreditation, and the accreditation checklists. Inspection by a CAP-provided team and an interim self-inspection are the cornerstones of the inspection requirement. Participating laboratories also field an inspection team when requested.

Accreditation Checklists

Each checklist is a detailed list of requirements that the inspector uses to determine if the laboratory meets the *Standards*. Each requirement is uniquely numbered and centers on a declarative statement. Checklists serve as instruments to guide the conduct of the inspection. Checklists are revised annually and customized for each laboratory based on its testing menu. All CAP checklists minimally meet the CLIA regulations and are approved by the CMS on an annual basis. Detailed information on the checklists is included in the [Accreditation Checklists](#) section and [Appendix A: Accreditation Checklists Overview](#).

ACCREDITATION PROGRAM TYPES

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Utilizing a unique peer-inspection model, annual checklist updates, and year-round education, the CAP's accreditation programs cover the entire spectrum of laboratory disciplines.

The CAP's accreditation programs offer:

- A blueprint for operating a high-quality facility
- Confidence in the accuracy of clinical reports
- Improved risk management
- Access to best practices
- The right to display the CAP Accreditation Mark.

Five unique programs, specifically tailored to the type of laboratory or facility, are available.

Laboratory Accreditation Program

The Laboratory Accreditation Program (LAP) was established in 1961. The current range of laboratory disciplines includes:

- Anatomic Pathology
- Chemistry and Toxicology
- Clinical Biochemical Genetics
- Cytogenetics
- Cytopathology
- Flow Cytometry
- Hematology
- Histocompatibility
- Immunology
- Microbiology
- Molecular Pathology
- Point-of Care Testing
- Transfusion Medicine
- Urinalysis.

The LAP accredits a wide variety of laboratories in different settings, such as community hospitals, university-based hospitals, out-patient clinics, and reference laboratories. The program uses a two-year accreditation cycle where laboratories have an inspection every two years by an inspection team made up of practicing professionals.

The CAP's comprehensive program incorporates all of the required standards from CLIA, US Food and Drug Administration (FDA) and the US Occupational Safety and Health Administration (OSHA). Our program will exceed the standards where doing so materially adds to patient care and safety. The CAP retains deemed status with the US Centers for Medicare & Medicaid (CMS), The Joint Commission, the United Network for Organ Sharing (UNOS), the National Marrow Donor Program (NMDP), the Foundation for the Accreditation of Cellular Therapy (FACT), and many other US agencies.

Eligibility Requirements:

- The CAP accredits laboratories performing testing on clinical biological specimens using methodologies and clinical application within the expertise of the program. Laboratories must be appropriately licensed to perform testing when required by law.
- The LAP is available to both domestic and international laboratories. Information specific to international laboratories interested in laboratory accreditation is available in the [Accreditation Program Requirements for International Laboratories](#) section.

Laboratories that are part of a healthcare system with highly integrated laboratory services may be eligible for the System Inspection option. Refer to section [Applying for Accreditation](#) for more information.

Reproductive Laboratory Accreditation Program

The Reproductive Laboratory Accreditation program (RLAP) was originally designed in collaboration with the American Society of Reproductive Medicine (ASRM) in 1993. The services covered in the RLAP include:

- Andrology
- Limited clinical laboratory testing (eg, hormone assays, hematology, urinalysis)
- Embryology
- Cryopreservation
- Reproductive tissue storage

Laboratories in the RLAP have an inspection every two years by an inspection team made up of practicing professionals. They are inspected with the Reproductive Laboratory, Laboratory General, Director Assessment, and All Common Checklists. Other discipline-specific, checklists are added if the scope of clinical testing so warrants.

The RLAP accreditation may be used to demonstrate compliance with the CLIA '88 regulations for andrology and other tests regulated under CLIA. The CAP has been approved as an accrediting organization by the CMS and is recognized by The Joint Commission. In addition, the Society of Assisted Reproductive Technology (SART) recognizes RLAP accreditation to

meet membership requirements for in vitro fertilization facilities.

Eligibility Requirements:

- Laboratories that perform at least one embryology-related procedure or perform semen analysis for infertility and at least one additional high-complexity test are eligible for the RLAP.

Information specific to international laboratories interested in laboratory accreditation is available in the [Accreditation Program Requirements for International Laboratories](#) section.

Forensic Drug Testing Program

The Forensic Drug Testing Program (FDT) was designed for the unique needs of forensic drug testing laboratories for nonmedical purposes. This program is not intended for medical testing or CLIA compliance.

The program ensures confidence in the accuracy of forensic drug test results through evaluation of checklist requirements for sample integrity and security using robust chain-of-custody, annual validation of all methods, tight controls on test systems, and secondary review of all confirmatory test results.

Laboratories in FDT have an inspection every two years by an inspection team made up of practicing professionals. They are inspected with the Forensic Drug Testing, Laboratory General, Director Assessment, and All Common Checklists.

Eligibility Requirements:

- The FDT program is intended for laboratories that perform screening and confirmatory testing on urine, oral fluid, hair, nail, meconium, umbilical cord, and whole blood.
- The program also accepts laboratories that only screen the specimen types listed above by nonwaived methods. Confirmatory testing must be performed by a laboratory accredited by the CAP Forensic Drug Testing Program or one certified by the Substance Abuse and Mental Health Services Administration.

Information specific to international laboratories interested in laboratory accreditation is available in the [Accreditation Program Requirements for International Laboratories](#) section.

Biorepository Accreditation Program

The Biorepository Accreditation Program (BAP) is the world's first accreditation program designed specifically for biorepositories that collect, process, store and distribute biospecimens for research. The goal of the program is to provide requirements for standardization in biorepository processes that will result in high-quality specimens that can be used to support research, drug discovery, and personalized medicine.

Diagnostic patient testing must be performed within a CLIA licensed laboratory. In 2019, the CMS approved the CAP's biorepository checklist requirements as being consistent with CLIA regulations. Alignment of the checklists from the CAP's Biorepository Accreditation Program and Laboratory Accreditation Program help ensure:

- Confidence in specimen provenance – A clinical laboratory director may decide to accept specimens for testing from a BAP-accredited repository because of the formal CLIA-approved requirements in specimen collection integrity.
- Confidence in pre-analytic variable tracking and control for samples used in drug trials with associated biomarker development
- Improved alignment of accreditation preparation and inspection processes for repositories affiliated with CAP-accredited laboratories.

Services covered include biorepository specimen collection/procurement, specimen distribution and agreements, specimen informatics, specimen processing, and specimen storage.

Facilities in the BAP have an inspection every two years by an inspection team made up of practicing professionals. They are inspected with the Biorepository, Laboratory General, Director Assessment, and All Common checklists.

Eligibility Requirements:

- Applies to facilities that receive, store, process, and/or disseminate biospecimens, their derivatives, and relevant data for research purposes
- Not applicable to tissue storage for transplant purposes

CAP 15189™ Accreditation Program

Accreditation to the ISO 15189 standard strengthens the quality management system throughout the laboratory and all parts of the organization that interact with the laboratory, enabling process improvement, risk reduction, and improved operational efficiency.

CAP 15189 accreditation complements the universally recognized best-in-class standards and laboratory practices found in the CAP Laboratory Accreditation Program. It adds the process rigor and quality system scope of the ISO 15189 standard, allowing the CAP to probe deeper for system-related issues and vulnerabilities in laboratory operations.

The CAP 15189 Program accredits to the ISO 15189 standard for laboratories in the United States and Canada that have already demonstrated compliance to the CAP's core accreditation program (LAP). Recognizing that some accredited laboratories have core and branch laboratories located in other countries, we offer the CAP 15189 program to multi-national organizations who have standardized their practices across their global network to include both the core CAP accreditation program and to the ISO 15189 standard. The CAP has recently expanded to other markets where sufficient demand exists. Please contact the CAP at cap15189@cap.org for further information.

Laboratories in the CAP 15189 program have an on-site assessment every three years by experienced assessors that have practical knowledge of medical laboratory testing and ISO quality management systems auditing. The CAP program uniquely offers an assessment of the maturity of laboratory's quality management system, in addition to online education courses on quality management systems.

Eligibility Requirements:

- Accreditation to ISO 15189 through the CAP is available to US-based and Canadian medical laboratories.
- Laboratories applying to CAP 15189 must first be accredited by the CAP Laboratory Accreditation Program.

ACCREDITATION PROGRAM PHILOSOPHIES

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Peer Review

Purpose: To improve laboratory performance through objective evaluation and constructive feedback.

The inspector can enhance the spirit of peer review and the educational benefit of the inspection process by adhering to the following:

- As representatives of the CAP Accreditation Program(s), inspectors must strive to be objective and fair. There is often more than one way to comply with a requirement.
- The inspection team leader should be a peer of the laboratory director.
- Deficiencies should be presented factually, and recommendations for improvement may be provided when appropriate.
- A negative, unduly critical, or punitive attitude should be avoided.
- Deficiencies cited by the inspection team may be challenged. If resolution of a disagreement between laboratory personnel and an inspector cannot be achieved before or during the summation conference, the laboratory may challenge the deficiency during the post-inspection process. For more information, refer to the section [After the Inspection: Laboratory - Challenging a Deficiency](#).

Thoroughness

The CAP is approved by the Centers for Medicare and Medicaid Services (CMS) as an accrediting organization and must meet all federal regulatory requirements for those laboratories subject to US regulations. Participating laboratories expect a thorough, detailed, and fair inspection. All applicable items in a customized checklist must be inspected. As part of providing quality patient care, laboratories must be inspection-ready at all times. Laboratories

appreciate validation of the work they do and deserve a comprehensive inspection. A deficiency should not be overlooked because it seems minor.

Judgment

The CAP Accreditation Programs rely upon the inspector's judgment more than any other attribute in the assessment of a laboratory. This attribute is the most difficult to standardize. There will be occasions when a conscientious inspector will have difficulty deciding whether a laboratory is compliant with a checklist requirement. Many of these decisions involve assessment of partial compliance with a checklist requirement. Therefore, the inspector must describe the observations as completely as possible in the Inspector's Summation Report (ISR). This description should include details of the sampling performed to assess compliance with the requirement. For example, a description may include, "In the review of xx number of records for a specific expected result, the laboratory was found to be noncompliant with yy records." With this detailed information, the CAP can better assess the corrective action that the laboratory proposes.

Disputes

To help resolve questionable citations, the inspector and/or laboratory personnel may contact the CAP's accreditation technical staff by telephone during the inspection (800-323-4040 ext. 6065 or 847-832-7000). Following the inspection, if a laboratory wishes to challenge a particular citation, it must state its disagreement in the deficiency response and provide documentation to demonstrate how it was compliant before it was inspected. The regional commissioner will review disputed items and determine if the deficiency can be removed from the inspection record.

Harassment

Personnel at laboratories inspected by the CAP are entitled to a workplace environment that is free from sexual or other prohibited forms of harassment. Harassment includes any conduct (verbal or nonverbal, written or through media of any kind) that has the effect of interfering with work performance, or which creates an intimidating, disrespectful, degrading, hostile, or offensive environment. Also prohibited are behaviors that harass an individual based on race, ancestry, color, religious belief, gender, gender identity and/or expression, age, ethnic or national origin, immigration status or citizenry, political affiliation, sexual orientation or preference, transgender status, veteran status, physical or mental disability, genetic characteristics, pregnancy, childbirth, family or medical leave status, marital status, or any other legally protected status in accordance with federal, state, and local laws.

CAP inspection team leaders and team members must never display conduct that can reasonably be construed as harassment. Team leaders must ensure that the behavior of team members are consistent with this position and must intervene actively if inappropriate conduct is observed.

Laboratory personnel should report inappropriate conduct by CAP team leaders or team

members to CAP headquarters. The CAP does not tolerate harassment. In cases of documented harassment, the CAP will take appropriate action.

CAP inspectors should expect laboratory personnel to treat them with equivalent respect, free from unlawful harassment, and not create an adverse experience for the inspector. Inspection team members should also report any inappropriate conduct by the laboratory personnel to CAP headquarters.

Solicitation

Inspectors must not in any way solicit the institution, the laboratory, or its personnel for any purpose. They must never display conduct that can be reasonably construed as a solicitation. Inspectors should not request any information from the institution or laboratory regarding fees or other business-related matters. The inspector should not request any information regarding the laboratory director's contractual relationship with the institution's administration. However, when the laboratory director is present less than full-time, it is appropriate to ask about contractual agreements indirectly to ensure that the needs of the institution are met.

Confidentiality

All inspection findings are confidential and should not be discussed in any context other than the inspection itself. Moreover, inspection findings should not be disclosed to anyone not associated with the accreditation process unless appropriate prior documented consent has been obtained.

Confidentiality – HIPAA Privacy Rule and HITECH Act

Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the CAP is considered a "business associate" of any CAP-accredited laboratory that is designated a "covered entity" under HIPAA. The CAP is required, therefore, to enter into a Business Associate Agreement (BAA) with such a laboratory to protect the privacy and security of patient health information. The CAP has developed a standardized model BAA for its accredited laboratories to meet HIPAA, the privacy and security regulations promulgated thereunder, and Subtitle D of the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). The model BAA may be found on cap.org in e-LAB Solutions Suite under Organization Profile – Additional Information.

The CAP further protects the CAP-accredited laboratory by requiring all CAP inspectors to attest on the inspection report that they will keep all patient information confidential and use it only for purposes of the CAP inspection. Other CAP personnel or agents who may have access to protected health information are trained with regard to their obligation to keep this information confidential and to use such information only within the context of the inspection and accreditation services provided to the laboratory. In addition, the CAP requires that laboratories submit only documentation and other materials to the CAP that have been de-identified of all protected health information (PHI), as that term is defined in 45 CFR Parts 160 and 164, in accordance with HIPAA and its implementing regulations (see 45CFR164.514(b)) unless the laboratory must submit PHI to the CAP in order to respond to a deficiency or complaint

investigation.

Inspector Liability

The CAP bylaws include a provision that indemnifies volunteers, including inspectors, against liability and expenses, including attorney fees, incurred in connection with any legal action in which the individual is made a defendant by reason of the individual's good faith efforts on behalf of the CAP. Inspectors approached in this regard by a laboratory, patient, or an attorney regarding inspection activities should contact the CAP immediately to invoke this provision. Inspectors may not discuss any inspection findings with anyone outside the inspected laboratory or the CAP.

Conflict of Interest

Accreditation must be carried out in an impartial and objective manner, uninfluenced by any personal, financial, or professional interest of any individual acting on behalf of the CAP. Inspectors must not be engaged in close personal, family, business, or professional relationships with any personnel in a laboratory that they inspect. An inspector must not solicit or accept gifts of any type, including personal gifts, products, services, or entertainment. Neither shall inspectors discuss, solicit, accept, or have an employment or consulting arrangement, referral of business, or other business opportunity with the laboratory that they inspect.

Laboratories may challenge any deficiency citation. The CAP believes that team leaders and inspectors will conduct inspections objectively and professionally, regardless of whether they are in competition with the subject institution. Prior to conducting inspections, the CAP requires team leaders to sign a statement attesting to the absence of conflict of interest.

The laboratory is notified in advance of the team leader's name and institution. The laboratory may contact the inspector if logistical considerations need discussion. Prior to the inspection, the laboratory may discuss the specifics of a perceived conflict of interest with CAP staff or the state and/or regional commissioner, or complete and return the conflict of interest form that is found in the self-inspection materials. CAP headquarters will evaluate and discuss this information with the state or regional commissioners for final a determination. All state or regional commissioners have discretion to recommend reassignment if there appears to be a valid conflict of interest.

APPLYING TO CAP ACCREDITATION PROGRAMS

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Accreditation Application Process

Laboratories seeking accreditation by the CAP must submit an Accreditation Program Application Request Form along with a nonrefundable application fee. The CAP will send a Welcome Kit letter via email once the application request is processed. The Welcome Kit letter will include instructions for:

- Creating an online account
- Accessing and completing the application in Organization Profile
- Scheduling an onboarding conference call
- Accessing links to several other resources, such as the Master Accreditation Checklists to help the laboratory prepare for the inspection.

Laboratories seeking first-time accreditation typically complete the first inspection cycle in one year of the application request submission. The timing of events are approximately:

- Year 1: Weeks 1-12:
 - Submit application request
 - Review Welcome Kit
 - Complete application in Organization Profile
- Year 1: Weeks 13-26:
 - Internal CAP application review including proficiency testing audit
 - Receive customized checklists
 - Schedule inspection date
 - Host inspection day
- Year 1: Weeks 27-52
 - Respond to all deficiencies and submit evidence of corrections to any cited deficiencies
 - Support the CAP review process if additional documentation is needed

- Receive certificate of accreditation
- Year 2:
 - Perform self-inspection
 - Maintain continuous compliance

Laboratories with separate CLIA numbers seeking CAP accreditation are accredited separately, even when operating within the same institution. Laboratories under separate CLIA numbers seeking CAP accreditation at the same address must have separate CAP numbers, and likewise must enroll in separate proficiency testing (PT) products. Laboratories operating under separate CLIA numbers must submit separate fees and application request forms. If a laboratory chooses to have its inspections coordinated with an existing CAP-accredited laboratory, this information must be requested in the application.

Proficiency Testing (PT) Prerequisite

- Laboratories applying for accreditation must accurately report each patient-reportable test that it performs to the CAP.
- For analytes that require external proficiency testing (PT), each laboratory must enroll and participate in a CAP-accepted PT program. Information on PT enrollment and CAP-accepted PT programs are found in the [Proficiency Testing: Enrollment and Handling](#) section.
- For tests that do not require enrollment in a CAP-accepted PT program, the laboratory must perform an alternative performance assessment semiannually to determine the reliability of testing. The most common way to do this is by purchasing an external PT product. Other acceptable alternative performance assessment procedures are listed in the [Proficiency Testing: Enrollment and Handling](#) section.
- International laboratories are required to enroll in CAP PT for all test/activities if a CAP PT program is available.

For international laboratories not subject to US regulations seeking CAP accreditation, enrollment in a CAP Proficiency Testing program is required for a minimum of six months prior to requesting an Accreditation Program Application Request Form.

Application and Supplemental Materials – New Laboratories

Each laboratory must complete the application by accessing the Organization Profile through e-LAB Solutions Suite. All required fields are indicated with a red asterisk (*). Short video tutorials are available on each page of the Organization Profile.

- Required documents to be uploaded include:
 - CLIA Certificate (laboratories subject to US regulations) or CLIP certificate (United States Department of Defense laboratories)
 - Previous inspection report (if applicable)
 - Laboratory Director CV
 - Additional required laboratory director documents, as applicable
 - Copy of current state medical license

- State laboratory director license
- Board certification
- Equivalency evaluation
- Organization chart
- Litigation Packet (FDT only)

NOTE: Laboratories applying for Forensic Drug Testing (FDT) Program accreditation must submit the following “litigation packet” information:

- A copy of the overall chain-of-custody (COC) procedure with a flow chart illustrating the various steps used by the laboratory to ensure specimen integrity from the initial receipt of a specimen to its final disposition
- Provide a recent (past 30 days) example of a positive THC-COOH data pack in a litigation format, including:
 - Standard operating procedure (SOP) for the screening procedure
 - Screening data for the specimens, calibrator(s), and controls
 - Evidence of review of the screening batch
 - SOP for the confirmation procedure
 - Chromatographic data for the specimens, calibrator(s), and controls
 - Determination of ion ratios
 - Evidence of review
 - Copy of the final report (identity of person tested should be redacted)
 - Copies of specimen and aliquot internal COC documents
- Complete Organization Profile Sections:
 - Demographics
 - General Information
 - Relationships
 - Roles/Personnel
 - Sections/Departments
 - Inspections

Laboratory Disciplines

A discipline is a CAP-defined term used to describe testing or services grouped within a major category of clinical laboratory science. All disciplines practiced by the laboratory must be listed in the application, and all disciplines will be inspected. The CAP does not accredit portions of laboratories.

CAP disciplines/subdisciplines and CMS specialties/subspecialties will be determined by the selection of activities from the Master Activity Menu. The accreditation letter lists only the disciplines that are reviewed at the time of the inspection. Laboratories that add disciplines and/or analytes after the inspection must update their Activity Menu online in the Organization Profile. In some cases, additional inspections for added disciplines may be required. (Refer to the [Non-routine Inspections](#) section of this manual.)

Activity Section and General Questionnaire

The laboratory provides information about its scope of testing and lists all reportable assays and applicable method/scope codes through its Activity Section and answers the General Questionnaire. The information provided is used for the following purposes:

- Customizing checklists
- Determining disciplines for which accreditation is granted
- Verifying and monitoring proficiency testing enrollment
- Determining whether inspectors with specialty training are required
- Determining the laboratory's annual fee.

Inaccuracies in activities or scopes of service may result in a non-routine inspection and additional fees.

Research or Non-CLIA Testing/Procedures

Laboratories are not required to include testing performed solely for the purpose of research use on activity menus, but may opt to include such testing if the laboratory wants it to be inspected and accredited by the CAP.

- Testing performed for research is defined as laboratory testing on human specimens where **patient-specific** results are **not** reported for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients.
- If patient-specific results are reported from the laboratory, the testing is subject to CLIA and must be inspected by the CAP.

For non-CLIA testing (eg, forensic or pre-employment drug testing) and procedures (eg, embryology, biorepository specimen processing), all tests and procedures must be included on a laboratory's activity menu unless they are distinctly delineated as separate from the laboratory (eg, separate ownership, separate workspace, separate policies, and procedures).

Reapplication Process

Every two years the laboratory enters a reapplication phase at which time all data and attachments are reviewed by the laboratory and updated in Organization Profile, if necessary. Laboratories should update data often to keep all information current. Individuals in key roles should maintain their profile information (eg, email address, phone number) in **MyProfile** on cap.org.

AABB Coordinated Inspection

Laboratories wanting a CAP/AABB coordinated inspection of their transfusion medicine service must add an AABB relationship under Licensure and Certification in the Relationship

Section of Organization Profile. Laboratories will need to request CAP/AABB coordination as part of their Accreditation Application. Additionally, these laboratories must notify the AABB national office at 301-907-6977 as early as possible in the application/reapplication process to allow sufficient time for administrative processing. Due to differences in the timing of CAP and AABB inspection cycles, a coordinated inspection may not be possible for an initial inspection. CAP will alert a laboratory when coordination is not possible for an initial inspection and will work with the laboratory to assist with planning for the next inspection cycle.

NOTE: A coordinated inspection with the AABB assessor is pertinent only to the laboratory that has dual CAP/AABB accreditation. There may be other laboratories in the system providing transfusion services that are CAP-accredited but not AABB-accredited. Member(s) of the CAP system inspection team must inspect these. For questions on preparing for the inspection or at the time of the inspection, call 800-323-4040 ext. 6065 or 847-832-7000 to consult with a CAP technical specialist.

INSPECTION OPTIONS

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Inspection Methods

The CAP offers options to meet the needs of both laboratories and inspectors to complete the inspection process. These options ensure a safe, collegial, and educational inspection for all. Use of technology such as document sharing, live streaming, and video conferencing support the inspection method. All options enable laboratories to be inspected and remain accredited using the inspection options best suited for their laboratory. The virtual inspection is an option for laboratories in good standing seeking reaccreditation. All options provide opportunities to continue the shared experience and exchange of ideas that foster the connection and pursuit of learning that are hallmarks of CAP inspections.

To meet each laboratory's unique needs, inspection methods may include:

- In-person or virtual laboratory inspections
- Document review before or during the inspection
- A blend of these options.

Affiliated Laboratories

Affiliated laboratories located within 15 miles or 30 minutes driving distance from the primary laboratory may have coordinated inspections by the same inspection team. Laboratories that do not meet the distance criteria may be assigned to another inspection team or a CAP staff inspector (refer to the [CAP Staff Inspection](#) section below).

Affiliated laboratories are located at physically separate sites but are connected to another laboratory by management and/or ownership.

- Each site is evaluated as a separate laboratory and has its own CAP number and CLIA number (if applicable).

- Each laboratory has separate:
 - Application materials
 - Customized checklists
 - Proficiency testing
 - Inspections
 - Post-inspection review and accreditation decisions
 - Accreditation certificates
 - Inspection fees.
- Affiliated laboratories may request their own summation conference.
- Each grouping of affiliated laboratories designates a primary laboratory for communication with the CAP (eg, blackout dates) and the team leader.
- Examples of affiliated laboratories include:
 - Two or more hospitals that provide some services at each site (one often designated as full service and the other as a core laboratory)
 - A large commercial laboratory that has branches in different geographic locations
 - A hospital and on-site or remote limited service or special function laboratories, such as blood gas laboratories, oncology clinics, or smaller branch laboratories that perform limited testing.

Laboratories may identify and maintain affiliated laboratories for inspection on cap.org in e-LAB Solutions Suite in Organization Profile by updating the information in the Inspection Unit link under the Relationships heading. Affiliated laboratories must share the same accreditation anniversary date as the primary laboratory.

CAP Staff Inspections

The CAP offers an option for laboratories that perform limited testing to be inspected by CAP staff instead of a volunteer team. This option is in keeping with the CAP's philosophy of peer review because it uses CAP-employed medical technologists that have experience performing and supervising laboratory testing to perform these inspections.

Laboratories participating in this option typically include:

- Affiliated laboratories that are located **more than** 15 miles or 30 minutes from the main laboratory
- Hospitals with 150 beds or fewer that perform basic testing only (such as that seen in a core laboratory). If on-site anatomic pathology services are offered, they must be limited to frozen sections, specimen accessioning, and/or FNA adequacy assessment to qualify for this type of inspection.

Laboratories interested in this option may contact the CAP at 800-323-4040 or 847-832-7000 to discuss if this option is appropriate for their laboratory.

System Inspection Option

Laboratory directors of integrated health care delivery networks may benefit from having their laboratories participate in the CAP System Inspection option. A CAP System Inspection consists of **two or more full-service laboratories** and any associated affiliated laboratories under the same ownership and administration inspected by **one** team of inspectors over the course of several days. These laboratories have highly integrated services and must meet additional specific eligibility requirements outlined below. Laboratories interested in participating in the CAP's System Inspection option should review the information on the CAP website (cap.org) and download, complete, and return the System Inspection Option Application. The system inspection application fee should also be remitted with the completed system inspection application.

System Inspection Eligibility Criteria

Laboratories participating in the system inspection option must:

- Have common administration and ownership
- Be located within three hours travel time (ground transportation) of a system-defined central location
- Participate in the CAP Laboratory Accreditation Program
- Meet the system option eligibility criteria for the degree of integration within the system.

Each individual laboratory within the system must meet at least six of the following eight eligibility criteria:

- Operate on the same set of administrative policies and procedures
- Report directly to one or more central management teams
- Perform common competency assessment at each site utilizing a system-wide standardized program
- Participate in a system-wide quality improvement plan
- Use the same QC interpretive standards and guidelines for common instruments and procedures
- Have an integrated information/central data repository or common laboratory information system (LIS)
- Participate in a common safety program with a common safety manual
- Use a common specimen collection manual.

A CAP inspection specialist schedules and conducts an on-site pre-inspection visit with any group that is new to the CAP System Inspection option to assess the degree of integration and develop a plan for the inspection. For existing laboratories participating in the System Inspection option, an inspection specialist conducts a pre-inspection conference call with the system approximately four to six months prior to the laboratory's anniversary date to reassess the system's level of integration of services and plan for the inspection. The information obtained by the inspection specialist is shared with the team leader and team coordinator to assist with the

inspection planning and team building processes.

System Pathologist Role

A designated system pathologist is responsible for various duties relating to the system's CAP accreditation as well as the performance of reciprocal inspections.

System pathologist duties relating to the system's CAP accreditation include:

- Approving whether a laboratory can join or leave the system
- Ensuring the system planning for an effective and efficient on-site inspection
- Overseeing standardization of activities across all laboratories in the system.

Note that the system pathologist is not responsible for the compliance of each separate laboratory within the system. The CAP/CLIA laboratory director for each site has the ultimate responsibility for laboratory compliance (eg, sign-off on all policies and procedures, approve individualized quality control plans, carry out laboratory director responsibilities).

System pathologist duties relating to the performance of reciprocal CAP system inspections include:

- Accepting (or rejecting) a system inspection assignment when contacted by the CAP
- Ensuring the planning for the performance of an effective and efficient system inspection.

Note that the system pathologist is not obligated to take the team leader role for reciprocal inspections. It may be delegated to another pathologist.

System Inspection Team Preparation

The inspection process is similar to that required to inspect a single laboratory/facility. However, team size and composition require particular attention and planning. Travel and lodging can be complex; therefore, **use of the CAP Travel Desk staff at 800-323-4040 ext. 7800, is required for all air travel and hotel accommodations.** Once the final team count and inspection dates have been approved by CAP headquarters, the CAP Travel Desk staff arranges for direct billing of airfare and lodging and negotiates the best rates for both.

Upon receipt of the inspector's packet and the pre-inspection report, the team leader will determine the number of inspectors and days needed to complete the inspection. The CAP recommends that inspection teams use inspectors who can inspect multiple areas; this decreases disruption of services at the laboratory and decreases inspection costs. To assemble the team, the team leader:

- References the Planning Guide for Area(s) of Responsibility and the System Pre-inspection Information form (refer to the [System Inspection Inspector Tools](#) section below)
- Include a CAP Inspection Specialist on the team as an active team member. CAP

Inspection Specialists can inspect any clinical checklist, frozen sections, specimen accessioning, and/or FNA adequacy assessment

- Shares the plans with the assigned CAP Inspection Specialist and inspection assignment specialist to determine if there is agreement on team size, composition, time allocation, and the preferred week the inspection will occur.

Inspectors need to prepare for the inspection well before the inspection dates and clarify what will and will not be inspected. For instance, a system with a central histology/cytology processing location, but with frozen section and/or interpretive services provided at multiple locations requires inspection of each laboratory using the relevant portions of the Anatomic Pathology and/or Cytopathology Checklists.

System Inspection Inspector Tools

One of the goals of a system inspection is continuity in the inspection process. Therefore, the same inspector should be used to inspect the same discipline in all labs. If this is not possible, all inspectors inspecting the same discipline must compare their findings between laboratories before the summation conference to ensure a consistent approach and interpretation of compliance.

The following supplements are provided in the Systems Inspector's Inspection Packet:

1. **Assessment of System Integration form** – Form completed by the system administration and/or management team at reapplication time that includes information used to assist in team building. The information can also be included in the global summation conference to discuss degrees of integration for the system.
2. **Planning Guide for Inspector Area(s) of Responsibility** – Customized Excel spreadsheet used by the team leader to build the team and ensure adequate inspectors are used, as well as ensure any specialty inspector needs are met.
3. **System Pre-Inspection Information form** – Form completed by the system administration and/or management team before the pre-inspection call/visit and is updated by the inspection specialist based on discussion with the laboratory. The team leader uses it to assist in team building.

System Summation Conferences and the Global Summation

A separate summation conference should take place at each laboratory inspected. (Refer to the Summation Conference section of this manual for detailed instructions related to conducting a summation conference.)

On the last day of the system inspection (or the following morning if the last day of inspection is a full day of inspecting), a global summation conference is held that includes:

- A brief presentation for the system personnel being inspected

- A discussion on how the system can further integrate
- System-wide deficiencies and opportunities for improvement
- Areas of excellence and strengths noted during the inspection.

The global summation conference is not intended to be a reiteration of all the deficiencies and recommendations cited during the inspection of the individual laboratories in the system.

PREPARING FOR THE INSPECTION: LABORATORY

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Laboratory Inspection Packet

After the laboratory completes its application or reapplication, the CAP sends a Laboratory Inspection packet with the following documents:

- Cover letter, including the dates of the inspection window
- Inspection Supplemental Information (inspection blackout dates and hours of operation)
- Activity Menu report
- Checklist Selection report
- Accreditation Checklists (customized).

The checklist edition assigned for an inspection is the current edition available at the time the application/reapplication is initiated. The inspection checklist edition may be different than the edition used for the previous or next self-inspection.

The inspection team receives an inspector inspection packet, which includes the customized checklists based on the laboratory's activity menu, the responses in the General Questionnaire, and other information provided by the laboratory in their Organization Profile. Laboratories should carefully review all of the information to ensure that it is current. The laboratory must update its information if there are changes prior to the inspection because changes may impact the customized checklists. Laboratories should make activity menu changes in Organization Profile through e-LAB Solutions Suite on cap.org.

The inspection may be in-person, virtual, or a blend of these options, and may include advance document review. The laboratory will work with the inspection team leader to determine the inspection method. Advance document review is most efficient for laboratories that have a web-based document management system where guest access can be provided to the inspectors, and the laboratory has most of their records available electronically. Laboratories that are primarily paper-based are not recommended to request advance document review. Use of technology, such as document sharing, live streaming, or video conferencing may be used to facilitate the inspection. Refer to the Inspection Options section for more information.

Laboratories seeking **initial CAP accreditation** will typically be inspected within six months of receiving the laboratory inspection packet. The inspection team leader will contact the laboratory to schedule a mutually agreeable inspection date. CAP-accredited laboratories **reapplying for accreditation** will be inspected sometime within the 90 days prior to the laboratory's anniversary date, with the date of the inspection chosen by the inspection team. The team leader may contact the laboratory to discuss logistics for the inspection. Blackout

dates and US Federal holidays will be honored.

Inspection Preparation Tips

The following tips may help the laboratory prepare for inspection:

- Prepare references that describe how the laboratory complies with each requirement.
Example:
 - Download customized checklists from cap.org in the Excel format (refer to the [Accreditation Checklists](#) section for information on downloading the checklists in different formats)
 - Add columns to the spreadsheet for comments and/or hyperlinks to compliance documents.
- Refer to the **Checklist Changes only** version of the checklists available on cap.org to identify new requirements and checklist changes from the previous edition.
- Update the Laboratory Personnel Evaluation Roster to include changes in personnel or supervisor responsibilities.
 - Ensure that all CLIA roles relevant to the testing performed by a laboratory are filled by qualified individuals. For example, a technical consultant must be listed if any moderate complexity testing is performed. A technical supervisor and general supervisor must be listed if any high complexity testing is performed.
 - Audit personnel records to ensure that all required records are readily available. Have the updated roster ready to present to the inspection team.
- For laboratories reapplying for accreditation, review inspection findings and records of corrective actions from the last CAP inspection and the interim self-inspection and confirm ongoing correction of deficiencies. Ensure that the self-inspection records will be readily available the day of inspection.
- Review the Activity Menu report to confirm that it accurately reflects testing performed in each section and the laboratory is either enrolled in CAP-accepted proficiency testing (PT) or performing alternative performance assessment for each activity/test. Ensure that PT and alternative performance assessment records are readily available and have been reviewed, with records of corrective action, as applicable.
- Update the List of Individualized Quality Control Plans (IQCP) form if one or more IQCPs are used in the laboratory. Have the form available to present to the inspection team. Ensure that related documents supporting the IQCP(s) (eg, risk assessment, quality control plan, quality assurance monitoring) are readily available.
- Develop a process for timely retrieval of off-site records, such as personnel training records and initial instrument/method validation/verification studies. Store on-site documents and records in a central location so that they are easily accessible during the inspection. Ensure that key personnel know how to locate or retrieve the documents and records.
- Train all personnel to be familiar with the checklists and the inspection process. Ensure that staff in each laboratory section know where to find specific documents needed for the inspection.
- Participate in educational activities offered by the CAP to gain a better understanding of accreditation requirements (refer to [Appendix E for the resource locations on the CAP](#)

[website](#)).

- **Focus on Compliance webinar series** - CAP accreditation presentations that focus on key accreditation topics aimed at laboratory professionals. Register for live events or listen to previously recorded presentations on [cap.org](#).
- **Fast Focus on Compliance:** Online modules developed to provide information on a variety of challenging topics in a bite-sized learning format.
- **Laboratory Inspection Preparation Course:** Short videos on a variety of accreditation topics designed to help prepare for a CAP inspection.

Inspection Plan

The laboratory should prepare an inspection plan to avoid confusion and delays on the day of inspection, including the following elements:

Plan Elements	Example Tasks
One-hour security notification for inspections	<ul style="list-style-type: none"> • Ensure that a responsible person will be available to receive the one-hour security notification call from the inspection team • Confirm that the cell phone or other contact information for the responsible individual is correct • Define what activities need to occur when the call is received (eg, notification tree)
Designated central contact	<ul style="list-style-type: none"> • Designate one or more individual(s) as the central contact to coordinate events throughout the day • Greet the inspection team and make introductions • Arrange for a short laboratory tour at the beginning of the inspection
List of key personnel	<ul style="list-style-type: none"> • Identify a list of key personnel who have knowledge of policies, procedures, and the location of key documents (eg, QC, PT, instrument and equipment maintenance and function checks) for each area of the laboratory • Include backup personnel in case a contact is not available on the day of inspection
Interviews with team leader	<ul style="list-style-type: none"> • Identify representatives from medical staff and administration who will be available for an interview with the team leader • Include backups in case the designated representative is not available on the day of inspection

Communication	<ul style="list-style-type: none"> • Communicate with all parties within and outside of the laboratory that may be involved in the inspection process • Schedule interviews with representatives from the medical staff and administration
Meeting rooms and workspace	<ul style="list-style-type: none"> • Identify options for meeting rooms or workspace to be used by the inspection team, including a “home base” in a location convenient to the laboratory • Identify locations for introductions and for the summation conference
Transportation to test sites and facilities	<ul style="list-style-type: none"> • Establish a mechanism to escort team members to testing sites • Provide transportation and/or directions for off-site locations, if needed
Staffing needs	<ul style="list-style-type: none"> • Assess workload and staffing to determine if modifications are needed to prevent disruption of patient care
Inspection team needs	<ul style="list-style-type: none"> • Arrange for refreshments (water, coffee, etc.) and lunch for the inspection team or provide information on locations for dining located near the laboratory (provision of refreshments/lunch is optional and at the discretion of the laboratory) • Provide personal protective equipment • Make office supplies available in the inspection team work area (eg, pads of paper, pens, sticky notes/flags, etc.) • Provide internet and telephone access
Records	<ul style="list-style-type: none"> • Provide centralized records to be available throughout the course of the inspection for policies, procedures, and other records • Ensure that personnel files are readily available • Arrange for off-site records needed for the inspection to be delivered to the laboratory
Conclusion of the inspection	<ul style="list-style-type: none"> • Provide copying services prior to the summation conference • Provide facilities for inspectors to securely dispose of inspection materials

PREPARING FOR THE INSPECTION: INSPECTION TEAM

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Inspection Team Leader Assignment

The CAP's accreditation programs use a peer-based inspection model. CAP-accredited laboratories are required to provide a trained inspection team comparable in size and scope if requested by the regional and/or state commissioner, at least once every two-year accreditation period as a term of accreditation. The assignment is made by matching a team leader from one laboratory (or group of laboratories) to another laboratory (or group of laboratories) after screening against multiple criteria, including known conflicts of interest, geographic distance, and size and complexity of the respective laboratory.

Assignments can be made up to 15 months prior to the anniversary date of the laboratory being inspected. The team leader receives an inspection assignment letter to confirm an assignment and report any conflicts of interest. (For information on conflicts of interest, refer to the [Accreditation Program Philosophies](#) section.)

Team Leader Qualifications and Responsibilities

Team leaders should be:

- A peer of the laboratory director, with similar status, type of practice, and hospital or laboratory size
- Preferably a board-certified pathologist* and a CAP Fellow

- Affiliated currently or has past experience with a CAP-accredited laboratory
- Trained in the inspection process and in team leader responsibilities
- Not engaged in a close personal, family, business, or professional relationship with any personnel in a laboratory that he/she will inspect.

* A nonpathologist inspector may serve as the team leader for a laboratory that is typically not directed by a pathologist (eg, a cytogenetics laboratory) so long as the inspector is a peer of the laboratory director. For a pathologist-directed laboratory, however, a nonpathologist inspector may serve as the team leader only with the prior agreement of the laboratory director.

The team leader for a biorepository inspection must have the qualifications to be a laboratory director of a biorepository.

For anatomic pathology sections, a pathologist, board certified in anatomic pathology, must perform the inspection, or supervise the inspection if performed by a qualified histotechnologist or cytotechnologist. One exception is for small laboratories offering anatomic pathology limited to specimen accessioning, frozen sections, and/or fine needle aspiration adequacy assessment that are routinely inspected by a CAP staff inspector team. (Refer to the [CAP Staff Inspections](#) section)

Inspection team leaders are responsible for:

- Assembling an inspection team of appropriate size and experience for the laboratory or laboratories being inspected
- Communicating with the laboratory to determine the inspection method (refer to the [Inspection Options](#) section)
- Ensuring that team members are appropriately qualified and have completed CAP inspector training
- Setting the inspection date within the correct window
- Making inspection materials available to inspection team members
- Providing overall supervision and time management of the team throughout the inspection process
- Evaluating compliance with the Director Assessment Checklist, including interviews with the laboratory director and other institutional representatives
- Conducting the inspection summation conference
- Submitting the post-inspection findings and materials to the CAP.

Inspector's Inspection Packet

The CAP Inspector's Inspection Packet contains:

- Team leader inspection materials
 1. Team Leader Inspection Planner
 2. Summary of the laboratories to be inspected
 3. Inspection Supplemental Information sheet (days and hours of laboratory operation, blackout dates for inspections)

4. Inspection Assignment Worksheet by Laboratory form
 5. Travel and Lodging Information form
 6. Inspection Team Building Tip Sheet
 7. CAP Accreditation Resources for Inspector
 8. Team Leader and Team Member training information sheet
 9. *Standards for Accreditation*
 10. Prepaid mailer envelope to return the packet to the CAP within 24 hours after the inspection is completed
 11. Team Leader Evaluation form
 12. Form to claim Inspection Reimbursement
 13. Packet Table of Contents
 14. To Cite or Not to Cite guide
 15. Name tags for the team (every team member should wear a name tag while in the host facility)
 16. Security clearance forms, if needed.
- Accreditation unit (AU) materials (for each laboratory being inspected)
 1. Laboratory Synopsis Report
 2. Letter for laboratory director announcing inspection
 3. Instructions for Sampling & Evaluating Laboratory Personnel Records
 4. Personnel Requirements sheet
 5. Laboratory Personnel Evaluation Roster (PER)
 6. Complaint Report, if applicable
 7. Inspector's Summation Report (ISR) forms (Part A and "extra copy" pages)
 8. Laboratory organization chart
 9. Laboratory director's curriculum vitae (CV)
 10. Inspector's Summation Report from the previous inspection (not included for initial inspections)
 11. Laboratory-Specific Activity Menu (list of tests and testing modalities).
 - Section unit (SU) materials (for each section unit/department)
 1. Laboratory Section Synopsis Report
 2. Team Member Inspection Planner
 3. Instrumentation list
 4. Proficiency Testing Performance Report
 5. Team Member Evaluation form.
 - Checklist section (separate subsection for each section unit/department)
 1. Previous Inspector's Summation Report (ISR)
 2. Laboratory-Specific Activity Menu
 3. ISR Deficiency form
 4. ISR Recommendation form
 5. Customized checklist (based on the laboratory's activity menu for each section).

- Post-inspection Instructions for Responding to Deficiencies (Blue Folder).

The inspection team should contact the CAP if there are any materials missing or with questions about the inspection packet.

The CAP provides an electronic inspection packet for volunteer and staff inspectors. The electronic inspection packet is intended to complement the standard paper packet and make it easier for a team leader to distribute inspection materials to team members and specialty inspectors.

Team leaders will receive an email notification with a download link when the electronic inspector packet is available and each time a change is made that impacts the inspection. The team leader may also access this information by logging onto cap.org and navigating to the inspection download through the Inspection Packets for Team Leads link in the Inspector Training and Resources section on the Laboratory Improvement/Accreditation page.

A team leader can share an electronic packet with the team members. When selecting the share link in the Action column, a pop-up window opens that includes link to the electronic packet and allows the team leader to enter a recipient email address.

Assembling the Inspection Team

The team leader should **immediately review** the materials in the Inspector’s Inspection Packet upon receipt and begin assembling the inspection team. The packet contains the information on the appropriate number of inspectors and the expertise needed. It recommends the “number of inspector days” to perform the inspection, based upon the disciplines and test volumes declared by the laboratory.

For inspections of large or multisite laboratories, the team leader may decide to spend more than one day on site with a smaller team, rather than taking a team large enough to complete the inspection in one day. This approach is helpful when section supervisors are responsible for more than one site and may not be available at more than one site during a one-day inspection.

General guidelines for assembling the inspection team:

- One inspector is needed for the Laboratory General inspection. More than one inspector may be needed for large, full-service laboratories, such as a university hospital laboratory. Alternatively, inspectors assigned to other checklists may be able to assist the Laboratory General inspector with sections of the checklist (eg, computer, safety).
- One inspector may be able to inspect with more than one discipline-specific checklist or inspect more than one laboratory section during an inspection depending on the experience of the team member, the scope of testing performed, and set up of the laboratory. Common combinations include:
 - Hematology and Urinalysis
 - Chemistry and a separate blood gas laboratory
 - Microbiology and Immunology – A second inspector may be needed if the

laboratory offers extensive services in microbiology in all subdisciplines (bacteriology, mycobacteriology, mycology, parasitology, virology, and molecular microbiology).

- Anatomic Pathology and Cytopathology
- Transfusion Medicine and Immunology – A second inspector may be needed for hospital laboratories that have extensive donor and transfusion activities.
- Fewer inspectors are needed for laboratories with very limited test menus. One generalist inspector may be able to inspect using the Limited Service Laboratory Checklist.
- Adjustments to the number of inspectors should be made based upon the experience of the inspectors and the extent of testing in the laboratory.

The Inspection Team Building Tip Sheet found in the inspection packet contains additional information for assembling the team.

The CAP requires the use of a specialty inspector for inspections performed with the following checklists:

- Cytogenetics
- Flow Cytometry
- Histocompatibility
- Clinical Biochemical Genetics
- Molecular Pathology.

Specialty inspectors will be listed on the Inspector Candidate Roster Report. Potential team members not on the report may apply to be a specialty inspector on cap.org by logging in to My Profile, selecting the “Business/Professional” tab and then “Request to be Inspector” to complete the data needed for the inspector database. The team leader may bring the potential team member only if he or she receives approval for that specialty.

If a team leader wants to take more inspectors than the CAP recommended number provided in the inspector packet, the team leader must contact the CAP prior to the inspection to obtain approval. Additional inspectors may not be reimbursed without prior approval. The team leader must:

- Complete the Inspection Assignment Worksheet by Laboratory form included in the packet and explain why additional inspectors are needed
- Email the form to accred@cap.org.

The CAP will review the request and notify the team leader within two business days about the approval decision.

Team leaders may obtain assistance to identify additional inspectors to perform the inspection by contacting the CAP at 800-323-4040, ext. 6061 or 847-832-7000, ext. 6061. The CAP can provide lists of qualified inspectors from its CAP inspector database.

Inspection Team Member Qualifications and Responsibilities

The team leader assembles the inspection team by selecting team members with the necessary expertise in the assigned inspection areas. All inspectors must be trained on the inspection process (refer to the Inspector Team Leader and Team Member Training Options section).

Inspectors may include:

- Experienced medical technologists/clinical laboratory scientists, preferably with laboratory supervisory or manager experience
- Cytotechnologists
- Histotechnologists
- Doctoral scientists
- Pathology residents and fellows
- Pathologists.

Inspectors must not:

- Inspect a laboratory or facility for which he/she/they has provided or is likely to provide consultative services
- Be engaged in close personal, family, business, or professional relationships with any personnel in a laboratory that the inspector inspects.

Inspection team members must prepare several weeks prior to the inspection to perform a thorough and efficient inspection.

- Review information provided by the team leader from the inspector's packet (refer to the Conducting the Inspection: General Principles and Meetings section)
- Complete inspection team member training and participate in optional educational activities.

Team Leader and Team Members Training Options

The CAP requires inspectors to successfully complete CAP-approved training prior to inspecting. Training promotes a more thorough and effective inspection through development of a consistent understanding of program standards and a uniform application of inspection techniques. Training is mandatory for all team leaders and team members. Team leaders must ensure that their team members have fulfilled the training requirement.

Specially designed online training options are available on cap.org that emphasize the knowledge and skills required to perform an inspection, including:

- Team Leader Inspection Training
- Team Member Inspection Training.

Completing online inspection training fulfills the training requirement and offers CME/CE credit to participants. Trained inspectors are encouraged to review the content that is most relevant to

their needs as the training courses are updated annually. In addition to online inspection training, certain live inspection training events may satisfy the training requirement as well. These events are specifically designated as such by the CAP.

To enroll and participate in online training, go to cap.org, click on the Learning Tab, then under Choose Your Learning Path you will be able to select Learning for Laboratory Professionals, then Inspector Training – View Courses.

Optional Educational Activities

The CAP offers different educational activities to help inspectors and laboratories stay current. (Refer to [Appendix E](#), CAP Accreditation Program Website Tools for the location on cap.org.)

Fast Focus on Compliance: Online modules developed to provide information on a variety of challenging topics in a bite-sized learning format. Inspectors are encouraged to review these modules prior to inspecting for the most up-to-date information and inspector tools.

Focus on Compliance webinar series: CAP accreditation presentations that focus on key accreditation topics aimed at laboratory professionals. Register for live events or listen to previously recorded events on cap.org.

Arranging the Inspection Date

The team leader is responsible for arranging the inspection date and notifying the CAP of the chosen date. Inspections are performed as either announced or unannounced depending on the type of inspection or laboratory. This information is found in the Team Leader letter in the inspection packet. The following types of inspections are generally conducted as announced inspections:

- Laboratories seeking initial CAP accreditation through the Laboratory Accreditation Program
- Laboratories participating in the Reproductive Laboratory Accreditation Program, Forensic Drug Testing Accreditation Program, or Biorepository Accreditation Program
- International laboratories.

All other types of inspections are conducted as unannounced inspections.

Announced Inspections

To arrange the inspection date, the team leader must:

- Contact the laboratory director(s) within two weeks of receiving the Inspector's Inspection Packet. Contact **all** directors if special function laboratories are to be inspected in conjunction with the main clinical laboratory.
- Ensure that the **inspection occurs no more than 90 calendar days before the laboratory's anniversary date for routine inspections**. If a mutually agreed upon date

cannot be determined, please contact the CAP to discuss.

- Send a courtesy letter to the laboratory director(s) or phone call to discuss:
 - The inspection date/time
 - Inspection Method: in-person or virtual (must meet eligibility criteria)
 - Laboratories preference for document review during the inspection, in advance, or a blend of both
 - Projected schedule
 - Team listing
 - Special requests (eg, histology slides for review) and preliminary instructions regarding availability of documentation (personnel and training records, procedure manuals, proficiency testing results, test validation studies, QC and maintenance records, and a sampling of completed case records [as applicable])
 - Key contacts.
- Notify the CAP of the inspection date and the number of inspectors by telephone at 800-323-4040 or 847-832-7000 or email at accred@cap.org.

Unannounced Inspections

To arrange the inspection date, the team leader must:

- Review Inspection Supplemental Information sheet in the Team Leader materials for the days and hours of operation and inspection blackout dates
- Ensure that the **inspection occurs no more than 90 calendar days before the laboratory's accreditation end date of initial accreditation for routine inspections**
- Notify the CAP of the inspection date and the number of inspectors by telephone at 800-323-4040 or 847-832-7000, or email to accred@cap.org
- Consider preparing an inspection schedule that can be handed to the laboratory director at the beginning of the day. At minimum, this would consist of a list of inspectors and their section/checklist responsibilities
- The team leader may contact individuals from the laboratory being inspected to discuss logistics, including inspection method.

Arranging Inspection Team Travel

The CAP will assist the inspection team in meeting its travel needs and requires that all arrangements be made through the CAP Travel Desk. The travel desk agents can be reached by:

- Phone: 800-323-4040 ext. 7800 or 847-832-7800, from 8:00 AM–5:00 PM Central Time
- Fax: 847-832-8800
- Email: captraveldesk@cap.org.

When booking travel, the inspection team must provide:

- The five/six-digit Inspection Instance (II) identification number of the laboratory to

- be inspected (found on the Laboratory Synopsis page of the inspector packet)
- Inspector names, including gender and birthdates **exactly** as they appear on the photo identification used for traveling.

The CAP encourages booking two months prior to travel in order to obtain favorable rates. When arranging travel, follow the recommended number of inspector days. For requests to bring additional inspectors beyond the CAP recommended number, contact the CAP at 800-323-4040 or 847-832-7000. Do not make travel arrangements until the additional inspector days have been approved.

The CAP Travel Desk agents can also arrange hotel accommodations and rental cars, if applicable. The CAP Travel Desk can negotiate a master account to cover the room rates and taxes for inspectors. Inside the US, inspectors should decline insurance for rental cars. Outside the US, the inspectors should purchase the rental car insurance. Prior to the inspection, inspectors should contact their personal auto insurer to advise them that they will be driving outside of the US.

Team members needing to change any travel should contact the CAP Travel Desk agents as soon as possible.

Requests for Inspection Delays

The Council on Accreditation policy requires that laboratories performing patient testing be prepared for inspection at any time. Any problems encountered in scheduling inspections should **immediately** be brought to the attention of the CAP at 800-323-4040 or 847-832-7000 for resolution.

Internal CAP Validation Inspections

The CAP randomly selects a small number of on-site inspections to perform an internal CAP validation inspection. The assigned inspection team is expected to participate in the internal CAP validation inspection if selected. The CAP notifies the team leader prior to the inspection if a validation inspection will occur.

The internal CAP validation inspection is a quality assurance process designed to improve the consistency and thoroughness of CAP Accreditation Program inspections. A CAP staff inspector is added to the inspection team as an observer for the on-site inspection to gather information on how the team uses the inspection tools and to identify best practices from the team that could be added to the inspector training course. The process includes:

- Observation of the volunteer inspection team during the inspection by a CAP Inspection Specialist
- Inspection of 20 checklist requirements by a CAP Inspection Specialist independent of the volunteer inspection team and then comparing the results and reconciling any differences
- Asking the inspectors questions about the inspection process and suggestions for improvement.

AABB Coordinated Inspection

The CAP has an agreement with the AABB to coordinate the inspections of transfusion services for laboratories accredited by both the CAP and AABB upon request of the laboratory. The coordinated inspection may occur on the same or different day than the rest of the laboratory but must occur before the CAP anniversary date. The following process is followed for AABB coordinated inspections:

- When the CAP receives notification from the AABB that an AABB assessor has been assigned, the CAP sends a notification to the team leader, the AABB assessor, and the laboratory director, to provide contact information and define each inspector's responsibilities. The CAP team leader and AABB assessor should work together to determine if a coordinated inspection can occur on the same day.
- The CAP will send the AABB assessor a packet containing the Transfusion Medicine, Laboratory General and All Common Checklists, an Inspector's Summation Report (ISR) form, the laboratory director's CV, an organizational chart, a Personnel Evaluation Roster (PER), instructions, a letter informing the assessor of the name and telephone number of the CAP team leader, and a return envelope.
- The AABB assessor will notify the CAP of the inspection date.
- After the AABB inspection, the AABB assessor completes the CAP Transfusion Medicine inspection report, leaves a copy with the laboratory, and returns the original to the CAP in the envelope provided.

The CAP team leader should not hold his/her report to await the AABB assessor's report. The CAP accreditation decision will occur only when inspector findings from both organizations have been submitted to the CAP.

Each organization (the CAP and AABB) makes separate accreditation decisions, and one organization's decision does not affect the other.

PROFICIENCY TESTING: ENROLLMENT AND HANDLING

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Proficiency Testing Enrollment

Each accredited laboratory must enroll and participate in a CAP-accepted proficiency testing (PT) program for all analytes that require PT to assess the accuracy of testing performed. In some countries, proficiency testing may be referred to as an external quality assessment (EQA) program. Laboratories should place orders with the PT provider by December 1st each year to ensure full participation.

The following tools can be used to determine which analytes require enrollment in a CAP-accepted PT program:

- Master Activity Menu with PT Options report available through the e-LAB Solutions Suite customer portal on the CAP website (cap.org)
- CAP Surveys catalog - Analyte/Procedure Index section (available on cap.org).

The CAP accreditation programs do not typically require PT enrollment for calculated analytes; however, there are a few exceptions where PT enrollment is required (eg, estimated hemoglobin, calculated hematocrit, and non-waived INR calculation).

International laboratories are required to enroll in CAP PT where the CAP offers a PT program for all test/activities that they are performing in the laboratory. For analytes that do not require PT enrollment, international laboratories must use CAP PT for alternative performance assessment, when available.

Laboratories subject to US regulations must participate in one CAP-accepted PT program for each required analyte for one year before designating a different CAP-accepted PT program for PT compliance and reporting to the Centers for Medicare and Medicaid Services (CMS). If a laboratory enrolls in PT mid-year due to a new application for accreditation or the introduction of new testing, the laboratory may change to another CAP-accepted PT provider at the next enrollment period without waiting a full year. If a laboratory enrolls in PT from multiple PT providers for one required analyte, it must designate only one PT provider to submit a performance score to the CMS for the year.

Alternative performance assessment (APA) must be performed at least semi-annually for tests for which CAP does not require enrollment in PT. The laboratory director must define such

APA procedures. The criteria for APA must be in accordance with good clinical and scientific laboratory practice. The laboratory must evaluate each unacceptable PT and each APA result that does not meet the laboratory's acceptability criteria. Examples of APA include (in order of preference):

- Participation in an external PT program supplied by the CAP
- Participation in an ungraded/educational PT program
- Split-sample analysis with referral or other laboratories
- Split-sample analysis with an established in-house method, assayed material, or regional pools
- Clinical validation by chart review, or other suitable and documented means.

CAP-Accepted Proficiency Testing Programs

The CAP accreditation programs have defined criteria for CAP-accepted PT programs and analytes. Each PT provider maintains its own list of accepted analytes. Not all analytes within a PT provider's program are necessarily accepted by the CAP accreditation programs. It is the responsibility of accreditation participants to verify analyte acceptance with their PT provider.

NOTE: International laboratories not subject to US regulations seeking CAP accreditation, must enroll in the CAP PT Program for a minimum of six months prior to initiating the CAP application process. Laboratories may use acceptable alternatives, contingent on CAP approval, when the CAP is unable to deliver PT due to oversubscribed programs, stability issues, or customs denial.

Proficiency Testing Enrollment for Multiple Matrices

PT may be required for multiple matrices for some tests. The laboratory must enroll in a PT program specific for that matrix if a CAP-accredited PT program is required. If PT is **not** required, laboratories must perform alternative assessment (refer to COM.01500).

Proficiency Testing Handling

Among the requirements of the Clinical Laboratory Improvement Amendments (CLIA) regulations (42CFR 493.801) is that the laboratory must test PT samples in the same manner as it tests patient specimens. The PT handling requirements described below apply to waived and nonwaived testing. This means that:

- PT samples should be tested along with the laboratory's regular workload by personnel who routinely perform the testing (eg, if a laboratory tests each patient specimen only once, PT specimens must also be tested only once).
- PT samples should be rotated over time among all staff members and all shifts that routinely perform the patient testing.

The CLIA regulations also specify the following for PT on waived and nonwaived testing:

- Laboratories may not engage in any inter-laboratory communications pertaining to the results of PT samples until after the deadline for result submission to the PT provider has elapsed.
- Organizations that have laboratories at different test sites with different CAP/CLIA numbers must prevent such inter-laboratory communication.
- A laboratory may not refer any PT material for testing to another laboratory and may not accept PT material from a laboratory with a different CLIA/CAP number.

A laboratory must only report results for PT performed in its own laboratory location. It may not refer PT specimens to another laboratory and report those results. Here are examples of inappropriate PT referral:

- A laboratory's routine process for patient testing is to perform only preliminary testing and to refer the specimen to another laboratory for confirmatory testing. Staff referred PT samples to another laboratory for confirmation in error. (The laboratory should have reported the preliminary result to the PT provider and not referred the specimen for confirmatory testing.)
- A satellite laboratory's procedure requires abnormal blood smears to be reviewed by a pathologist at the main laboratory prior to reporting. Staff at the satellite laboratory sent abnormal blood smears from the PT to the main laboratory in error. (The laboratory should have submitted a PT response indicating that the test is not performed on-site and would refer to another laboratory.)
- A main laboratory has all PT kits for its satellite laboratories shipped directly to the main laboratory. The main laboratory accidentally forwarded a kit to the wrong satellite laboratory. The satellite laboratory then reported its results under the wrong CAP/CLIA number.

The laboratory director must ensure that there is a well-established process for the handling of PT materials, including circumstances that could be considered PT referral. The penalty for violating PT referral regulations, according to the CMS, may be "revocation of the laboratory's CLIA certification for at least one year" and the potential prohibition of the owner or laboratory director to own or direct a laboratory for two years. The CAP accreditation programs may impose additional sanctions including loss of accreditation.

The sole exemption to the "no referral" rule is those laboratories that send slides to another facility for immunohistochemistry (IHC) staining but perform the interpretation in-house. Staining is not considered a test. In that case, the IHC staining (and only the staining) of the PT slides may be referred to the usual outside facility.

Other methods often used in distributive testing such as in situ hybridization, next-generation sequencing, and flow cytometry are classified as testing under CLIA; therefore, proficiency testing samples for this testing may not be referred to another laboratory.

PROFICIENCY TESTING: FAILURES AND MONITORING

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Evaluation of Proficiency Testing (PT) and Alternative Performance Assessment (APA)

Laboratories must review the reports from their PT providers for each PT event and their APA results to evaluate their performance, investigate each unacceptable result, and take appropriate corrective action. All records for the event must be retained, including original worksheets and follow-up investigations.

When investigating PT or APA failures and biases, the following actions may be necessary:

- Check reporting forms and records of sample preparation and testing for non-analytic (eg, clerical) and analytic errors
- Review QC performance, instrument calibration, and reagent performance prior to, during, and after the time of PT failure
- Verify that the PT material was stored, handled, and processed according to the kit instructions (eg, test in correct instrument mode, correct units of measure).
- Investigate biases or trends (as defined in the laboratory's policy on PT review)
- Contact the instrument/reagent manufacturer for assistance
- Repeat the PT challenge, if possible, using a different reagent lot or instrumentation system
- Confirm that patient/client results were not affected during the period of time the PT was unacceptable.

The laboratory must evaluate and retain records of investigation for **each** unacceptable PT or APA result. Corrective actions that may be taken include:

- Repeat instrument function or testing system verification
- Modify the frequency of calibration
- Revise or replace the analytic procedure
- Design a process to double check clerical entries prior to submitting PT results

- Ensure all staff know when PT kits are scheduled to arrive and due dates for PT results submission
- Retrain testing personnel in the proper procedures for sample preparation, testing, and reporting.

Occasionally PT challenges are not graded. The CAP accreditation programs require laboratories to perform a self-evaluation when a PT result is not graded. The laboratory director is responsible for choosing a self-evaluation method appropriate for the laboratory's individual circumstances. Any PT results falling outside the laboratory's established criteria for acceptable performance must be investigated and corrective action taken, as would be done for graded PT results.

Proficiency Testing Monitoring

The CAP monitors three PT compliance processes:

- Confirmation of enrollment in required PT
- Participation in required PT
- Successful PT performance.

Laboratories will receive a Proficiency Testing Compliance Notice (PTCN) for failure to enroll in PT, participate in PT, or for unsatisfactory performance. The PTCN contains instructions regarding the actions that must be taken. The CAP Accreditation Programs' PT Compliance Department evaluates the actions taken to ensure that the underlying compliance issue is corrected, and the testing is performed in a manner that will not jeopardize patient safety.

A description of each type of PTCN follows. For help or more information on PT enrollment or assistance with troubleshooting PT failures, accreditation participants may:

- Refer to the Proficiency Testing/External Quality Assurance Toolbox available through the e-LAB Solutions Suite under Accreditation Resources on cap.org
- Contact the CAP at 800-323-4040 or 847-832-7000.

For ideas on troubleshooting analytical issues, participants may refer to the Clinical and Laboratory Standards Institute Guideline QMS24-ED3, "Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality [2016]."

Proficiency Testing Compliance Notice (PTCN) – Missing PT/Non-enrollment

The CAP will send a PTCN if a laboratory is not enrolled in PT for a required analyte that is listed on its Laboratory-Specific Activity Menu. Enrollment is monitored on a continuous basis.

To respond to the PTCN, the laboratory must take one of the following actions:

- Enroll in the appropriate PT
- Submit payment. Orders cannot be shipped until payment is received

- Provide import permits or certificates of origin, if applicable. Orders cannot be shipped until all permits are received by the CAP.
- Delete activity from the Laboratory-Specific Activity Menu if the test is no longer performed
- Contact the PT provider to send enrollment data to the CAP if enrolled with a CAP-accepted PT provider other than the CAP
- Respond to the CAP with supporting documentation that the intended, CAP-accepted, PT program is oversubscribed or otherwise unavailable. The laboratory must implement an APA for the affected analyte(s) using, at minimum, the same number of challenges as the event missed. For regulated analytes, if the CAP and CAP-accepted PT programs are oversubscribed, the CMS requires the laboratory to attempt to enroll in another CMS-approved PT program.

Proficiency Testing Compliance Notice (PTCN) – Non-participation

The CAP monitors participation in PT for each testing event, looking at all analytes that require PT according to the Laboratory-Specific Activity Menu. A PTCN for non-participation is sent to a laboratory when it is enrolled in PT for a particular analyte, but the CAP accreditation programs did not receive PT scores for that analyte. This is due to a failure to submit results to the PT provider. This can occur for several reasons, such as:

- A discontinued test was not removed from the Laboratory-Specific Activity Menu.
- Results were transmitted improperly.
- The PT kit was not received by the laboratory.
- PT results were submitted after the due date.

NOTE: Under both CLIA and CAP requirements, failure to participate in a testing event or failure to return results by the due date is equivalent to a zero score (0%) for the testing event and is considered unsatisfactory performance.

A laboratory must respond to every non-participation PTCN. The response to the CAP is to include:

- Reason results were not reported
- Evidence of alternative assessment (if appropriate)
- Records of corrective action taken to prevent recurrence of the error.

If PT was performed, but results were not reported, the laboratory may self-evaluate its own performance on the event by comparing the laboratory's results to the statistics in the Participant Summary Report and use that as evidence of APA. If other means of APA is used, it should be performed to the same extent as the missed event (eg, number of challenges).

Proficiency Testing Compliance Notice (PTCN) – Performance

PT performance monitoring is a process that looks for instances of unsatisfactory performance continuously across all testing events. If the performance of an analyte or subspecialty falls

below the acceptable criteria, a PTCN for performance is sent to the laboratory and the laboratory must respond to the CAP as directed. The laboratory must investigate each unacceptable PT result and record the investigation to include:

- Reason for the PT failure
- Evidence of how the laboratory ensured the accuracy of patient results
- Specific corrective action taken to prevent recurrence of the problem
- Evidence of APA (if appropriate).

First time PT failures for most analytes or subspecialties (other than predictive markers) do not require a response to the CAP. Investigate the reason for each PT failure. The inspector will review and evaluate records of the investigation and corrective action during the next inspection.

Subsequent PT failures for the same analyte or subspecialty results in unsuccessful PT performance, the laboratory must complete the PTCN response form, including the reason for the first failure and provide records of corrective action to the CAP. The laboratory must retain copies of the correspondence and corrective action.

CAP PT Compliance technical staff will request additional information if the response is incomplete. CAP staff may also provide informational letters with recommendations to assist the laboratory with improving its current testing processes for the analyte or subspecialty in question.

Cease Testing Requirement

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) mandate that if a laboratory has repeat unsuccessful performance in PT for a CLIA-regulated analyte, test, subspecialty, or specialty, the laboratory will be directed to cease testing for **six months**. As an accrediting organization deemed by the Centers for Medicare and Medicaid Services (CMS), the CAP has been directed to enforce this requirement.

Repeat unsuccessful PT performance occurs when the laboratory incurs either three consecutive or two sets of two out of three unsatisfactory scores over the most recent 12 PT events, for a CLIA-regulated analyte, subspecialty, or specialty. This is defined based on current policies and guidance from CMS and information available in the CLIA PT monitoring system.

A laboratory that has repeat critical performance for a non-regulated analyte/test may also be directed to cease testing (not subject to the six-month period stipulated for CLIA-regulated analytes/tests).

Before the laboratory can resume testing, it is required to:

- Submit an acceptable plan of corrective action to the CAP
- Provide evidence on how the laboratory ensured the accuracy of patient results
- Demonstrate minimum acceptable performance on reinstatement PT
 - At least 80% on reinstatement PT for a regulated analyte/subspecialty/specialty

- 100% for ABO, Rh, and compatibility testing.

If the laboratory refuses to cease testing when directed, its accreditation will be in jeopardy. The inspection team will verify that laboratories have ceased patient/client testing, if directed by the CAP, during the next inspection.

ACCREDITATION CHECKLISTS

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Accreditation Checklists

Each checklist contains a detailed list of requirements used by laboratories for inspection preparation and by inspectors to assess compliance. The full set of checklists includes approximately 2,800 requirements in 21 different checklists organized around specific laboratory disciplines and/or important management operations. ([Appendix A: Accreditation Checklists Overview](#))

The checklists are revised periodically (usually once a year) based on input from the CAP's practicing experts, such as its scientific committees, inspectors, and participants, to stay current with advancements in technology and laboratory medicine and ensure regulatory compliance. The checklist edition used for an inspection is the edition provided at the time of application/reapplication, even if a newer edition has been published. This checklist edition may be different than the edition used for the previous or next self-inspection.

The Checklists are copyrighted works of the College of American Pathologists (CAP). The CAP has authorized copying and use of the checklists by CAP inspectors in conducting laboratory inspections for the CAP's accreditation programs and by laboratories that are preparing for such inspections. Laboratories may upload their electronic checklists into a secure software system used for managing accreditation compliance. Laboratories may not provide the accreditation checklists to software providers for broader distribution.

Except as permitted by section 107 of the Copyright Act (17 U.S.C. section 107 – Limitations on exclusive rights: Fair Use), unauthorized use or distribution of the Checklists constitutes infringement of the CAP's copyrights in the Checklists. The CAP will take appropriate legal action to protect these copyrights. Individuals seeking to use the Checklists for other purposes must contact the CAP to request permission at checklistcomments@cap.org.

Checklist Components

The Checklists define the accreditation program requirements, often with additional language to explain a requirement, or to streamline the inspection process. Checklists are made up of the following elements:


- **Table of Contents:** List of the headings of each checklist in the order in which they appear.
- **Summary of Checklist Edition Changes:** List of new, revised, and deleted/moved/merged requirement numbers in each checklist.
- **Introduction:** Information included in the beginning of the checklist or a section of the checklist to help orient users to that checklist or section.
- **Definition of Terms:** A glossary of commonly used terms found in the Laboratory General, All Common, Director Assessment, and Biorepository Checklists.
- **Inspector Instructions: Read-Observe-Ask-Discover (ROAD):** An inspection tool that shows the inspector how to assess compliance through focusing on a group of related requirements rather than assessing each requirement individually. The ROAD instructions appear in the checklist version sent to inspectors and are also available in the Master versions of each checklist.
- **Requirements:** Specific elements that CAP-accredited laboratories must comply with to be eligible for accreditation.

Requirement Components

Every requirement includes a Requirement Number, Subject Header, Phase, and Declarative Statement. Many requirements also include a Policy/Procedure icon, a NOTE, Evidence of Compliance, and/or References.

Example Requirement

A GEN.41303 **B** Patient Confidentiality **C** Phase II

E  **D** The laboratory ensures that internal and external storage and transfer of data maintains patient confidentiality and security.

F *NOTE: Written procedures must address patient confidentiality during transfer of data to external referral laboratories or other service providers. This must include cloud based computing (eg, for storage of confidential data), as appropriate*

The laboratory must audit compliance with the procedures at least annually.

G **Evidence of Compliance:**
 ✓ Records of patient privacy audit for compliance with the Health Insurance Portability and Accountability Act (HIPAA)

H **REFERENCES**
 1) Title 45 – Code of Federal Regulations – Parts 160, 162, and 164, Health Insurance Reform: Security Standards; Final Rule, Federal Register, Published Feb. 20, 2003.

- Requirement Number:** Unique identifier assigned for each requirement made up of a three-letter checklist abbreviation followed by a five-number code (eg, GEN.23584).
- Subject Header:** Key words that identify the content of the requirement.
- Phase:** Designation used by the CAP's accreditation program to differentiate deficiencies based on the potential impact to the quality of services and the actions required when cited as a deficiency. The following chart summarizes the differences between Phase I and II deficiencies:

PHASE	DESCRIPTION
Phase II	<ul style="list-style-type: none"> • Requirements for items that may seriously impact the quality of services, endanger patients, clients, or personnel, or impact regulatory compliance • Citations require a written response of compliance and supporting documentation prior to accreditation
Phase I	<ul style="list-style-type: none"> • Requirements for items that may compromise the quality of services, but not endanger patients, clients, or personnel • Citations require a written response to the CAP indicating corrective actions, but do not require supporting documentation unless specially requested by the CAP

- D. **Declarative Statement:** One or more sentences that define elements required for compliance.
- E. **Policy/Procedure (P/P) icon:** A visual cue indicating that a written policy or procedure is required to demonstrate compliance with a specific requirement. All laboratory testing, functions, and/or processes must be defined in written policies and/or procedures.
- F. **NOTE:** Information that provides additional details to assist in interpreting the requirement. Information in the NOTE is considered integral to the requirement and must be complied with as part of the declarative statement itself, unless it is expressed as a best practice or a recommendation.
- G. **Evidence of Compliance:** List of suggested ways to demonstrate compliance with the requirement (eg, policies, procedures, records, reports).
- H. **References:** Resources, such as peer-reviewed journals, regulations, professional guidelines, and textbooks that may be helpful. This component is present in the Master version of the checklists.

Checklist Customization

Because no two laboratory sections or departments are the same, the CAP provides customized checklists for inspections. Customized checklists include requirements applicable to the activities (eg, tests, methods, and services) reported by the laboratory to the CAP.

The Laboratory General checklist is also customized based on the answers provided in the General Questionnaire at the time of application/reapplication. Laboratories that only perform certain types of testing (eg, waived only testing, slide/image interpretation only, Mohs only) will receive a reduced number of requirements tailored to the scope of the laboratory.

Laboratories performing Next Generation Sequencing (NGS) using the 2022 CAP Molecular Pathology Checklist and subsequent checklist editions will have an added level of customization. In addition to the CAP checklist customization process which includes or excludes content at the requirement-level based on the laboratory section's activity menu, an

enhanced NOTE-level customization allows for inclusion of the technical detail needed for specific NGS applications (inherited disease testing, oncology testing, infectious disease testing, histocompatibility testing) while right-sizing the content to what is relevant for a given laboratory.

These enhanced customization features benefit laboratories and inspectors by providing clear guidance that is relevant to the testing being performed. To ensure proper customization of a checklist, participants must:

- Carefully complete the Organization Profile including the General Questionnaire and activity menu **and**
- Update the General Questionnaire and/or activity menu on cap.org whenever testing changes occur.

Information on completing the activity menu or changing the activity menu can be found in the sections on [Applying to CAP Accreditation Programs](#) and [Maintaining Accreditation](#).

Downloading Checklists from cap.org

To stay current with changes to the checklist, the CAP encourages participants to download and review checklists at any time from the e-Lab Solutions Suite customer portal on the CAP website (cap.org). The website Master versions contain elements that are not found in the customized print versions mailed to accreditation participants that may be helpful, such as the References and Inspector Instructions (ROAD).

Accreditation participants have the following dropdown options through the portal:

- Section/Department – identify the area of interest
- Checklist Module – choose from different checklists used in that area
- Checklist Edition – select the desired checklist edition
- Checklist Type - select the Master, Custom, or Changes Only
- Checklist Format - choose from PDF, Word/XML, and Excel formats

The following table describes the different checklist types available:

Type	Features	Availability
Master	<ul style="list-style-type: none"> • Contains all requirements in the specified checklist • Includes references and inspector instructions • Useful when starting new types of testing or services 	<ul style="list-style-type: none"> • Accessed via cap.org (log-in required) • Available for purchase by non-participants in CAP accreditation

Custom	<ul style="list-style-type: none"> Includes only those requirements pertinent to the tests or services offered based on the section unit/department activity menu and the responses by the laboratory in the General Questionnaire Focuses attention on applicable requirements 	<ul style="list-style-type: none"> Accessed via cap.org (log-in required) Mailed to accreditation program participants for inspection preparation and performance of interim self-inspections Included in the inspection packet materials provided inspection team leaders
Changes Only	<ul style="list-style-type: none"> Contains only those requirements that have been changed, added, or deleted since the previous edition Quickly identifies changes to requirements in a track changes format 	<ul style="list-style-type: none"> Access via cap.org (log-in required)

Identifying Checklist Changes

There are four ways to identify checklist edition changes.

- **Summary of Checklist Edition Changes:** Following the Table of Contents in each checklist there is a listing of new, revised, and deleted requirement numbers. These requirements remain on the list for 18 months.
- **NEW and REVISED Flags:** Each new or significantly revised requirement is marked directly in the checklist with a “NEW” or “REVISED” flag and the date of the edition in which the requirement first appeared or was changed. The flags remain for 18 months.
- **Changes Only Checklist:** This checklist type may be downloaded from cap.org (log-in required). It shows what has been changed, added, or deleted since the previous edition in a track changes format.
- **Focus on Compliance Webinar Series:** The annual “Checklists Update” webinar provides information on the principal changes to each edition. Search for “Focus on Compliance” in the e-Lab Solutions Suite customer portal on the CAP website.

Assistance with Checklist Interpretation

For help or more information on accreditation checklist requirements and interpretation, contact the CAP’s LAP Technical Specialists:

- Telephone: 800-323-4040 or 847-832-7000
- Email: accred@cap.org
- Chat: The “Chat Now” button is located on the right side of the Contact and Support page on cap.org.

The LAP Technical Specialists are medical technologists (most with advanced degrees, certifications, and management experience) who can coach you in how to ensure compliance, as well as provide clarity on regulatory requirements. In addition to checklist knowledge, the

LAP Technical Specialists also offer expertise in checklist interpretation and deficiency response review.

CONDUCTING THE INSPECTION: GENERAL PRINCIPLES AND MEETINGS

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Beginning the Inspection

On the **day of inspection**, the team leader should:

- Plan sufficient time to conduct a thorough inspection. Inspections usually begin at 8 am.
- Contact the laboratory **one hour prior** to arrival using the one-hour security notice phone number provided in the inspection packet cover letter.
- Arrive at the predetermined time.
- For virtual inspections, sign into video-conferencing system early to allow for the meeting to begin on time.

Upon arrival at the inspection site, the team leader should:

- Present a photo ID to the facility representative (if requested)

- Present the announcement letter supplied by the CAP to the laboratory director or designee verifying that the inspection is to occur on that day under the direction of the team leader
- Introduce team members and give a brief overview of the day's schedule
- Request a brief tour of the laboratory.

General Principles: How to Inspect

Inspectors use the checklists and other tools included in the Inspector's Inspection Packet to conduct the inspection. A listing of the contents of the packet is included in the [Preparing for the Inspection: Inspection Team](#) section.

The Laboratory-Specific Activity Menu and instrumentation list help the inspector understand the type and scope of testing within each laboratory section. The inspection checklists are customized based on the activity menu and the responses in the General Questionnaire. Inspectors need to assess whether the listed activities match the laboratory's current testing (eg, compare with tests listed in the procedure manuals, ask about newly introduced tests). If testing is noted which is not included in the activity menu, inspectors should contact the CAP to obtain additional checklist sections or requirements that may be needed (refer to the [Inspecting Additional Activities, Disciplines, and Laboratories](#) section below).

Reviewing documents, observing to see if practice matches policy or procedure, and asking related questions all play an important role in obtaining accurate information about laboratory practices. Document review may occur in advance of the inspection if the laboratory has elected to upload select documents to CAP's Organization Profile. Refer to the [Inspection Options](#) section and cap.org for additional information.

Inspection team members should:

- Spend more time in the laboratory observing the testing process and asking questions of bench technologists and supervisors than in a room reading documents
- Continue inspecting while laboratory personnel retrieve needed records
- Rephrase the questions being asked until the request is understood by the laboratory
- Ask open-ended, probing questions that require more than a yes/no answer, such as "Could you explain how you track QC data?" or "Explain the system you use for..." or "How do you document...?". It is more effective than reading the checklist requirement out loud.

CAP inspection team members must avoid the following topics when inspecting a laboratory:

- Financials – discussion of the laboratory's finances or contracts
- Billing – discussion of the laboratory's billing practices
- Proprietary – discussion of the laboratory's contractual agreements
- Marketing – solicitation of the inspection team's services available to laboratories (eg, reference laboratory or consulting laboratory services).

Inspection Techniques

The CAP's online inspection training course describes a variety of inspection techniques that may be used when performing an inspection, including:

- “Following a specimen” through the laboratory is an effective technique to address preanalytic, analytic, and postanalytic aspects of laboratory testing. This process is generally followed by review of the laboratory’s documentation. This inspection technique allows the inspector to not only ensure that the laboratory’s paperwork is in order, but also to assess personnel knowledge of the laboratory’s processes.
- The “teach me” approach - The inspector selects an analyte or instrument and laboratory staff “teaches” the inspector about the procedure, process or instrument operation.
- Read-Observe-Ask-Discover (ROAD) provides a structure for inspectors to conduct an evaluation of a laboratory’s performance. ROAD icons are placed at the group level within the inspector’s copy of the checklists. The following icons flag specific instructions to the inspector:
 - **Read**/review documentation
 - **Observe** procedures/techniques
 - **Ask** probing questions
 - **Discover** the path of a process.

Samples of ROAD instructions:



Read and review policies, procedures, and records that must be looked at during the inspection.

For example:

- Review the error/accident log; do not simply verify that the laboratory has such a log.
- Review a sampling of the transfusion reaction workups for the past two years.



Observe laboratory practices by watching laboratory personnel in action.

For example:

- Observe a phlebotomy from receipt of requisition to delivery of the specimen to the laboratory.
- Note if practice deviates from the written policies/procedures.



Ask open-ended, probing questions. This will allow you to:

- Obtain information in their own words, not yours
- Improve your understanding of records and observations
 - Assess the laboratory’s interpretation of the requirements. For example, use questions that begin with phrases, such as:
 - “Show me how ...”
 - “Tell me about ...”
 - “What would you do if ...?”

The combination of direct observation and probing questions helps to ensure that:

- Outcomes for any problem areas have been adequately investigated and resolved

(eg, proficiency testing (PT) failures and issues/problems identified through the quality management process).

- Previously cited deficiencies have been corrected.



Discover additional facts by digging more deeply into one or two areas of special interest. For example, track a selected specimen from collection to reporting. This will cover elements in multiple checklist requirements such as:

- The specimen collection manual
- Phlebotomy
- Verbal orders
- Identification of patients and specimens
- Accessioning
- Result reporting, including
 - Appropriate reference ranges
 - Retention of test records
 - Maintaining confidentiality of patient data
 - Proper handling of critical results and revisions to reports

What to Look at

Inspectors review relevant documents, such as:

- Procedure manuals
- Quality management system (QMS) documents
- Quality control (QC) records
- Proficiency testing (PT) records
- Instrument maintenance and function check records
- Test method validation and verification studies
- Calibration, calibration verification, and analytical measurement range verification records
- Method comparison records
- Interim self-inspection records
- Competency assessment
- Delegation of responsibilities.

The Inspector's Inspection Packet contains the following tools to help focus inspection efforts and identify areas of concerns:

- **Previous Inspector's Summation Report** – includes the list of deficiencies from the previous inspection for the inspector to confirm that all previous deficiencies have been appropriately addressed to identify recurring deficiencies. Starting with inspections conducted with the 2022 checklist edition and subsequent editions, information on previously cited deficiencies will also appear in each inspector checklist.
- **Proficiency Testing Performance <100% Report** (if applicable) - lists by analyte, all PT scores below 100% during any of the last six testing periods. For each failure, inspectors should:
 - Confirm that the laboratory has conducted an investigation promptly after receiving

- the PT report
- Review the testing records to confirm that samples were handled and reported in the same manner as patient samples
- Review the records for the event following PT failures to confirm that testing personnel followed the policies and procedures as written. Look for inappropriate actions such as duplicate testing of PT samples.
- Confirm that the PT results have been reviewed by the laboratory director or designee in a timely manner.

NOTE: The Proficiency Testing Performance <100% Report is not intended to demonstrate a laboratory's enrollment in CAP-accepted PT, as it only includes information on analytes where proficiency testing performance has been less than 100% in at least one of the previous six mailings. Analytes that have had 100% performance in the previous six mailings will not be listed on the report.

How Much to Look at

The review of records, forms and documents is intended to cover a **full two-year** time frame. Inspectors of laboratories undergoing an initial CAP inspection should review records from the time of their application through the inspection date to look for a pattern of compliance with CAP requirements.

Because there is not sufficient time to look at all records, inspectors must use a sampling strategy. Inspectors should:

- Consult the Laboratory-Specific Activity Menu and selectively focus on areas of highest and lowest test volume, common problem areas, and test results with the highest impact on patient care since the last inspection.
- Refer to the laboratory's quality management and incident report records to aid in selection of analytes to review
- Review a representative sampling of analytes or procedures to include:
 - Data selected from the beginning, middle, and end of the interval since the last inspection
 - Records in the pre-analytic (order entry and specimen collection, processing and transport), analytic (procedures, QC, PT, instrument setup, and maintenance), and post-analytic categories (reports, reference intervals, and critical value notification); if problems are discovered, review similar records for additional analytes.

Inspecting Additional Activities, Disciplines, and Laboratories

If the inspection team discovers that testing is being performed under the same CLIA number that is not listed on the Laboratory-Specific Activity Menu, the inspection team leader or member should:

- Contact the CAP immediately
- Advise the CAP whether a member of the inspection team has the expertise to inspect the discovered discipline or activities

- Verify that the laboratory is enrolled in appropriate PT for these analytes/activities.

Once notified, the CAP will immediately:

- Determine if inspection of the discovered activities may proceed
- Fax or email a customized checklist to the team member (as needed).

After receiving instructions from the CAP, the inspector should indicate in the Inspector's Comments section of Part A of the ISR if the activity/discipline in question has been inspected.

Laboratories that perform testing under a **different CLIA number** or laboratories that are under separate administrative and professional direction (eg, blood gas laboratory or pediatric hematology laboratory) and have not applied in advance for inspection **must not be inspected unless indicated in the inspection packet to do so**. The inspector should advise the laboratory director to submit a formal application to the CAP if indicated. The CAP will schedule an inspection at a later date. Contact the CAP with any questions regarding the laboratory to be inspected.

Using the Checklists

Each discipline has its own checklist (such as Hematology (HEM)), which is used along with the All Common (COM) to inspect each laboratory section.

One copy of the Laboratory General Checklist (GEN) is provided to each inspection team. While this checklist may be assigned to one inspector, each inspector should verify compliance with the safety and physical facility requirements for their designated areas and report findings to the assigned GEN inspector.

Inspectors should focus on groups of requirements using the ROAD instructions included within the checklist and other inspection techniques mentioned above instead of going through the checklist requirement by requirement.

The Evidence of Compliance (EOC) section of a checklist requirement lists suggested ways to show compliance; some elements are required. The word "AND" in the list indicates that more than one element may be needed to demonstrate compliance. For example, the EOC for COM.01500, Alternate Performance Assessment reads:

- List of tests defined by the laboratory as requiring alternative performance assessments **AND**
- Records of these assessments.

If the intent of a checklist requirement is not clear, inspectors may contact the CAP for clarification prior to or during the inspection by email at accred@cap.org, or phone at 800-323-4040 ext. 6065 or 847-832-7000, during the hours between 8:00 AM to 5:30 PM CST.

Inspection of Patient Care Areas

During the course of the inspection, some team members will visit patient care areas when

appropriate based on current CAP or facility safety measures. Examples include:

- Observation of transfusion of blood components issued by the laboratory
- Point-of-care testing (if under the laboratory's CAP/CLIA number)
- Observation of phlebotomy blood draws performed by laboratory staff
- Observation of arterial blood gas specimen collection and testing.

Meeting with direct health care providers and observing the tests and procedures they perform can help inspectors determine compliance with checklist requirements and evaluate oversight of those services.

The visit should include:

- Review of laboratory records within the patient medical record
- Assessment, through interviews, of laboratory responsiveness to clinical needs
- Identification of concerns to be communicated to the laboratory director.

If performing a virtual inspection, the use of cameras is not secure and should not include patient care areas. Discuss these areas with staff instead of visiting via conferencing system.

Using the Director Assessment Checklist

The team leader or team member who is qualified and trained to be a team leader must complete the Director Assessment Checklist (DRA). This checklist:

- Evaluates the qualifications of the laboratory director and the effectiveness of the laboratory director in implementing the *Standards for Laboratory Accreditation* including requirements to evaluate the overall performance characteristics of the laboratory. Assists the team leader to recognize and document systemic problems with the laboratory's QMS.
- Contains instructions for conducting interviews with the laboratory director, hospital administrator/chief executive officer (CEO), and representative of the medical staff.
- Focuses upon those aspects of the laboratory that are at the core of quality: the laboratory director's responsibilities, the QMS, and the laboratory's relations with the institutional medical staff and administration.

The interviews conducted by the team leader with the laboratory director, hospital administrator/CEO, and representative of the medical staff provide some of the information needed to complete the inspection with the DRA Checklist. The interviews may be conducted in-person or virtually. They are an essential part of the inspection. If, for any reason, an interview cannot be conducted, the team leader should report the circumstances in the Inspector's Summation Report (ISR).

The team leader may record information from these interviews in Part A of the ISR. Deficiencies, if found, are to be cited on the DRA Deficiency page of the ISR.

Meeting with the Laboratory Director

Meeting with the laboratory director helps determine if the laboratory director has sufficient responsibility, authority, and involvement in the operations of the laboratory. The inspector should allow at least 15 to 20 minutes for the meeting. If the laboratory director is not present for the inspection, the inspector should try to conduct this interview by telephone or other means. Conversations with technical staff, administration, and the representative of the medical staff may be used to validate the laboratory director's involvement.

The interview is an opportunity to:

- Evaluate the laboratory director's activities as listed in the DRA Checklist and the *Standards for Laboratory Accreditation*
- Review any problems that the inspection might serve to resolve (eg, workspace issues, staffing shortages)
- Determine if the laboratory director also functions as a technical supervisor, clinical consultant, general supervisor, or as one of the testing personnel.

Meeting with the Hospital Administrator/Chief Executive Officer (CEO)

Meeting with the hospital administrator/chief executive officer (CEO) provides an opportunity to extend the CAP's appreciation for the facility to participate in the accreditation program and to record an evaluation of the laboratory from the administration's viewpoint.

The team leader should allow approximately a 15 to 20 minute discussion and should understand the laboratory's operations beforehand.

For hospital laboratory inspections, the team leader may find it useful to meet with the institutional quality assurance manager (sometimes called the quality/risk manager). This individual may have insights into the laboratory-related, patient care issues.

For independent laboratories, the team leader should meet with an executive from the parent organization.

The interview is an opportunity to:

- Ascertain the administration's perception of the laboratory service (eg, if the laboratory service level is appropriate to the requirements for the institution)
- Discuss administration's view of the laboratory director's role in ensuring high-quality laboratory services to fulfill the needs of the institution's patients and clinicians
- Determine if the institution gives the laboratory director the authority to fulfill the laboratory director's responsibilities under the CAP and CLIA
- Inquire to what extent the pathologists participate in hospital-wide committees
- Determine how effective pathologists are in working with the medical and administrative staffs

- Identify areas of conflict or challenges confronting the laboratory that are known to administration.

Discussion points during the interview should include:

- The goals of the CAP's accreditation programs: education, laboratory improvement, and the establishment of best practices in laboratory medicine based on input from national experts
- The role of PT in the program
- The responsibility of the laboratory director for the overall operation of the laboratory, per the requirements of the CAP's accreditation programs and CLIA regulations
- Express appreciation that the organization has chosen the CAP as its laboratory's accreditation provider.

The interview should include a discussion of all laboratories being inspected (eg, point of care, special function and satellite laboratories). **The CAP prohibits discussion of the laboratory's financial and/or contractual arrangements.** If the laboratory hospital administrator/CEO is not present for the inspection, the inspector should try to conduct this interview by telephone or other means.

For facilities participating in the **Biorepository Accreditation Program**, the team leader may choose to interview a member of administration if available, but this step is not required. Interviews may be conducted via telephone or other means if an in-person interview is not possible.

Meeting with a Representative of the Medical Staff

Meeting with a representative of the medical staff can provide an opportunity to determine whether the laboratory director and laboratory staff have an established working relationship with the medical staff and are effectively supporting patient care. For laboratories associated with organized medical staff, it is important for the team leader to interview the chief of the medical staff (or other knowledgeable medical staff representative, such as the chief medical officer or a physician who uses the laboratory's services frequently). The team leader should allow for a 15 to 20 minute discussion and should understand the laboratory's operations beforehand.

The interview is an opportunity to:

- Evaluate the effectiveness of the scope, quality, and timelines of the laboratory services to meet the patient care needs of the hospital
- Assess the contribution of the pathologists and laboratory staff to teaching conferences and meetings
- Determine how well the medical staff and pathologists work together to resolve problems
- Judge the medical staff perception of the effectiveness of the laboratory director and other pathologists
- Determine if the laboratory director has sufficient authority to fulfill the needs of the

medical staff and their patients.

Citing Deficiencies

Inspectors must cite deficiencies when the intent of a checklist requirement is not being met. Inspectors should not expect the laboratory to do things exactly as they are performed in the inspector's facility. However, when the laboratory's processes or procedures are not in compliance, deficiencies must be cited.

Examples include:

- When a required policy or procedure does not exist
- When the written policy or procedure is not being followed
- When results or corrective actions are not recorded
- When a required record of review does not exist
- When the procedure is ineffective or inappropriate laboratory practice is in place
- When the records are incomplete or missing
- For **any** non-compliance issues related to personnel qualifications, proficiency testing, QC/QA, and director oversight.

When records are incomplete, inspectors should:

- Determine whether the degree of partial compliance is likely to have adverse effects on test accuracy, patient care, or worker safety
- Determine if laboratory staff was aware of the inconsistency
- Look for evidence of corrective actions.

Deficiencies are also cited when systemic problems exist. For example, when a pattern of missing temperatures on the weekend without corrective actions is evident, then a deficiency must be cited. When systemic or serious issues are identified, the inspection team members must bring them to the attention of the team leader, who will determine if a deficiency needs to be cited from the DRA Checklist for the related laboratory director responsibility.

Examples of serious or systemic issues include:

- QMS not implemented across the laboratory
- Inconsistent quality control and corrective action
- Improper handling of proficiency testing materials or lack of follow-up for unacceptable results
- Lack of validation or verification records for new tests or instruments
- Unsafe practices compromising the safety of personnel
- Duties delegated by the laboratory director not being effectively performed
- Write the checklist item number and checklist requirement phase, followed by a brief description of the reason for the deficiency
- Provide specific details about the nature of the non-compliance with stated examples (eg, dates involved, analytes affected, instruments or kits used, name of record or probation, etc.), whenever possible and not just restate the checklist requirement as

- written
- Write/print legibly.

When the inspector and the laboratory representative interpret a checklist item differently, they are encouraged to **call the CAP’s technical support line at 800-323-4040 or 847-832-7000 during the inspection.**

A three-way dialogue between the inspector, laboratory, and accreditation program technical specialist often helps clarify the intent of the checklist item. Contacting the CAP can result in fewer improperly cited deficiencies and laboratory deficiency challenges post-inspection.

Deficiencies Corrected During Inspection

Some deficiencies may be corrected while the inspectors are still on site. **Correction during inspection is a relatively rare occurrence** and includes minor corrections, such as signing one or two procedures, inserting minimal changes in a procedure, or writing a policy to match existing practice. **In all cases, inspectors must cite the deficiency and indicate on the Deficiency form (ISR pink sheet) how the deficiency was corrected.**

Other more extensive deficiencies cannot be corrected during inspection. Examples include:

- Lack of a Quality Management System
- Lapse in performance or review of QC or proficiency testing, or implementation of a new or significantly changed procedure
- A change to a process, policy, or procedure that requires additional training or retraining of personnel
- When previous patient results must be evaluated for impact to patient care (eg, when expired reagents are found to be in use or when incorrect result calculations are identified)
- Recurring deficiencies.

Deficiencies corrected during inspection are deficiencies and will remain in the laboratory record. The CAP may request documentation from the laboratory concerning how a deficiency was corrected during inspection; for Phase II deficiencies, both a corrective action plan and evidence to support implementation may be requested.

Recommendations

Recommendations are considered suggestions for laboratory improvement and are listed on the “Recommendations” **yellow** page of the ISR. Recommendations may be given in the following situations:

- When a laboratory is in compliance, but can improve its process
- When an inspector has a suggestion that does not pertain to a specific checklist requirement.

Recommendations may not substitute for deficiency citations if the laboratory is not in compliance. Laboratories are not required to take corrective action in response to recommendations, *unless* requested to do so later by the CAP. Based on the information provided with the laboratory's response, recommendations may be converted to deficiencies.

The following are examples of recommendations:

- "List the acceptable ranges of temperature dependent equipment on recording logs in addition to the maintenance procedure to allow staff to easily identify variances"
- "Store personnel competency records in a centralized location rather than have portions of the records in multiple sections"
- "Standardize document control processes across all sections of the laboratory."

Recommendations are recorded on the designated **yellow** pages of the ISR. Inspectors should:

- Write the checklist number and checklist requirement phase (if applicable), followed by the recommendation
- Write or print legibly
- Discuss the recommendation with the laboratory personnel prior to the Summation Conference.

Recommendations need not be presented at the Summation Conference. In situations where there are a large number of deficiencies, it is recommended that the team focus on the deficiencies and not present the recommendations because this can lead to confusion and cause the summation conference to be unduly long.

Completing the Inspector's Summation Report (ISR)

The Inspector's Summation Report (ISR) is used to record the findings of a CAP inspection. It consists of two parts.

- **Part A- General Summary-** used to report any fundamental disparities between the intent of the *Standards* and the activities of the laboratory and of the role of the laboratory director. The inspector's confidential comments, listed in Part A, are pivotal in accreditation decisions, particularly those relating to denial of accreditation. This narrative section is completed by the Team Leader with input from all team members. The Team Leader provides explanatory comments in the ISR Part A regarding unexpected testing encountered, as well as inappropriate checklists included in the packet.
- **Deficiency Summary-** includes the Signature Page, Deficiency forms (pink pages), and Recommendation forms (yellow pages). The laboratory director and team leader sign the Signature Page at the conclusion of the inspection to attest that the laboratory received a copy of the ISR. Each Deficiency form includes space to record detailed comments to support the cited deficiencies and an attestation statement to be signed by the inspector.

Tips for completing the ISR:

- The Team Leader provides explanatory comments in the ISR Part A regarding unexpected testing encountered, as well as inappropriate checklists included in the packet.
- Team member inspectors should only use the assigned ISR pages for each discipline. It is not appropriate to cross out sections or include additional checklist titles on the ISR pages. An extra (blank) pink page may be found at the end of the ISR packet and copied as needed to record additional deficiencies.
- Each inspector must complete the bottom of the deficiency form attesting to the completeness of the inspection, the confidentiality of information, and the lack of a conflict of interest.
- If multiple inspectors participated in the inspection for the same discipline/checklist, additional members can sign the form.
- If corrections need to be made to remove a deficiency (eg, appropriate records have been provided to show that the laboratory was in compliance), the deficiency should be redacted from the pink page using a single strikethrough line, initialed and dated by the inspector.
- If the deficiency was corrected during inspection, the inspector should write “corrected during inspection” next to the deficiency and describe how the laboratory corrected the deficiency.

NOTE: If serious deficiencies or systemic issues are identified or any question from Part A is answered “NO”, the Team Leader must ensure that the appropriate Laboratory General or section-specific checklist requirements relating to the issue are cited, as well as the DRA Checklist requirement(s) related to laboratory director responsibility.

Pre-summation Team Meeting

The pre-summation team meeting begins with the pre-summation preparation, a 30 to 60 minute private meeting between the team leader and the inspection team members. The goals of the meeting are to ensure that the written inspection reports are complete, that the reports are consistent across the team, and that their oral summaries will reflect the written report.

During the meeting, the team leader should:

- Resolve team member questions
- Ensure consistency in recording similar findings (eg, deficiency versus recommendation)
- Identify serious deficiencies that may jeopardize patient care and systemic problems where inspectors cited the same or related deficiencies in multiple laboratory sections.

Before concluding the pre-summation meeting, the Team Leader should ensure that:

- All areas of the laboratory have been inspected
- Every inspection team member has completed (pink) deficiency and (yellow)

recommendation forms that correspond to the laboratory section(s) for which he/she is responsible and have provided contact information on the back of the appropriate forms

- Each pink and yellow copy has been signed and dated by the respective inspection team member attesting that the inspector has no conflict of interest and that all relevant checklist requirements have been evaluated
- Appropriate checklist items have been cited and the correct deficiency numbers are listed on the pink deficiency sheets
- Any changes that may have occurred during the pre-summation conference (additions or deletions in deficiencies) are communicated to the appropriate laboratory representatives
- The **“This laboratory section has no deficiencies”** box and/or **“No recommendations for this section”** box have been checked as applicable
- No deficiency (pink) or recommendation (yellow) page is missing or has been left blank or unsigned
- All deficiency and recommendation pages have been accounted for by comparing the completed pages to the list that appears on the pink inspector Summation Report (ISR) Page Index. If the inspector is concerned that a provided checklist is not needed, the CAP must be contacted prior to marking any ISR page “not used.”

The Summation Conference

The summation conference may be the most important part of the inspection. It is the final opportunity for interaction between the inspection team, the laboratory staff, and administration.

The summation conference in coordination with the laboratory should be scheduled for a time when personnel involved in the inspection can attend, such as the end of the workday. The inspection team should identify areas that require improvement, share information regarding how other laboratories accomplish compliance, and make recommendations for changes to patient care services.

Attendees should include the:

- Laboratory director
- Key laboratory personnel
- Hospital administrator
- Chief of the medical staff/medical staff representative, if applicable.

At the start of the summation, the team leader should state the objective of the CAP’s laboratory accreditation programs. Talking points include:

- The College of American Pathologist Laboratory Accreditation Program seeks to improve laboratory medicine for the benefit of patients through voluntary, educational, peer review
- Regulatory requirements must be met, but these are not the only goals of the program
- The primary objective is not to find deficiencies, but to assist the laboratory in validating

its ongoing process and assessing their compliance with CLIA and CAP checklist requirements.

The laboratory should encounter **no surprises** when the inspection report is presented. To ensure this, it is critical for inspectors to have discussed their findings with the supervisors during the inspection and/or at the conclusion of each section.

Each team member should:

- Begin with a brief self-introduction and word of thanks for the staff that assisted them in the inspection process
- Present the inspection findings in a brief and professional manner, including the deficiencies identified and areas where the laboratory did particularly well
- Allow time to answer questions from the laboratory team.

The summation conference is also an appropriate time to:

- Report any unresolved differences regarding the interpretation of the *Standards* or checklist requirements. Unresolved differences should be noted by the Team Leader in Part A of the ISR
- Recognize any positive aspects of the laboratory encountered during the inspection.

Talking points for the team leader at the close of the summation conference:

- Approximate the total number of checklist requirements that were used to inspect the laboratory so that those in attendance can put the number of identified deficiencies into perspective.
- Explain that deficiency responses, documentation of corrective action, and documentation of the laboratory director's signatory approval of the responses are to be **submitted to the CAP within 30 calendar days of the inspection date**. An accreditation decision usually takes approximately 75 days after the inspection.
 - Phase I deficiencies require a written response.
 - Phase II deficiencies require a response, a plan of corrective action, and supporting documentation that demonstrates implementation.
 - Deficiencies corrected during inspection do not require a response but are counted as deficiencies.
- Express the team's gratitude and extend congratulations to the laboratory and the staff for participation in the program and their work in preparing for and participating in the inspection. Acknowledge the hospitality and cooperation of the staff during the process.
- Thank the laboratory director for supporting the CAP accreditation program.
- Recognize the contributions of pathologists that help contribute to the quality of the laboratory.
- Explain that the copy of the handwritten Inspector's Summation Report Form left at the end of the inspection (not including Part A comments) is the official report from the CAP. There will be no printed list of deficiencies sent from the CAP to initiate the laboratory's corrective action and response to the CAP.

It is not necessary to present DRA deficiencies at the Summation Conference if they were previously discussed with the laboratory director.

Concluding the Inspection

The team leader has several additional responsibilities immediately after the summation:

- **The laboratory director and the inspection team leader must both sign page 3 of the ISR Part A Deficiency Summary Signature Page.**
- Arrange for the inspection checklists, other documents that were used during the inspection, and any remaining inspection materials to be discarded confidentially (eg, immediately shredded). All materials **except** the list of previous deficiencies may be left with the laboratory to shred. The list of previous deficiencies contains the Part A confidential comments from the previous inspection team leader and therefore should not be left at the laboratory.
- Ensure that the Inspector Comments section of Part A of the ISR includes:
 - The team leader's opinion of the quality of the laboratory and ability of the laboratory to maintain continuous compliance
 - Issues of disagreement between the inspector(s) and the laboratory staff
 - Anything else that may impact the accreditation decision.
- Ensure that each page of the ISR has been photocopied and left with the laboratory director except for pages 1 and 2 of Part A (do not leave Part A comments). These pages are only returned to the CAP and are confidential.
- Provide the envelope that contains the deficiency response instructions to the laboratory director or designee.

If the inspection team discovers that they forgot to cite a deficiency after the inspection, the team leader must notify the CAP immediately upon this discovery and provide details of the deficiency in writing.

AFTER THE INSPECTION: INSPECTION TEAM

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Process for Returning the Inspector's Summation Report

All deficiency (pink) and recommendations (yellow) Inspector's Summation Report (ISR) pages (except for the "extra" page), along with pages 1-3 of the ISR Part A and the ISR Index Page must be returned in the mailing envelope provided. The mailer has a United Parcel Service (UPS) prepaid label and can be used in the 48 contiguous states.

- For laboratories located in the US, except Hawaii and Alaska, the ISR must be returned within two business days after the inspection.
- For all other inspections, the ISR must be returned within two days after returning to the contiguous 48 states.
- For non-routine inspections and any inspection that has identified significant, concerning issues, the ISR must be returned within 24 hours.

Returns can be:

- Sent from the team leader's facility mail center for pick-up by UPS
- Given to any UPS driver making a regular pickup
- Taken to any UPS authorized shipping location.

To locate the nearest UPS location or to arrange for a special pickup, either access the UPS website (www.ups.com) or call 1-800-PICK-UPS (800-742-5877).

For shipping internationally, the following options should be considered:

- Searching the ups.com website
- Calling 1-800-782-7892
- Contacting an alternative local carrier that ships to the US.

The Claim for Inspection Reimbursement and the Team Leader/Member Evaluation forms may be returned to the CAP with the ISR or within 90 days.

Claim for Inspection Reimbursement

Return of the completed ISR must not be delayed while waiting for the collection of expense claims because this can delay the accreditation process for the inspected laboratory.

The Claim for Inspection Reimbursement form includes instructions for expenses that are reimbursed, maximum allowable expenses, and receipt requirements. Reimbursement claims should be submitted within 90 days of the inspection.

Team Leader and Team Member Evaluation Forms

Critique of the inspection process and experience by both team leaders and team members is essential feedback for the improvement of the accreditation programs. Team leaders should complete the Team Leader Evaluation questionnaire and each member of the inspection team should complete a Team Member Evaluation questionnaire.

Remaining Inspection Materials

Any remaining inspection packet materials, including checklists, must be discarded. Laboratory-specific information must be shredded to maintain confidentiality.

Inspector Feedback Process

To improve the quality of inspections, the CAP provides inspection team leaders with feedback on the performance of their inspection team once the inspected laboratory has completed the post-inspection review process and the accreditation decision has been made. This feedback includes, as applicable:

- Comments from the inspected laboratory
- Information on trends noted based on expungement of any deficiencies
- Information on conversion of recommendations to deficiencies
- Other comments identified during the post-inspection review of the inspection findings and corresponding laboratory responses.

Feedback may be provided to the team leader via mail, email, or phone call. The team leader should share the information with their team.

AFTER THE INSPECTION: LABORATORY

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Responding to Deficiencies

Before the inspection, the laboratory will receive a Laboratory Inspection Packet that contains instructions for online submission of responses to any deficiencies cited during the inspection. In the event an online submission is not an option, contact the CAP headquarters at 800-323-4040 or 847-832-7000.

At the conclusion of the inspection, the inspection team will give the laboratory:

- A blue envelope containing instructions for responding online to deficiencies cited
- A copy of the Inspector's Summation Report (ISR) listing the deficiencies and recommendations.

The deficiencies will be available online approximately one week after the inspection once the ISR is processed by the CAP. The laboratory may enter the cited deficiencies after the inspection if the laboratory does not want to wait for the ISR to be processed by the CAP. Laboratories undergoing their initial inspection must have their deficiencies entered by the CAP. Laboratories can print a typed replica of the inspection findings by logging into cap.org in e-Lab Solutions Suite under Accreditation-Accreditation Reports-Inspection Summary Report. **The laboratory must submit appropriate responses electronically to the CAP within 30 calendar days** of the inspection by logging into cap.org in e-LAB Solutions Suite under Deficiency Responses. Failure to respond may result in denial or revocation of accreditation.

Phase I deficiencies require a response that describes the corrective action taken. Supporting documentation of deficiency correction is not required unless specifically requested by the CAP.

Phase II deficiencies require a response and supporting documentation to demonstrate that the laboratory is now in compliance. Responses should explain the purpose of each document

submitted. Deficiencies noted as “corrected during inspection” require the laboratory to either approve or challenge the deficiency.

Examples of supporting documents for Phase II deficiencies include:

- New or revised policies or procedures with evidence of the laboratory director’s review and approval (with the portions pertained to the deficiency underlined or otherwise indicated)
- Quality control, calibration, maintenance records, and instrument printouts
- Log sheets with recorded data (blank log forms are unacceptable)
- Purchase orders, work orders, photos, diagrams, and floor plans
- Evidence of staff review or retraining on new, revised, or existing procedures.

Recommendations are suggestions for improvement, and the laboratory is not obligated to implement or respond to them. **NOTE: A recommendation that should have been cited as a deficiency during the inspection will be changed to a deficiency after the inspection, and the laboratory will be required to respond. Recommendations that have been converted to deficiencies will be listed on the Accreditation Letter that is sent to the laboratory by the Regional Commissioner.**

Protected health information (PHI) must be redacted from submitted documents in accordance with HIPAA requirements. The following patient data must be de-identified prior to submission:

- Name
- Address
- Any elements of dates, excluding the year, for dates directly related to an individual, including birth date, admission date, discharge date, date of death
- Telephone numbers
- Fax numbers
- Email addresses
- Social Security number
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Biometric identifiers, including finger and voiceprints
- Device identifiers and serial numbers
- Certificate or license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Web Universal Resource Locators (URLs)
- Internet protocol (IP) addresses
- Full-face photographs or comparable images
- Any other unique identifying number, characteristic, or code.
-

Challenging a Deficiency

The laboratory may challenge any deficiency cited by the inspection team. The intention to challenge a deficiency must be clearly stated within the response. This can be accomplished

by:

- Indicating the challenge within the submitted online deficiency response
- Providing an explanation for the challenge within the response
- Uploading a document in the online deficiency response to support the claim that the laboratory was in compliance at the time of the inspection.

Supporting documentation is required for challenges to both Phase I and Phase II deficiencies. **Challenges must be made at the time initial responses are submitted.** Submission of records modified or created on the date of or after the inspection are not adequate to support a challenge to a deficiency.

Acceptance of a challenge and subsequent deficiency removal is at the discretion of the reviewing commissioner. If the challenge is not accepted, additional documentation showing correction of the deficiency may be required, and the deficiency will appear in the final list of deficiencies included in the accreditation packet. Deficiencies that have been approved for removal by the reviewing commissioner will not appear on the final list of deficiencies and are not part of the permanent inspection record. **Challenges to deficiencies will not be accepted after the accreditation decision has been made.**

Deficiencies Corrected During the Inspection

Deficiencies corrected during inspection will remain in the record as deficiencies. The CAP reserves the right to request documentation from the laboratory demonstrating how a deficiency was corrected during inspection. For Phase II deficiencies, both a corrective action plan and evidence to support implementation may be requested.

Deficiency Response Review

After the inspection, the laboratory director must ensure that:

- Responses for each deficiency are submitted online to the CAP within 30 calendar days of the inspection date
- Any resolved differences and challenges to the deficiencies cited are addressed in the laboratory's deficiency response. This includes supporting documentation to demonstrate that the laboratory was in full compliance at the time of the inspection.
- The electronic deficiencies are approved and submitted
- A copy of all deficiency responses is kept on file.

The CAP performs the remaining steps of the accreditation process:

- Using the information provided by the inspector, a technical specialist evaluates the deficiency responses for appropriateness and completeness.
- If additional information is needed to evaluate compliance, a request for documentation is sent to the laboratory via email. The laboratory is expected to respond online within 10 days of the initial request.

The assigned CAP reviewing commissioner will also review the responses. The reviewing

commissioner:

- Evaluates the acceptability of each response
- May request additional information from the laboratory prior to making an accreditation decision
- Determines whether challenged deficiencies will be removed
- May change a recommendation to a deficiency (if warranted)
- May add a deficiency based on comments that were included in the Part A Summary if the laboratory was clearly not compliant at the time of the inspection
- Makes an accreditation decision recommendation to the Accreditation Committee
- Notifies the laboratory that accreditation is recommended.

Immediate Review Criteria (IRC)

The CAP Laboratory Accreditation Programs have established criteria for expedited processing by the CAP staff and the reviewing commissioner. Immediate review occurs when a laboratory is cited for deficiencies on more than 2.5% of the total applicable Phase II requirements or when a directorship issue is cited.

Since laboratories with many deficiencies may have difficulties addressing all within the 30 day limit, the reviewing commissioner may:

- Communicate with the laboratory director and the state commissioner to determine if correction is possible
- Recommend to the Accreditation Committee a focused re-inspection of the problem areas
- Recommend probation, suspension, or denial of accreditation.

Accreditation

The Accreditation Committee grants accreditation when the laboratory has provided acceptable responses to Phase I and Phase II deficiencies and satisfactorily documented correction of all Phase II deficiencies. Laboratories granted accreditation may be required to meet additional requirements to maintain accreditation, such as:

- Submitting records at defined intervals supporting ongoing correction of deficiencies
- Undergoing a successful nonroutine inspection within a specified time-period to confirm ongoing compliance
- Undergoing a successful routine in-person inspection after a virtual inspection within a specified time-period to complete the full accreditation cycle.

For laboratories with too many deficiencies to be corrected within a reasonable period, the Accreditation Committee may place the laboratory on probation or decide to deny or revoke accreditation. Refer to the [Probation Categories](#) section below for more information.

Once the Accreditation Committee makes an accreditation decision, the CAP will mail an accreditation packet to the laboratory. The accreditation packet includes:

- The accreditation certificate and accreditation letter to the laboratory director (with copies of the letter to the administration where applicable)
- Letter of accreditation that specifies the CAP-accredited disciplines/sub-disciplines, CMS specialties/subspecialties, and requirements for continued accreditation
- Final list of deficiencies
- Press release (including instructions on how to use the CAP accreditation mark).

Accreditation is valid for two years from the date of the initial inspection and is renewable every two years on the accreditation anniversary date. Should accreditation processing go beyond the accreditation’s anniversary date, the state of the laboratory’s accreditation remains unchanged until that decision is made. During this period, if a laboratory receives requests from an outside entity to demonstrate continuing accreditation, a letter may be obtained from the CAP to verify its accreditation status.

Laboratories should **retain the final list of deficiencies on record for review by other accrediting agencies** (eg, The Joint Commission). The final list of deficiencies is also provided to the next inspection team to confirm continued compliance.

Post-inspection Critique

After the inspection, the CAP sends the laboratory director a Post-inspection Critique questionnaire. This questionnaire:

- Serves as an ongoing quality assurance tool for the inspection process
- Is used by the CAP to make continuous improvements at every level.

The laboratory director is strongly encouraged to solicit feedback from laboratory personnel who participated in the inspection, and to return the questionnaire to the CAP within three months of the inspection.

Probation Categories

The Accreditation Committee may place a laboratory on probation or any section of a laboratory on suspension. During probation, a cited laboratory or section is allowed to provide testing as an accredited laboratory. A suspended section is not allowed to provide accredited testing. When a probation or probation with suspension decision is made, agencies that recognize CAP accreditation, including, but not limited to, the Centers for Medicare and Medicaid Services (CMS) and The Joint Commission are notified. The laboratory will remain on probation until the Accreditation Committee removes the probationary status.

Probation may occur for conditions that do not appear to pose a substantial risk of harm to patients or to laboratory personnel, for instance:

- Available facts are insufficient to determine compliance
- The Accreditation Committee wishes to monitor the progress of deficiency correction
- Laboratory conduct is contrary to the policies of the CAP

- The Accreditation Committee has denied or suspended the accreditation of specific sections of a laboratory.

Probation with Immediate Jeopardy may occur for conditions that demonstrate potential serious adverse effects on safety to the public and/or laboratory staff and immediate action is warranted, such as:

- Lack of laboratory director oversight
- Patient/specimen identification issues
- QC issues that place patients at risk
- International normalized ratio (INR) issues.

Laboratories placed on probation with immediate jeopardy are given five business days to satisfactorily correct the deficiencies. The Accreditation Committee will review the laboratory's response and reconsider the accreditation status. This may result in revocation.

Probation with Suspension may occur if any of the following conditions is present:

- The laboratory has deficiencies that pose a substantial risk of harm to patients or to laboratory personnel, and the Accreditation Committee needs time to evaluate the situation further or concludes that the deficiencies can be corrected within a specified period
- The laboratory has failed to enroll in an approved PT program
- The laboratory has failed to meet PT performance criteria.

In general, the suspension will be resolved within 45 days. The Accreditation Committee will decide to either:

- Reverse the suspension of the specific section based on the laboratory's sufficiently addressing the issue cited OR
- Revoke the accreditation of the entire laboratory.

Denial or Revocation of Accreditation

Accreditation is denied or revoked when the laboratory fails to meet any of the standards within the CAP's accreditation programs or any other requirement for continued participation in the accreditation programs, and cannot institute corrective action in the time allowed. The checklists represent the requirements for meeting the *Standards*. Failure to correct cited deficiencies can be the basis for determining that a laboratory does not meet the intent of one or more of the *Standards*.

Laboratories undergoing formal denial or revocation of CAP accreditation will receive notification by mail for next day delivery. The laboratory using its CAP accreditation to meet regulatory standards must officially cease all testing in all sections affected. Agencies applicable to the laboratory accepting CAP accreditation, including but not limited to the CMS or the Joint Commission, will be notified.

A laboratory that has had accreditation denied or revoked may reapply for accreditation six months following the date of notification of denial or revocation.

Appeals

The laboratory may appeal denial or revocation within 30 days of receiving written notice of that decision. Appeals must be accompanied by appropriate documentation. A request for reconsideration shall not stay the denial of accreditation. Requests for information regarding appeal procedures must be directed to the Senior Director, Accreditation and Regulatory Affairs at the CAP headquarters at 800-323-4040 ext. 7243 or 847-832-7243.

For additional detailed information concerning accreditation, probation, suspension, denial, revocation, and appeals, refer to the CAP Accreditation Programs Policies Manual on cap.org in e-LAB Solutions Suite under Accreditation Resources – Accreditation Manuals/Retention Guidelines.

MAINTAINING ACCREDITATION

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Terms of Accreditation

As a condition of CAP accreditation, the laboratory director must sign the Terms of Accreditation attesting that the laboratory will comply with the conditions listed.

A CAP-accredited laboratory must:

- Provide a trained inspection team comparable in size and scope to that required for its own inspection at least once during the two-year accreditation period, if requested by the regional and/or state commissioner.
- Participate annually in a CAP-accepted proficiency testing (PT) program, as applicable.
- Promptly notify the CAP:
 - Of any changes in directorship, location, ownership, name, insolvency, or bankruptcy. Laboratories subject to the US CLIA regulations must also notify the Centers for Medicare and Medicaid Services (CMS) of pertinent changes in the 30 days prior to the change.
 - Of any changes in the laboratory's activity menu prior to beginning that testing or implementing scope of service/analytic method changes, or the laboratory permanently or temporarily discontinues some or all testing.
 - If the laboratory discovers laboratory personnel actions that appear to violate national, federal, state (or provincial), or local laws that regulate laboratories.
- Have a written procedure for employees to communicate concerns about quality and safety to management, and for management to investigate employee complaints. Incorporate corrective or preventive actions into the laboratory quality management program.
- Cooperate in any CAP investigation or inspection, and promptly notify the CAP if the laboratory becomes the subject of:

- An investigation by a government entity (including national, federal, state (or provincial), local, or foreign) or by another accreditation organization.
 - A validation inspection
 - Adverse media attention related to laboratory performance.
- Authorize the CAP to release its inspection and PT data and other information required by law to the appropriate regulatory or oversight agencies (eg, the CMS, The Joint Commission).
- If the laboratory is subject to the US CLIA regulations:
 - Make available, on a reasonable basis, the laboratory's annual PT results upon request of any person
 - Allow the CMS or its agent to perform a validation or complaint inspection at any time during the laboratory's hours of operation and permit the CMS to monitor the correction of any deficiencies found through such an inspection
 - Obtain a CLIA Certificate of Accreditation and pay all applicable fees as a CLIA-certified laboratory if it will use CAP accreditation to meet CLIA certification requirements.
- Submit a completed Self-Inspection Verification Form in the interim year.
- Submit only documentation and other materials to the CAP that have been de-identified of all protected health information (PHI) in accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations unless the laboratory must submit PHI to the CAP to respond to a deficiency or patient complaint.
- Accept and adhere to the *Certification Mark Terms of Use/Agreement for CAP Accredited Mark and Design* if the laboratory is, or will use, the CAP Certification Mark of accreditation. The agreement may be downloaded from cap.org.
- Refrain from copying or distributing the CAP Checklists or any content thereof except for use by inspectors in conducting a CAP inspection and by the laboratory in preparing for such an inspection.
- Laboratories participating in the Laboratory Accreditation Program are required to pay for CAP annual accreditation fees based on the applicable disciplines/sub-disciplines of the lab. Those fees are set based on complexity points, test volume points, base fee and specialty fees that apply at the time of the billing month for the site. Find further information about specific fees by emailing accred@cap.org.
- Laboratories participating in any CAP Specialty Programs, including Reproductive Laboratory Accreditation, Forensic Drug Testing Accreditation, Biorepository Accreditation, or System Inspection Option, are required to pay for these annual accreditation fees that apply at the time of the billing month for the site.
- International laboratories are subject to pay business class airfare for any United States-based inspector that inspects on-site.

Maintaining CAP Accreditation Information

As indicated in the Terms of Accreditation, laboratories are required to report changes to directorship, location, ownership, name, insolvency, or bankruptcy, and activity menu to the CAP on an ongoing basis.

Changes in activity menu and General Questionnaire, including tests performed, scope

of service, and analytical methods can affect checklist usage or the selected requirements included in the laboratory's customized checklist. It is imperative that the laboratory notify the CAP when changes occur. Submit test menu or General Questionnaire changes by logging onto cap.org, e-LAB Solutions Suite. Changes are submitted through Organization Profile.

Proficiency Testing Participation

Ongoing enrollment and successful participation in proficiency testing is required for maintaining accreditation. Refer to the following sections for additional information:

- [Accreditation Program Requirements for International Laboratories](#),
- [Proficiency Testing: Enrollment and Handling](#),
- [Proficiency Testing \(PT\) Failure and Proficiency Testing Monitoring](#).

Self-inspection

Accredited laboratories are required to complete a **mandatory self-inspection** at the start of the second year of the laboratory's two-year accreditation cycle using the checklists sent to the laboratory for this purpose. The laboratory must perform the self-inspection and return the Self-Inspection Verification Form signed by the laboratory director within 60 calendar days after receiving the self-inspection materials. The laboratory is required to correct all deficiencies cited and maintain records of corrective action. The next CAP inspection team will verify that all such deficiencies have been corrected. Deficiencies should be corrected within 30 calendar days of the self-inspection, similar to the correction of deficiencies cited by an inspection team. The laboratory must keep the self-inspection records, including the findings and corrective actions on file for future reference. Failure to perform the self-inspection is a serious deficiency and may result in an immediate on-site inspection or revocation of accreditation.

Anniversary of Accreditation

Accreditation is maintained on a continuous basis provided that the laboratory continues to meet the Terms of Accreditation. The CAP's accreditation programs function on a fixed accreditation cycle. This means that a laboratory will be **inspected every two years within the three-month period prior to the anniversary of accreditation**. Laboratories will receive a notification to complete the reapplication process online. The new checklists to be used in the inspection will be sent to the laboratory when the reapplication is complete.

CAP Reporting to Organizations and Other Government Agencies

The CAP's accreditation programs are recognized by various organizations and government agencies. As part of the recognition agreements, the CAP provides information on accredited laboratories to those organizations and agencies, where applicable, such as copies of inspection reports and other communications about the status of the laboratory's CAP accreditation or complaint investigations. The laboratory director's signature on the Terms of Accreditation form authorizes the CAP to provide accreditation information to the associated agencies and organizations. The CAP's accreditation program has a relationship with the following accrediting organizations and government agencies:

- ***The Joint Commission***

The Joint Commission accepts CAP accreditation of hospital laboratories. During the hospital's Joint Commission survey, an administrative surveyor will routinely examine laboratory safety and a physician surveyor will request and review information on the performance improvement activities of the laboratory and its medical staff. Additionally, a Joint Commission “tracer” investigation may involve the laboratory.

- ***The Centers for Medicare and Medicaid Services (CMS)***

The CAP’s accreditation programs have been approved as a private accrediting organization under CLIA by the CMS. Therefore, CAP-accredited laboratories may use their CAP inspection in lieu of routine inspection by a CMS agent. This recognition imposes the following obligations upon the CAP’s accreditation program:

- The CAP must ensure that laboratories are inspected every two years.
- The CAP checklist requirements must be at least as stringent as the CLIA regulations.
- The CAP number assigned to an accredited laboratory corresponds to one and only one CLIA certificate’s number.

- ***State Licensure***

Some states license clinical laboratories. The CAP makes the results of the accreditation decision available to state agencies upon request from the state agency.

The extent to which the CAP accreditation program is recognized by state governments varies. The CAP has a formal recognition program with several states where CAP accreditation can be used in lieu of a separate state inspection. The CAP has deeming authority with the following states: California, Florida, Washington, Georgia, and Tennessee.

- ***Other Agencies/Organizations***

The CAP also has reporting relationships with the following agencies/organizations:

- Department of Defense (DoD)
- Department of Veterans Affairs (VA)
- Society for Reproductive Assisted Technology (SART)
- United Network for Organ Sharing (UNOS)
- National Marrow Donor Program (NMDP)
- Foundation for the Accreditation of Cellular Therapy (FACT)

CAP Website Resources

The CAP has a variety of tools that can be used to help stay current with changes to the CAP accreditation programs and to manage laboratory information. Navigating the website using the search functionality allows you to quickly find what you need. In addition to the items listed below, laboratories may also refer to [Appendix E](#), CAP Accreditation Program Website Tools:

- ***e-LAB Solutions Suite***

e-LAB Solutions Suite (eLSS) is the CAP’s online portal to manage accreditation

and proficiency testing. The portal is a helpful and convenient way for laboratories to:

- Manage laboratory online access, user permissions, and individual profiles
- Manage laboratory accreditation documents, including customized accreditation checklist changes to activity menus, and updates to the General Questionnaire
- Complete the application or reapplication
- Enter, review, and approve proficiency testing (PT) results with the interactive online forms
- Monitor, enter, review, and approve deficiency responses post-inspection
- View and compare the laboratory's PT and inspection performance to the performance of other laboratories using the Performance Analytics Dashboard
- View and print copies of PT evaluations, participant summary reports, kit instructions, result forms, and the shipping calendar
- Access accreditation policies, templates, webinars, checklist requirement interpretation, toolboxes, retention guidelines, tip sheets, and more in Accreditation Resources
- Receive automated reporting email notifications with e-LAB Solutions Connect (eg, proficiency testing data receipt)

- **eAlerts**

The CAP issues eAlerts as a means to communicate time-sensitive, critical, and regulatory information. These may include significant changes to accreditation checklist requirements, information to assist with interpreting requirements, and updates to the inspection process. eAlerts are communicated by email and posted on the CAP website under Laboratory Improvement, News and Updates.

- **My Profile**

Personal demographic information is maintained through My Profile on the [cap.org](https://www.cap.org) login section. Individual users (eg, directors, supervisors, laboratorians, inspectors) can create an account and update demographic information such as address, telephone, and emails, as well as credentials and inspector availability.

- **Education**

The CAP provides complimentary educational resources on the CAP website under Education. The Education page provides access to the inspector training course, Focus on Compliance webinars, educational survey programs, and more. CME/CE may be available for some programs.

NON-ROUTINE INSPECTIONS

Any in-person inspection performed in addition to the laboratory's routine inspection is considered "non-routine". A non-routine inspection may be required for the following reasons:

- Evidence of non-compliance with the *Standards for Accreditation* or accreditation checklist requirements
- The need to confirm compliance with corrective actions taken after an inspection
- Repeated failures in proficiency testing
- Findings from a regulatory inspection
- The addition of a new discipline or sub-discipline
- Changes in directorship, ownership, or location
- Follow-up for a virtual inspection (if applicable).

The laboratory is responsible for the cost of a non-routine inspection, with the exception of a non-routine follow-up for virtual inspections, which is at no charge.

COMPLAINTS AND INVESTIGATIONS

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Complaints

A complaint is any formal notification to the CAP or the discovery by the CAP of information outside of the routine inspection process that raises the possibility of noncompliance with the *Standards for Accreditation* and/or checklist requirements in a CAP-accredited laboratory or in a laboratory seeking CAP accreditation.

The Complaint Process

Investigation begins as soon as CAP records a complaint. The investigation may include:

- A request for information from the laboratory
- A search of past inspection and proficiency testing results
- An inspection of the laboratory.

The CAP only investigates complaints related to the *Standards for Accreditation* and/or accreditation checklist requirements. The CAP does not routinely investigate complaints such as billing issues, human resource issues (eg, employee hiring practices) or result interpretation as it relates to the general practice of pathology.

The CAP notifies the laboratory director of the complaint and communicates with the laboratory director during the complaint resolution process. The complainant's identity is kept confidential and never released to the laboratory unless permission is obtained from the complainant.

If an inspection is conducted to investigate a complaint, the inspection is performed as an unannounced inspection.

Once information gathering is complete:

- The Complaints and Investigations Committee (CIC) will consider the evidence to determine whether the basis for the complaint has been substantiated.
- The CIC will determine what remedial actions, if any, need to be taken.
- Depending on the nature of any identified deficiencies, the CAP's Accreditation Committee may be asked to determine whether the facility will continue to be accredited, accredited with requirements, placed on probation, or have its accreditation revoked.

The complaint will be closed as substantiated, not substantiated, not applicable or inconclusive. At the conclusion of the complaint investigation, the CAP will send a letter to both the laboratory

director and the complainant (if contact information is provided), indicating that the CAP has completed its investigation. The CAP is required to report all substantiated complaints, and/or changes in accreditation status due to the complaint investigation to the appropriate state, federal, or other oversight accreditation agencies.

CMS Validation Inspections

As part of the CAP's approval for deeming authority as an accrediting organization for clinical laboratories under the CLIA program, a percentage of CAP accreditation decisions are validated by the Centers for Medicare or Medicaid Services (CMS) or its agents, or the state survey agency. Validation ensures that the CAP inspection process continues to be equivalent to or more stringent than the CMS laboratory survey. As a term of CAP accreditation, laboratories must notify the CAP as soon as the facility finds itself to be the subject of a CMS validation survey.

CMS validation inspections may occur either simultaneously with the CAP inspection or within the 90-day timeframe following the CAP inspection. The CAP inspection team uses the CAP's inspection checklists; the CMS surveyor conducts the validation using the CLIA regulations.

Following a validation inspection, the laboratory receives a validation inspection report from the CMS surveyor and is asked to submit responses to the CMS following the instructions provided to the laboratory. Laboratories must also submit to the CAP a copy of the responses with the plan of correction for the deficiencies cited by the CMS including documentation that demonstrates corrective action.

ACCREDITATION PROGRAM REQUIREMENTS FOR INTERNATIONAL LABORATORIES

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Special Instructions for International Accreditation

The College of American Pathologists accredits clinical laboratories worldwide. The drive to improve the quality of laboratory medicine and ultimately ensure better patient care is universal. International laboratories with CLIA certificates must comply with all applicable US regulations.

Proficiency Testing/External Quality Assurance

International laboratories seeking CAP accreditation must:

- Enroll and participate in CAP PT for all tests/activities across all disciplines under the same laboratory director, if a CAP PT program is available, for a minimum of six months prior to applying for accreditation
- Participate in PT on an ongoing basis and renew annually. Order by December 1st to ensure full participation
- Contact the CAP on how to meet PT requirements if the PT product cannot be shipped because of governmental restrictions or stability issues
- Obtain special/import permits or licenses for PT products that contain hazardous

materials, such as microbiology products. It is the laboratory's responsibility to ensure the CAP receives these permits prior to shipment. If the product cannot be released due to the lack of a special permit or license, the laboratory will receive a zero (0%) score for that PT shipment and the laboratory is then required to perform an alternative performance assessment.

Laboratory Director

The laboratory seeking accreditation must have a qualified laboratory director. The laboratory director must be an MD, DO, or PhD, and meet all applicable qualifications defined in the CAP's Director Assessment Checklist requirement DRA.10100.

If the laboratory is subject to the CLIA regulations, and the laboratory director was educated outside of the US, the laboratory must have records of an equivalency evaluation by a recognized organization, such as the National Association Credential Evaluation Services, Inc. (NACES) (<http://naces.org>) or the Association of International Credential Evaluators, Inc. (AICE) (<http://aice-eval.org>). The laboratory director must also have appropriate licenses as required by national, federal, state or provincial, and local law.

Laboratory Personnel

Supervisors and testing personnel must meet defined qualifications based on their role and the complexity of testing performed.

- If the laboratory is subject to the CLIA regulations and has personnel or supervisors fulfilling a CLIA role (clinical consultant, technical consultant, technical supervisor, or general supervisor) that were educated outside of the US, the laboratory must have records showing that the credentials of these personnel are equivalent to those required in the CLIA regulations. The equivalency evaluation must be performed by a recognized organization, such as the National Association Credential Evaluation Services, Inc. (NACES) (<http://naces.org>) or the Association of International Credential Evaluators, Inc. (AICE) (<http://aice-eval.org>).
- Laboratories not subject to the CLIA regulations may authenticate educational achievement according to prevailing governmental rules.

Scope of Disciplines

All testing and disciplines performed by a laboratory in the same location (physical address) must be included in the application. The CAP does not accredit portions of laboratories.

Test Volume

Laboratories are required to report test volumes in the online CAP accreditation application as follows:

- International laboratories (including Canada) that have a CLIA certificate must:
 - Report the test volume for moderate and high complexity testing performed on patient specimens received from the US on the Non-waived section of the

- application
 - Report the non-waived and waived test volume for non-US citizen specimens in the Waived section of the application.
- International laboratories that do not have a CLIA certificate must:
 - Report the test volume for all testing complexities in the **Total** section of the application.

Limitations on Offering of Accreditation

The CAP may not be able to accept laboratories located in some geographic regions if there are commercial prohibitions or any other country risks.

Documentation Required in English

If English is not the operational language of your laboratory, the following requirements must be met:

- Prior to scheduling an inspection, English translation of the following documents must be available:
 - Laboratory organization structure
 - Instrument list
 - Quality assurance/improvement programs
 - Quality control programs
 - Sample procedure for each laboratory discipline.
- If a US-based inspection team is requested, the laboratory must have staff conversant in English or have interpreters available to support the inspection team with highly specialized translations in the laboratory disciplines. The number of staff or interpreters should be sufficient to accommodate each English-speaking inspector. The details on the number of staff or interpreters needed should be discussed with the US-based Team Leader prior to the inspection.
- Responses to any deficiencies cited at the inspection must be provided in English. Certain supporting documentation to a deficiency may be in your native language provided that the key elements that demonstrate compliance, as well as titles and major headings, are in English.
- Responses to any Proficiency Testing Compliance Notices (PTCN) must be available in English. Supporting documentation to a PTCN may be in your native language provided that the key elements that demonstrate compliance, as well as titles and major headings, are in English.

Resources for International Laboratories

More information and other resources are available online. To access this information, go to cap.org, under the Laboratory Improvement heading, select Laboratories Outside the USA.

Accreditation Fees and Charges

All fees and accreditation-associated charges (including international travel or non-routine inspections) must be paid in full. Failure to do so will suspend any further advancement in the

accreditation process, including issuance of accreditation.

Inspection Dates

Inspections of international laboratories are conducted as announced inspections because of logistical challenges and the common requirement for travel visas. Therefore, inspection dates for international laboratories are arranged, and the laboratory is aware of the scheduled date.

- The inspection team leader will contact the laboratory director(s) within two weeks of receiving the Inspector's Inspection Packet to schedule the date.
- The inspection must occur no more than 90 calendar days before the laboratory's anniversary date for routine inspection. A mutually acceptable date is preferable, but in the case of disagreement, the inspection is scheduled at the convenience of the inspector.
- International laboratories not subject to CLIA regulations may undergo inspection beyond the 90 calendar day timeframe after testing commences to accommodate scheduling multiple inspections in the same country or region.
- The inspection team leader will send a letter to the laboratory director indicating the inspection date, projected schedule, team member listing, any special requests, and documentation instructions.

Since the inspections are scheduled in advance, inspection teams are not required to notify the laboratory one-hour prior to arrival at the laboratory.

Modified Inspection Process: Virtual Inspections

In response to the global health emergency and associated travel restrictions, the CAP has modified the laboratory inspection processes to allow international inspections at laboratories not subject to the CLIA regulations to be virtual instead of in-person. This is a temporary process implemented in response to the global pandemic. Because the duration of the pandemic and associated travel restrictions is unknown, we recommend that accredited international laboratories continue to budget for their inspection expenses, including airfare for US inspectors. If either a) an on-site inspection is required based on the findings from the virtual inspection, or b) the international laboratory has a CLIA license where an on-site inspection is required, the laboratory will be billed for the airfare expense. For additional information about virtual inspections go to cap.org and use the search function for "virtual inspections".

Inspection Teams

Most Team Leaders for inspecting international laboratories are US-based. The team leader will include appropriate qualified international inspectors as team members whenever possible and practical.

To be considered for an inspection team, inspectors based outside the US must have successfully completed training and maintain competency as a team leader or member. Likewise, the inspector must be currently or previously affiliated with a CAP-accredited laboratory.

Regional team member assignments are made from the same country or geographic region as the laboratory being inspected. Exceptions may be made with the approval of the chair of the Council on Accreditation or the CAP vice president for the CAP Accreditation Programs. Requests for exceptions should be submitted as early as possible.

Inspection Team Travel

Flights requiring airline travel are arranged based on the following:

- Inspectors originating in the US will:
 - Travel business class for all flight legs to countries outside of North America
 - Travel economy class for flights within the US or within destination country.
- Inspectors originating outside of the US will:
 - Travel business class for all portions of flights with total flight time exceeding five hours (excluding layovers)
 - Travel economy class for flights of five hours or less.
- US Department of Defense contract laboratory inspections will:
 - Travel economy class (the CAP Travel Desk books premium upgradable economy class airfare to allow inspectors the option to personally upgrade their tickets).

Inspector's Summation Report

International inspections are often grouped in tours to control costs for the participating laboratories. More than one laboratory in a country or region may be inspected in a short time span by one inspection team. The team leader must return the Inspector's Summation Report (ISR) to the CAP within two days of the inspector's return to the US. (Refer to [After the Inspection: Inspection Team](#) for shipping instructions).

Appendix A: Accreditation Checklists Overview

This appendix includes a complete listing of the accreditation checklists along with a brief description and notes relating to the usage of each checklist based on the October 24, 2022 Checklist edition. It does **not** include all possible uses for a particular checklist. Refer to the Accreditation Checklists section for more information on checklist components and accessing the checklists via [cap.org](https://www.cap.org). For questions about checklist usage, contact the CAP at 800-323-4040 or 847-832-7000.

All Common Checklist (COM)

- Proficiency testing
- Policy and procedure manuals
- Specimen collection and handling
- Quality management
- Reporting of results
- Reagents
- Instruments and equipment maintenance/function checks
- Thermometers and temperature dependent equipment and environments
- Pipettes and analytical balances
- Waived test implementation
- Test method validation/verification-nonwaived tests
- Individualized quality control plan

NOTE: The COM Checklist is used in conjunction with the discipline-specific checklists (eg, Anatomic Pathology, Chemistry and Toxicology) to inspect each laboratory section.

Anatomic Pathology Checklist (ANP)

- Surgical pathology
- Intraoperative consultation
- Fine-needle aspiration (FNA)
- Histology
- Immunohistochemistry and immunofluorescence microscopy
- In situ hybridization (ISH)
- Predictive marker testing
- Digital image analysis
- Circulating tumor cell analysis
- Flow cytometry data interpretation
- Autopsy pathology
- Forensic autopsy
- Electronic microscopy
- In vivo and ex vivo microscopy

NOTE: If FNAs are screened by a cytotechnologist, the Cytopathology Checklist must be used for inspection. If the technical component of flow cytometry is performed at the laboratory, the Flow Cytometry Checklist must be used for inspection.

Biorepository Checklist (BAP)

- Quality management
- Biospecimen collection and handling
- Biospecimen processing and quality, including DNA/RNA extraction/amplification, cell fractionization, cell and tissue culture, and histology
- Specialized techniques, such as whole slide imaging, digital image, tissue microarray, laser capture microdissection, and molecular methods
- Inventory management systems
- Storage
- Source and sponsor facilities
- Informed consent and institutional review board
- Distribution policies and agreements

NOTE: The BAP Checklist is only for facilities enrolled in the Biorepository Accreditation Program.

Chemistry and Toxicology Checklist (CHM)

- Automated chemistry procedures
- Blood gas analysis
- Therapeutic drug monitoring
- Toxicology screening and confirmatory testing
- Prenatal screening
- Cystic fibrosis sweat testing
- Tumor marker, immune system, and infectious disease immunoassays
- Hemoglobin separation
- Methods, such as thin layer chromatography (TLC), gas chromatography (GC), high performance liquid chromatography (HPLC), mass spectrometry (MS), Imaging MS, radioimmunoassay (RIA), and electrophoresis

Clinical Biochemical Genetics Checklist (CBG)

- Diagnostic testing for inborn errors of metabolism
- Methods such as enzyme assays, TLC, GC, HPLC, MS, electrophoresis, and RIA
- Newborn screening

Cytogenetics Checklist (CYG)

- Cytogenetic studies for constitutional and neoplastic disorders
- ISH for constitutional and neoplastic disorders, including predictive marker testing
- Digital image analysis
- Genomic copy number analysis using microarray

Cytopathology Checklist (CYP)

- Gynecologic cytopathology
- Non-gynecologic cytopathology, including fine-needle aspiration
- Cytology processing and staining
- Immunocytochemistry, including predictive marker testing
- Cytology screening, manual and automated

NOTE: Laboratories that perform histology processing of cell blocks and tissues must be inspected with the Anatomic Pathology Checklist.

Director Assessment Checklist (DRA)

- Laboratory director qualifications
- Laboratory director responsibilities

NOTE: One copy of the Director Assessment Checklist is provided to the team leader for each laboratory inspected.

Flow Cytometry Checklist (FLO)

- Blood lymphocyte subset enumeration
- CD34 stem cell enumeration
- Leukemia and lymphoma immunophenotyping
- DNA content and cell cycle analysis
- Rare event flow cytometric analysis

Forensic Drug Testing Checklist (FDT)

- Non-medical drug testing
- Screening and confirmatory testing for different specimen types (urine, blood, oral fluid, hair, meconium, umbilical cord, and nails)
- Specimen handling and chain-of-custody
- Certification/inspection of results
- Methods, such as immunoassays, LC, GC, and MS

NOTE: The FDT Checklist is only for laboratories enrolled in the Forensic Drug Testing Program.

Hematology and Coagulation Checklist (HEM)

- CBC and differentials, automated and manual
- Reticulocytes, automated and manual
- Bone marrow preparations
- Abnormal hemoglobin detection
- Blood film examination for microorganisms

- Body fluid cell counts (automated and manual) and differentials
- Semen analysis, automated and manual
- Routine coagulation assays
- Specialized coagulation assays, including factor assays, mixing studies, D-dimer, electrophoresis studies, and platelet function assays

Histocompatibility Checklist (HSC)

- HLA testing by serologic, molecular, flow cytometry, immunoassay, and solid phase methods
- Class I and II antigen typing
- HLA antibody screening, identification, and crossmatching
- DNA typing, including low and high resolution typing, and DNA sequence-based typing
- Donor-recipient histocompatibility, including renal, stem cell, and non-renal organ transplants
- Hematopoietic progenitor cell engraftment monitoring

NOTE: Laboratories performing HLA testing by next-generation sequencing must also use the Molecular Pathology Checklist for inspection.

Immunology Checklist (IMM)

- General immunology assays, manual and automated
- Immune system profiles
- Tumor marker and infectious disease immunoassays
- Microbial antigen testing
- Waived molecular-based microbiology tests
- ABO/Rh and antibody screening (non-transfusion-related)
- Syphilis serology
- HIV primary diagnostic testing
- Western blot

Laboratory General Checklist (GEN)

- Quality management system
- Specimen collection
- Chain-of-custody specimen collection and handling
- Direct-to-consumer testing
- Specimen transport and tracking
- Result reporting
- Quality of water
- Laboratory computer services
- Telepathology and remote data assessment
- Whole slide imaging
- Personnel
- Physical facilities
- Laboratory safety
- California laboratory licensure requirements

NOTE: A Laboratory General Checklist is provided for inspections of all laboratories and biorepositories.

Limited Service Laboratory Checklist (LSV)

- Automated and manual hematology testing, including CBC, reticulocytes, and differentials
- Routine coagulation assays
- Body fluid analysis, including semen analysis
- Automated general chemistry
- Blood gas analysis
- Therapeutic drug monitoring
- Screening for drugs of abuse
- Tumor marker and infectious disease immunoassays
- Urinalysis dipstick and microscopy, manual and automated methods
- Microbiology specimen setup, direct specimen examination, stains, and antigen typing for various subdisciplines
- General immunology assays, including anti-nuclear antibody testing, HIV primary diagnostic testing, and immune system profiles
- Non-transfusion-related immunohematology testing
- Syphilis serology
- Waived molecular-based microbiology tests

NOTE: The LSV Checklist is used to inspect freestanding laboratories or a section of a laboratory doing a limited number of basic tests in multiple disciplines (eg, outpatient or “STAT” laboratories). It is made up of a limited subset of requirements from other checklists to reduce the burden of using multiple checklists when a laboratory’s scope of services is confined to the most commonly performed tests. The All Common, Laboratory General, and Director Assessment Checklists are used along with the LSV Checklist for inspections. It is not appropriate for single-discipline or specialized laboratories; such laboratories must use the relevant discipline-specific checklist(s).

The ability of a laboratory to use the LSV Checklist is determined by a laboratory’s Accreditation Unit Activity Menu. Laboratories with activities extending beyond the scope of the LSV Checklist must use the discipline-specific checklists. The LSV Checklist does not cover the following services:

- Hematology — bone marrow evaluation, blood film examination for microorganisms, and abnormal hemoglobin detection (except the sickling test)
- Coagulation — factor assays, mixing studies, electrophoresis studies, and platelet function testing
- Chemistry — toxicology (other than drug of abuse screening and serum or whole blood alcohol), mass spectrophotometry, electrophoresis, chromatography, AFP, RIA, and sweat testing for cystic fibrosis
- Microbiology — cultures beyond initial plating, susceptibility testing, mycology other than KOH or wet preps, mycobacteriology, parasitology other than pinworm preparations,

- virology, and nonwaived molecular microbiology
- Transfusion medicine — pretransfusion testing, antibody identification, blood storage and issue
- Testing in the disciplines of anatomic pathology, clinical biochemical genetics, cytopathology, cytogenetics, histocompatibility, flow cytometry, molecular pathology, and point-of-care-testing.

Microbiology Checklist (MIC)

- Culture setup, staining, antigen typing, screening, identification, and susceptibility testing for bacteriology, mycology, mycobacteriology, and virology
- Parasitology, including stool for ova and parasites and blood film examination for microorganisms
- Molecular microbiology, including waived and nonwaived FDA-cleared/approved methods, modified methods, and laboratory-developed methods
- Microbial identification, using methods, such as MALDI-TOF MS, GC, HPLC, ISH, target and signal amplification, and sequencing.

NOTE: Laboratories performing molecular infectious disease testing by next-generation sequencing must also use the Molecular Pathology Checklist for inspection.

Molecular Pathology Checklist (MOL)

- Clinical molecular genetics testing, including oncology, inherited disease, pharmacogenomics, HLA typing, relationship testing, and forensic identity applications
- Molecular assay validation
- ISH for constitutional and neoplastic disorders, including predictive marker testing
- Methods, such as electrophoresis, PCR, arrays, in situ hybridization, digital image analysis, and sequencing
- Next-generation sequencing for inherited diseases, including non-invasive screening of maternal plasma to detect fetal chromosomal alterations, oncology, infectious diseases, and histocompatibility
- Hematopoietic stem cell engraftment monitoring

Point-of-Care Testing Checklist (POC)

- Tests performed at or near the patient bedside (nondedicated space)
- Kit tests or hand-carried instruments (or otherwise transported to the patient location)
- Waived and moderate-complexity testing
- Modified FDA-cleared/approved POCT
- Blood gas analysis
- D-dimer studies
- Waived molecular-based microbiology testing
- Provider-performed microscopy

NOTE: The POC Checklist is used for inspection of testing performed at or near the site where the patient is located only (with non-dedicated space). It contains a subset of requirements

found in other checklists. A discipline-specific checklist(s) may be required in addition to the POC Checklist if certain analytes warrant its use. Laboratories with fixed dedicated testing space require either a Limited Service Laboratory Checklist or additional discipline-specific checklist(s).

A separate checklist must be completed for each POCT location when POCT records are not maintained in a central location by a designated POCT coordinator.

Reproductive Laboratory Checklist (RLM)

- Complete semen analysis, automated and manual methods
- Biochemical testing
- Anti-sperm antibody testing
- Sperm processing for therapeutic insemination
- Embryology procedures
- Embryo and gamete cryopreservation
- Donor reproductive cell/tissue programs

NOTE: The RLM Checklist is only for laboratories enrolled in the Reproductive Laboratory Accreditation Program.

Transfusion Medicine Checklist (TRM)

- Immunohematology testing, manual and automated
- Compatibility testing, including computer crossmatches
- Perinatal testing
- Transfusion procedures and adverse reactions
- Therapeutic phlebotomy
- Donor and therapeutic apheresis
- Component preparation, storage, and modification
- Cellular therapy
- Tissue storage and issue
- Donor selection, collection, and testing

NOTE: Laboratories with immunohematology testing limited to ABO, Rh, antibody screens (non-transfusion), and direct antiglobulin testing may be inspected with the Immunology Checklist.

Urinalysis Checklist (URN)

- Urinalysis dipstick, automated and manual methods
- Manual urine microscopy
- Automated microscopy systems

Appendix B: Instructions for Determining Test Volume

These instructions are provided to assist CAP-accredited laboratories in calculating and reporting annual test volumes for laboratory sections/departments in Organization Profile on cap.org. The CAP uses this data for inspection planning and laboratory monitoring. The CAP also reports this data annually to the Centers for Medicare and Medicaid Services (CMS) for laboratories that are subject to US regulations.

The following types of test volume data is requested based on laboratory type:

Laboratory Type	Non-Waived	Waived	Total Volume
Laboratories subject to US regulations (CLIA, VA, or CLIP certificate)	X *	X	
Laboratories not subject to US regulations			X

Non-waived — Includes high and moderate-complexity testing Do not include calculations (eg, A/G ratio, MCH, base excess, anion gap, iron saturation, INR), quality control, quality assurance, proficiency testing assays, and tests sent to referral laboratories.

* **Laboratories located outside of the US with a CLIA certificate** must only include non-waived test volume for specimens received from the US or its territories. Test volumes for all other testing must be included under the waived category.

Waived — Includes waived testing and other tests or procedures to be inspected that are not classified by the CMS (eg, autopsy, employee drug testing, assisted reproductive technology-related procedures).

Total Volume – Includes test volumes for all testing complexities and procedures not classified by the CMS.

Specialty/Discipline information:

Specialty/Discipline	Instructions for Determining Test Volume
Chemistry	<ul style="list-style-type: none"> Count each non-calculated analyte (eg, a lipid panel consisting of a total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides equals four tests)

Cytogenetics	<ul style="list-style-type: none"> Count the number of tests by the number of specimen types processed on each patient (eg, a bone marrow and a venous blood specimen received on the same patient equal two tests) Count each special stain ordered and reported as a separate test <p>NOTE: For all other genetic tests, the number of tests is determined by the number of results reported in the final report.</p>
Cytology	<ul style="list-style-type: none"> For manual gynecologic and non-gynecologic cytology, count each slide (not each case) as one test for both Pap tests and non-gynecologic cytology For non-gynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide, count as one-half slide Refer to the manufacturer's product insert to determine how to count test volume for gynecologic slides screened by automated devices when only a portion of the slide is reviewed
Flow Cytometry	<ul style="list-style-type: none"> Count each measured individual analyte (eg, T cells, B cells, CD4) that is ordered and reported separately
Hematology	<ul style="list-style-type: none"> Count each measured analyte of a complete blood count, coagulation profile, and body fluid analysis that is ordered and reported separately Count white blood cell differentials as one test
Histocompatibility	<ul style="list-style-type: none"> Count each HLA typing, each HLA antibody screen, or each HLA crossmatch as one test (eg, a B-cell crossmatch, a T-cell crossmatch, and an auto-crossmatch between the same donor and recipient pair equals three tests) Count each disease-associated antigen test result (eg, HLA-B27) as one test
Histopathology	<ul style="list-style-type: none"> Count each block (not slide) as one test Add the number of special stains performed on histology slides to the total number of specimen blocks prepared by the laboratory Do not include autopsy services under the non-waived test volume
Immunohematology	<ul style="list-style-type: none"> Count ABO, Rh, antibody screen, crossmatch, direct antiglobulin test, and antibody identification as separate tests
Immunology	<ul style="list-style-type: none"> Count testing for allergens as one test for each allergen

Microbiology	<ul style="list-style-type: none"> Count susceptibility testing as one test for each group of antibiotics used to determine sensitivity for one organism Count cultures as one test request from each specimen regardless of the extent of identification, number of organisms isolated, and the number of tests/procedures required for identification Count molecular multiplex panels as one per test request from each specimen regardless of the number of organisms identified Count each Gram stain or acid-fast bacteria (AFB) smear requested from the primary source as one test Count each parasitology test request for each specimen regardless of the number of tests/procedures required for identification as one test <p><i>Example: if the order for a sputum specimen includes a routine bacteriology culture, Gram stain, a mycology test, an AFB smear, and an AFB culture, this would equal five tests. A stool parasitology direct smear, concentration technique, and review of the prepared slide are collectively counted as one test.</i></p>
Molecular Pathology	<ul style="list-style-type: none"> Count each genetic test ordered and reported as one test Count each next-generation sequencing test ordered with one report (eg, a gene panel, exome or genome) as one test
Point-of-Care Testing	<ul style="list-style-type: none"> Count point-of-care (POC) testing according to the specialty of the test Count non-waived and waived test volumes separately (for laboratories subject to US regulations) <p><i>Example: If blood gas testing is done as part of POC testing, count it the same as if it were done in a chemistry department. Similarly, a macroscopic (dipstick) urinalysis test done as part of POC should follow the urinalysis criteria listed below.</i></p>
Reproductive Laboratory Medicine	<ul style="list-style-type: none"> Count each test in a diagnostic semen analysis panel (eg, sperm count, motility, morphology) as separate non-waived tests Include volume for sperm preparation for insemination and assisted reproductive technology-related procedures (number of cycles, fresh and frozen) under waived testing
Urinalysis	<ul style="list-style-type: none"> Count macroscopic and microscopic examinations as separate tests Count dipstick testing as one test, regardless of the number of reagent pads on the strip

Reference: Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, Guidelines for Counting Tests for CLIA; Form CMS-116; <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>.

Appendix C: Minimum Period of Retention of Laboratory Records and Materials (CAP Policy PP)

The College of American Pathologists (CAP) makes the following recommendations for the minimum requirements for the retention of laboratory records and materials. They meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88). It may be appropriate for laboratories to retain records and/or materials for a longer period of time when required for patient care, education, quality improvement, medical/legal, or other needs, or if required by institutional policy. Some state regulations as well as federal mandates may require retention of records and/or materials for a longer time period than that specified in the CLIA 88 regulations. Therefore, any applicable national, federal, state (or provincial) or local laws should be reviewed carefully when individual laboratories develop their record retention policies.

Material/Record	Period of Retention
GENERAL LABORATORY	
Accession records	2 years
Specimen requisitions (including the patient chart or medical record if used as the requisition)	2 years
Chain-of-custody collection, receipt, accessioning, and handling records	2 years (or longer as applicable)
Quality management records	2 years
Instrument/equipment maintenance and function check records (including temperature charts)	2 years
Proficiency testing records	2 years
Policies and procedures	2 years following discontinuance
Test method validation/verification records (method performance specifications)	Length of time the test is in use, plus 2 additional years
Quality control records	2 years
Individualized Quality Control Plan (IQCP), including risk assessment and supporting data, and approval of quality control plan	Length of time the test is in use, plus 2 additional years following discontinuation of the IQCP
Ongoing IQCP quality assessment data	2 years
Computer system validation records	2 years beyond the life of the system
Records of changes to software, the test library, and major functions of laboratory information systems	2 years beyond the life of the system
Ongoing computer system checks (eg, calculation verification)	2 years
Training records	2 years

SURGICAL PATHOLOGY (including bone marrows)	
Wet tissue	2 weeks after final report
Paraffin blocks (including cell blocks)	10 years
Reports	10 years
Slides	
Immunohistochemistry batch control slides	2 years
Surgical pathology slides	10 years
Bone marrows slides with associated peripheral blood smear(s) included in the bone marrow report	10 years
Fluorochrome-stained slides	At the discretion of the laboratory director
<i>In situ</i> hybridization images (refer to Note 1) or permanent slides	10 years - Neoplastic disorders 20 years - Constitutional disorders
Digital images used for primary diagnosis	10 years (if original glass slides are not available)
Digital images for Circulating Tumor Cells	10 years
Datasets from ex-vivo microscopy (EVM) or in-vivo microscopy (IVM) systems used to aid in interpretation or diagnosis	10 years (data must be retrievable for this period)
ELECTRON MICROSCOPY	
Wet tissue	2 weeks after final report
Resin blocks	10 years
Pictures and reports	10 years
CYTOLOGY	
Reports	10 years
Slides	
Immunochemistry batch control slides	2 years
Gynecologic cytology glass slides	5 years
Non-gynecologic cytology glass slides (including fine needle aspiration (FNA) slides)	10 years
NON-FORENSIC AUTOPSY	
Wet tissue	3 months after final report
Paraffin blocks	10 years (refer to ANP.12500 for further detail)
Slides	10 years
Reports	10 years
Autopsy consent	10 years
FORENSIC AUTOPSY	
Wet stock tissue	1 year
Paraffin blocks	10 years

Reports	Indefinitely
Slides	50 years or 30 years if a DNA sample is available
Gross photographs/images	Indefinitely
Accession records	Indefinitely
Body fluids and tissues for toxicology	1 year
Representative sample suitable for DNA Analysis	Indefinitely
Body transfer and disposition records	Indefinitely
CLINICAL PATHOLOGY	
Testing Records	
Instrument printouts (not interfaced with laboratory computer system) and worksheets	2 years
Patient test results and reports, including original and corrected reports, and referral laboratory reports	2 years
Direct-to-consumer testing results, including reference intervals	10 years
Patient Specimens	
Serum and plasma	48 hours; exceptions may be made at the discretion of the laboratory director. Longer storage requirements may be necessary for patients admitted for suspected drug overdoses.
Citrated plasma	At the discretion of the laboratory director (see HEM.36940)
CSF and body fluids (except urine)	48 hours
Whole blood specimens, including blood gas specimens	At the discretion of the laboratory director
Urine	24 hours; exceptions may be made at the discretion of the laboratory director
Clinical Pathology Slides	
Peripheral blood films	7 days
Permanently stained body fluid slides	7 days
Permanently stained microbiology slides prepared from clinical specimens (including blood culture bottles)	7 days
CYTOGENETICS	
Final reports	10 years - neoplastic disorders 20 years - constitutional disorders

Images (in situ hybridization (ISH) or non-ISH) (refer to NOTE 1)	10 years - neoplastic disorders 20 years - constitutional disorders
Chromosomal microarray data Original scan	2 weeks after the final report is released
Sufficient original data to support primary results generated and re-analysis	2 years
Slides	
Permanently stained slides	3 years
Fluorochrome stained slides	At the discretion of the laboratory director
Chromosomal microarray slides	At the discretion of the laboratory director
Original specimens and cultures	Until release of the final report
Processed specimens or cell pellets	2 weeks after final report
MOLECULAR PATHOLOGY	
Fluorochrome stained slides	At the discretion of the laboratory director
Chromosomal array slides	At the discretion of the laboratory director
<i>In situ</i> hybridization images* (see Note 1) or permanent slides	10 years - neoplastic disorders 20 years - constitutional disorders
Reports	10 years - neoplastic disorders 20 years - constitutional disorders
Next Generation Sequencing Data	
Sequence read files (eg, FASTQ, uBAM, BAM, CRAM) and variant calling files (eg, VDF, gVCF)	2 years
Array Data	
Original scan	2 weeks after the final report is released
Sufficient original data to support primary results generated and re-analysis	2 years
FLOW CYTOMETRY	
Data for evaluation of hematolymphoid neoplasia, PNH, and congenital immunodeficiency	10 years
Data for routine lymphocyte subset and CD34+ enumeration	2 years
TRANSFUSION MEDICINE	
Policies and procedures, including approval, review, and discontinuance	5 years

Quality Management Records	
Proficiency testing records	5 years
Management reviews for the effectiveness of the quality system	5 years
Blood supplier agreements	5 years
Irradiation dose delivery	5 years
Control systems for patient testing	10 years
Control systems for donor testing	10 years
Instrument and equipment maintenance and function checks	10 years
Temperature monitoring (eg, graphs, logs) of refrigerators, freezers, and platelet incubator	10 years
Inspections of blood/critical materials	10 years
Inspection of weld for completeness	10 years
Specimens	
Patient pretransfusion testing specimens	7 days post-transfusion
Specimens from blood donor units	7 days post-transfusion
Patient Records	
Orders and requests for blood/blood components	5 years
Transfusion administration records	10 years
Final unit disposition	10 years
Patient pre-transfusion testing results/interpretation	10 years
Immediate evaluation/interpretation of transfusion reactions	10 years
Final inspection and verification of blood before issue	10 years
Evaluation/interpretation of delayed transfusion reactions	10 years
Emergency release of blood, including signature of requesting physician	10 years
Therapeutic phlebotomy/apheresis records	10 years
Transfusion problems such as transfusion reactions, unexpected antibodies, and special transfusion requirements.	Indefinitely
Donor Records	
Blood/component donor information, consent and collection	10 years
Donor blood testing	10 years
Rotyping of donor units	10 years
Donor notification of significant findings	10 years
Component production	10 years

Look back investigation/disease reporting	10 years
Final unit disposition	10 years
Irradiation of cellular components	10 years
Acceptability of returned units into inventory	10 years
Indefinitely and permanently deferred donors	Indefinitely
Donors placed under surveillance (for recipient protection)	Indefinitely
Personnel	
Competency records	5 years
Training records † (see Note 2)	5 years
Records of employee signatures, initials, identification codes, and inclusive dates of employment	10 years
Other Records	
Identification of individuals performing each significant step in collection, processing, compatibility testing, and transportation of blood and blood components	10 years
Traceability of blood, blood components and critical materials	10 years
Container qualification/process validations	10 years
Tissue Records (including hematopoietic progenitor cells)	
Daily temperature monitoring	10 years
Investigation of adverse events	10 years
Discontinued policies, procedures and other controlled documents	10 years
Collection, transportation, processing, issuing, and disposition	10 years beyond tissue's disposition or expiration, whichever is longest

* *Note 1: There is no retention requirement for images of glass slide preparations when the source slides remain readable for the required retention period. A scanned image may not take the place of the source slides.*

† *Note 2: The five-year retention requirement for transfusion medicine training records aligns with the AABB Standards to provide consistency for laboratories that have coordinated CAP/AABB inspections and for labs in states that are required to follow AABB regulations (eg, California). Reference Table 6.2C in the AABB Standard lists: Standard 2.1.2 - Training Records of Personnel – minimum retention time (in years) – 5.*

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): [42CFR493.1105].
2. Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Records. Washington, DC: US Government Printing Office, 1999(Apr 1): [21CFR606.160].
3. Fanaoff J. Retention of Pediatric Medical Records. American Academy of Pediatrics. March 2016. <https://www.aap.org/en-us/professional-resources/practice-transformation/managing-practice/Pages/Retention-of-Pediatric-Medical-Records.aspx>. Accessed April 15, 2019.

<p>Document ID: Retention of Laboratory Records and Materials</p> <p>Document type: Public Policy</p> <p>Responsible: Council on Scientific Affairs</p> <p>Approve: Board of Governors</p> <p>Consult: None</p> <p>Inform: CAP Policy Manual; CAP Website</p>	<p>Adopted August 1995</p> <p>Revised September 1995</p> <p>Reaffirmed August 1998</p> <p>Revised November 2000</p> <p>Revised May 2001</p> <p>Revised November 2001</p> <p>Revised November 2004</p> <p>Revised November 2005</p> <p>Revised August 2007</p> <p>Revised March 2010</p> <p>Reaffirmed June 2013</p> <p>Revised September 2016</p> <p>Revised September 2020</p> <p>Revised January 2021</p>
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Appendix D: Glossary of Terms

Additional definitions are found in the Accreditation Checklists.

Accreditation

The determination by the CAP that a laboratory or biorepository has successfully met the CAP's accreditation program *Standards*.

Accreditation Checklist

A detailed series of requirements designed to evaluate whether the laboratory or biorepository meets the standards set forth in the CAP's accreditation program *Standards*. Each checklist serves as a tool to guide the conduct of the inspection.

Accreditation Cycle

The sequence of events for laboratories spanning a two-year period that leads to an accreditation decision.

Accreditation Packet

The packet of information that is sent to a laboratory following a decision to grant accreditation. The packet contains a certificate of accreditation, CAP letter of accreditation, final list of deficiencies, and a press release.

Accreditation Unit (AU)

The laboratory, department, or other organizational unit that is evaluated and can receive accreditation. An AU usually has a unique CLIA number, is located in one building or campus, and falls under the leadership of a single laboratory director who is named on the CLIA certificate.

Accreditation Unit Activity Menu (Laboratory-Specific Activity Menu)

The list of tests and non-test activities specific to a laboratory. The AU-specific activity menu is used to create the customized checklists, monitor PT, inspect, and report accreditation.

Accreditation with Requirements

Accreditation status assigned to a laboratory that is able to demonstrate compliance with all accreditation requirements and all required corrective action, and supporting documentation indicates compliance with the applicable CAP's *Standards* for Accreditation; however, during the review process, a need has been identified to monitor ongoing compliance through a non-routine inspection, the submission of documents, or both.

Activity

A reportable assay (eg, glucose, serum), scope of service (eg, therapeutic drug monitoring), or analytic method (eg, dipstick, manual).

Activity Menu, Master

The list of all tests and non-test activities subject to inspection and accreditation.

Alternative Performance Assessment

A system for determining the reliability of laboratory examinations for which no commercial proficiency testing products are available, are not appropriate for the method or patient population served by the laboratory, or participation is not required by the accrediting organization.

Anatomic Pathology

The major branch of pathology dealing with gross, microscopic, and molecular alterations in tissues and cells. Anatomic pathology includes, but is not limited to, autopsy pathology, surgical pathology, cytopathology, related aspects of molecular pathology, and the laboratories providing service in these areas.

Anniversary Date

The fixed date at which the laboratory accreditation will terminate unless the laboratory reapplies or (under some circumstances) is in the process of accreditation. The anniversary date is fixed and biennial (occurring every two years).

Authority

The power or right to give orders, make decisions, direct someone, or control a process.

BAP

See *Biorepository Accreditation Program*.

Biorepository

A facility that collects, processes, stores, and distributes biospecimens for research.

Biorepository Accreditation Program (BAP)

A CAP accreditation program that accredits facilities that collect, process, store, and distribute biospecimens for research.

CAP 15189

- A voluntary, non-regulated program providing accreditation to the ISO 15189:2012 Standard as published by the International Organization of Standardization.
- Assesses a laboratory's quality management system to include all facets of laboratory management, technical testing, and interacting departments.
- A highly disciplined approach to implementing a quality management system, sustaining continual improvement and evaluating the laboratory's effectiveness and contribution to the quality of patient care.
- Does not replace the CAP's CLIA-based Laboratory Accreditation Program, but rather complements CAP accreditation and other quality systems.

CAP-accepted PT Programs

A commercial program for external proficiency testing (PT) that has met the criteria established by the CAP. Analytes within an accepted program are individually evaluated for acceptance.

CAP Staff Inspector

A CAP employee who is a supervisor-eligible or experienced medical technologist (MT) that conducts inspections on behalf of the CAP.

Checklist

See Accreditation Checklist.

Checklist, Custom

A checklist assigned to an individual laboratory which, based on its activity menu, includes only those requirements and groups of requirements that apply to the laboratory.

CLIA

An act of Congress—The Clinical Laboratory Improvement Amendments of 1988. The term *CLIA* is also used to refer to the regulations that implement the act.

CLIA Number

An identification number assigned to a laboratory by the Centers for Medicare and Medicaid Services.

Clinical Consultant

Individual qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment, and management of patient care.

Clinical Laboratory

A facility engaged in the testing of specimens for the diagnosis, management, prevention, and treatment of disease or the assessment of health. A clinical laboratory usually has one CLIA number, is located in one building or campus under the leadership of a single laboratory director who is named on the CLIA certificate and is owned by one entity.

Clinical Pathology

The major branch of pathology dealing with the identification of disease through chemical measurement, physical measurement, or culture of bodily fluids and tissues. Clinical pathology includes, but is not limited to, hematology, urinalysis, chemistry, microbiology, immunology, transfusion medicine, histocompatibility, related aspects of molecular pathology, and the laboratories providing service in those areas.

CLIP/CLIP Number

Clinical Laboratory Improvement Program of the US Department of Defense (DOD), an equivalent of **CLIA**. The DOD regulates itself with a Memorandum of Agreement with the Department of Health and Human Services, Centers for Medicare and Medicaid Services due to the unique mission requirements within the DOD that are not found in the civilian sector. A CLIP identification number is assigned to the laboratory by CLIP.

CMS

Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration). An agency within the US Department of Health and Human Services that administers Medicaid, Medicare, and Child Health Insurance programs and enforces the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and previous years.

Code of Federal Regulations (CFR)

A codification (arrangement of) the general and permanent rules published in the *Federal Register* by the executive departments and agencies of the Federal Government.

Commissioner, Deputy or Division or State

Individuals responsible for the assignment of inspection team leaders.

Commissioner, Regional

Individuals responsible for overseeing laboratory accreditation activities and recommending accreditation decisions for a specified set of laboratories.

Consultant

One who provides professional advice or services on request.

Consulting Pathologist

A pathologist who periodically visits a laboratory and serves the role of a technical consultant and/or performs anatomic pathology services.

Corrected During Inspection

The process used by an inspector to record a deficiency on the inspection summation report and indicate that the appropriate corrective actions have been satisfactorily completed by the laboratory during the inspection. This process is limited to deficiencies where minimal corrections are necessary. These citations appear on a laboratory's final list of deficiencies, but a response is not routinely required.

Corrective Action

Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.

Council on Accreditation

A CAP council that formulates policy and oversees the accreditation programs. The Chair of the Council on Accreditation is a member of the CAP Board of Governors.

Credentialing

The process of obtaining, verifying, and assessing the qualifications of a practitioner to provide care in a health care organization.

Critical PT Performance (Non-regulated analytes)

Failure to attain the minimum satisfactory score for an analyte/test for three consecutive or three of four consecutive testing events for non-regulated analytes. A laboratory that has repeat critical performance (four out of five PT events) for a non-regulated analyte/test may be directed to cease testing.

Custom Checklist

See *Checklist, Custom*.

Deemed Status

The right granted by one organization to a second organization that permits the second organization to determine whether entities meet requirements imposed by the first organization. For example, the Centers for Medicare and Medicaid Services has granted deemed status to the CAP, thereby permitting the CAP to determine whether CAP-accredited laboratories meet the requirements of the CLIA federal regulations.

Deficiency

Noncompliance with a requirement of the accreditation checklists.

Deficiency Response

For each deficiency cited, the laboratory is required to submit an Inspection Deficiency Response within 30 calendar days after the inspection. For Phase I deficiencies, the laboratory must submit a plan of corrective action. For Phase II deficiencies, the laboratory must submit a plan of corrective action and supporting documentation showing that steps have been taken to correct the deficiency.

De-identification

Removal of information that can be used to identify an individual.

Denial of Accreditation

The decision (by the Accreditation Committee) not to accredit a laboratory based on the findings from its initial application or CAP inspection.

Director of Laboratory

See *Laboratory Director*.

Discipline

A CAP-defined term used to describe testing grouped within a major category of clinical laboratory science (eg, hematology, microbiology, or transfusion medicine).

Distributive Testing

Laboratory testing performed on the same specimen, or aliquot of it, that requires sharing between two or more laboratories (with different CLIA/CAP numbers) to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test.

Doctoral Scientist

An individual who has achieved a doctoral degree in a clinical laboratory discipline such as clinical chemistry, microbiology, immunology, etc.

Expungement

The elimination of a deficiency from a laboratory's record when it is determined that the laboratory was in fact in compliance at the time of the citation.

FDA

1) For laboratories subject to US regulations, FDA refers to the US Food and Drug Administration, which is the regulatory body under Health and Human Services (HHS) with authority to regulate *in vitro* diagnostic products such as kits, reagents, instruments, and test systems. 2) For laboratories not subject to US regulations, FDA refers to the national, regional, or local authority having jurisdiction over *in vitro* diagnostic test systems.

FDA-approved Test

A test that is classified as a Class III medical device and that has been approved by the FDA through the premarket approval (PMA) process. (21CFR814.3).

FDA-cleared Test

A test that has been cleared by the FDA after analysis of data showing substantial performance equivalence to other tests being marketed for the same purpose. Such tests typically follow the 510(k) approval route. (21CFR807).

FDT

See *Forensic Drug Testing*.

Final List of Deficiencies

A document included in the Accreditation Packet that lists deficiencies (if any) that were found during a laboratory's accreditation inspection, exclusive of any deficiencies that were expunged during the post-inspection process.

Forensic Drug Testing (FDT)

The CAP accreditation program for laboratories that perform drug testing for nonmedical purposes (eg, workplace drug testing).

Full-Service Laboratory

A Laboratory that offers a variety of services in multiple laboratory disciplines (eg, chemistry, hematology, microbiology, transfusion medicine, cytopathology, anatomic pathology).

General Supervisor

A position defined by the Clinical Laboratory Improvement Amendments (CLIA) of 1988 as the individual who provides day-to-day supervision of testing personnel and reporting of testing results in a laboratory that performs high-complexity testing.

High Complexity

Rating given by the FDA to commercially marketed in vitro diagnostic tests based on their risks to public health. Tests in this category are seen to have the highest risks to public health.

Immediate Review Criteria (IRC)

Findings that indicate that review of a laboratory's inspection results should be given a higher priority throughout the accreditation review process. Such findings include an excessive percentage of deficiencies and problems with proficiency testing.

Inspection Instance (II)

A numerical identifier for each inspection that groups together laboratories and sections\departments (usually a single campus or geographic area).

Inspection Team Leader

The individual responsible for assembling and leading a team of inspectors and for submitting the Inspector's Summation Report to the CAP.

Inspection Team Member

An individual designated by the inspection team leader to perform a specific aspect of the inspection.

Inspection Unit (IU)

One or more laboratories that are inspected at the same time by an inspection team. An IU is used to track that the laboratories in the IU have fulfilled their inspection obligation.

Inspector

An experienced pathologist, resident or fellow in pathology, clinical scientist, medical technologist, or other laboratory personnel, as appropriate, who acts as an inspection team member or team leader.

Inspector's Inspection Packet

The packet of materials sent to an inspection team leader to be used to conduct an inspection. Included are the appropriate checklists, laboratory synopsis reports, the *Laboratory Accreditation Manual*, previous inspection results, and Inspector's Summation Report forms, and other needed materials.

Inspector's Summation Report (ISR)

The form returned by the inspection team leader documenting inspection deficiencies, recommendations, and inspector's comments.

IRC Laboratory

See *Immediate Review Criteria*.

Laboratory

Term used to refer to a clinical laboratory, biorepository, forensic drug testing laboratory, or reproductive laboratory participating in the CAP accreditation programs.

Laboratory Developed Test (LDT)

For the purposes of interpreting the checklist requirements, a laboratory-developed test (LDT) is defined as follows: A test used in patient management that has both of the following features:

1. The test is performed by the clinical laboratory in which the test was developed wholly or in part; **AND**
2. The test is neither FDA-cleared nor FDA-approved.

Laboratory Director

The individual who is responsible for the overall operation and administration of the laboratory, including provision of timely, reliable, and clinically relevant test results and compliance with applicable regulations and accreditation requirements. This individual is listed on the laboratory's CAP and CLIA certificates (as applicable).

Laboratory Inspection Packet

A packet of information sent to the laboratory prior to the inspection that contains the laboratory -specific activity menu, checklists, deficiency response sheets, and instructions on how and when to respond to deficiencies.

Laboratory-specific Activity Menu

See *Accreditation Unit Activity Menu*.

License

Right or permission granted in accordance with the law by a competent authority to engage in some business or occupation, which, but for such license, would be unlawful. For laboratories, a license may be granted by a municipal, state, or federal authority. For physicians, in the United States, a license is granted by the State Board of Medical Examiners.

List of Deficiencies

The set of checklist requirements that were established as deficiencies at an inspection of a specific laboratory.

Master Activity Menu

See *Activity Menu, Master*.

Moderate Complexity

Rating given by the FDA to commercially marketed *in vitro* diagnostic tests based on their risks to public health.

Non-routine Inspection

Any inspection performed on-site in addition to the biennial routine inspection. Non-routine inspections may be performed for a variety of reasons, including (without limitation) a change of laboratory director, addition of disciplines, determination of whether the laboratory has met conditions imposed by the CAP, or investigation of a complaint.

Nonwaived

Tests categorized as either moderately complex (including provider-performed microscopy) or high complexity according to a scoring system used by the FDA.

Pathologist

A physician who has successfully completed an approved graduate medical education program in pathology.

Pathologist Assistant

An individual qualified to perform high-complexity testing (under CLIA regulations), with appropriate training and/or education, who assists the pathologist in gross examination of surgical specimens, autopsies, and other procedures.

Pathology

The specialty of the practice of medicine dealing with the causes and nature of disease, including diagnosis, prognosis, and response to treatment, generally involving examination of biologic materials (eg, tissue, blood, or other fluids).

Personnel

The collective group of employees and contractors employed in the laboratory organization. Contractors may include those individuals contracted by the laboratory, such as pathologists, medical technologist, or nurses who perform patient testing. It would not include those individuals contracted outside the authority of the laboratory, such as medical waste disposal contractors, instrument service representatives, or cleaning contractors.

Point-of-Care Testing

Testing that is performed at or near the site where the patient is located, that does not require permanent dedicated space, and that is performed outside the physical facilities of the clinical laboratories.

Policy

Written statement of overall guidelines, strategy, approach, intentions, and directions endorsed by laboratory leadership that direct or restrict a facility's plans, actions, and decisions.

Postanalytic Phase (post-examination process)

Processes following the analysis (examination) of patient specimens, including review, formatting, interpretation, verification, reporting and transmission of the results, and storage of samples and results.

Preanalytic Phase (pre-examination process)

Processes prior to the analytic examination of patient specimens, including, in chronological order: the clinician's request, test order, preparation of the patient, collection of the primary sample, transportation to and within the laboratory, and sample preparation.

Preliminary Accreditation

Accreditation status that is applied to a laboratory when there is an urgent need for an accreditation decision prior to completion of the usual course of action for an accreditation decision, or when accreditation is required prior to the commencement of patient testing. This status remains in effect until such time the final accreditation process has taken its course and a final accreditation decision is made.

Preventive Action

Action taken to eliminate the cause of a potential nonconformity or any other undesirable potential situation.

Primary Source Verification Report

A document, usually prepared by a third party agent or company, that confirms that a job applicant's degree, certificate, or diploma is authentic, licenses were granted, and reported work history (company names, locations, dates and positions held) is accurate. The confirmation is obtained through direct contact with an institution, former employer, or their authorized agents.

Probation

An accreditation status assigned by the Accreditation Committee if any of the following inspection findings exist:

- Documentation is insufficient to determine compliance with the CAP's standards within the *Standards for Laboratory Accreditation*.
- The committee wishes to monitor the laboratory's progress in correcting deficiencies.
- The laboratory has engaged in conduct contrary to the policies of the CAP but such conduct is not sufficient to warrant denial or revocation of accreditation.

A laboratory on probation may continue to provide testing as an accredited laboratory.

Probation with Immediate Jeopardy

A status assigned by the Accreditation Committee when noncompliance with one or more requirements of the CAP has already caused, is causing, or is likely to cause serious injury, harm, or death to individuals served by the laboratory and/or to the health or safety of the general public and/or to laboratory workers or visitors.

Procedure

Set of specific instructions that describe the stepwise actions taken to complete a process, operation, activity, or task.

Process

A set of related tasks or activities that accomplishes a work goal; A set of interrelated or interacting activities that transforms inputs into outputs.

Proficiency Testing (PT) (Also termed: External Quality Assessment [EQA])

Evaluation of participant (or individual) performance against pre-established criteria by means of interlaboratory comparisons.

Proficiency Testing Performance <100% Report

A report included in the Inspector Inspection Packet that shows all variant PT performances (any score that is less than 100%) for the last six PT mailing events for the laboratory. This report is intended to help the inspector focus on possible problem areas. All variant PT results must be investigated, and corrective action documented.

Provider Performed Microscopy (PPM)

Testing that is personally performed by a physician in conjunction with the physical examination or treatment of a patient. PPM tests are limited to those listed in the accreditation checklists.

Quality Control

An integral component of quality management composed of the aggregate of processes and techniques used to detect, reduce, and correct deficiencies in an analytical process. Quality control (QC) is a surveillance process in which the actions of people and performance of equipment and materials are observed in some systematic, periodic way that provides a record of consistency of performance and of action taken when performance does not conform to standards set by the laboratory. QC is a set of procedures designed to monitor the test method and the results to ensure test system performance; QC includes testing control materials, charting the results and analyzing them to identify sources of error, and determining, performing, and documenting any remedial action taken as a result of this analysis.

Quality Improvement

A systematic method used to identify opportunities for improvement in clinical and nonclinical systems.

Quality Management

All activities of the overall management function that determine quality policy objectives and responsibilities and the implementation of them, including the preanalytic, analytic, and postanalytic phases of testing.

Quality Management System (QMS)

A set of policies, processes, procedures, and resources designed to ensure high quality in an organization's services.

Referral Laboratory

The laboratory that receives a specimen for analysis from another laboratory.

Referring Laboratory

The laboratory that initiates the transfer of a specimen to another testing facility for analysis.

Repeat Unsuccessful Proficiency Testing (PT) Performance (Cease Testing for Regulated Analytes)

Unsatisfactory PT performance for a CLIA-regulated analyte/test/subspecialty in three consecutive or two sets of “two out of three” (a failure in one event may be included in more than one set) over twelve PT events. A laboratory that has repeat unsuccessful PT performance for a regulated analyte/test/subspecialty may be directed to cease testing for six months.

Reproductive Laboratory Accreditation Program (RLAP)

The CAP accreditation program that accredits laboratories that perform andrology and embryology testing.

Required Analyte

An activity for which the CAP Accreditation Program requires PT enrollment and participation in a CAP-accepted PT Program. Both waived and nonwaived activities are included in the list of required analytes.

Responsibility

A duty or task that an individual is required or expected to do.

Reviewing Commissioner

The commissioner (ordinarily a regional commissioner) who reviews the Inspector’s Summation Report and the laboratory’s responses and makes an accreditation recommendation to the Accreditation Committee.

Revocation of Accreditation

Termination of a laboratory’s existing accreditation by the Accreditation Committee.

RLAP

See Reproductive Laboratory Accreditation Program.

Root Cause Analysis (RCA)

A systematic process for identifying the causal factor(s) that underlie errors or potential errors in care.

Section Director

The individual who is responsible for the technical and/or scientific oversight of a specialty or section of the laboratory.

Section Unit (SU)

An operational area or department of a laboratory, which may correspond to a laboratory specialty (eg, hematology, chemistry).

Self-Inspection

The laboratory-performed inspection that occurs in the year between CAP-performed inspections.

Standards

Collective term used to describe the *Standards for Laboratory Accreditation, Standards for Forensic Drug Testing Accreditation, Standards for Reproductive Laboratory Accreditation, and Standards for Biorepository Accreditation* as published by the CAP Council on Accreditation. The *Standards* are the core principles of the CAP's accreditation programs.

SU

See *Section Unit*.

Subdiscipline

A CAP-defined term used to describe related testing activities that reside under a particular discipline (eg, parasitology, virology, mycology).

Subject to US Regulations

Laboratories located within the United States, and laboratories located outside of the US that have obtained or applied for a CLIA certificate to perform laboratory testing on specimens collected in the US and its territories for the assessment of the health of human beings.

Supervisor

A person responsible for the daily activities of a section unit.

Suspension

Removal of accreditation from one or more sections of a laboratory. The suspended section(s) may not provide testing as an accredited laboratory. This status is assigned by the Accreditation Committee pending the laboratory meeting conditions assigned by the committee. The suspended status may exist for no more than 45 days.

Target Inspection Date

The date that signifies the end of the calendar day window during which the inspection should occur. For accredited laboratories, the target inspection date and the anniversary date are usually the same.

Technical Consultant

A position defined by CLIA as the individual responsible for the technical and scientific oversight of a laboratory performing moderately complex testing. The technical consultant may or may not be the same individual as the laboratory director, depending on the qualifications of the laboratory director and the manner in which the laboratory is organized. The technical consultant may be a pathologist, other physician, doctoral scientist, or possess other required qualifications.

Technical Supervisor

A position defined by CLIA as the individual responsible for technical and scientific oversight of a laboratory performing high complexity testing. The qualifications required for the technical supervisor may vary, depending on the laboratory specialty. The technical supervisor may be a pathologist, other physician, doctoral scientist, or possess other required qualifications.

Telepathology

The practice of pathology and cytology in which digitized or analog video, still image(s), or other data files are examined, and an interpretation is rendered that is included in a formal diagnostic report in the patient record. It also includes the review of images by a cytotechnologist when a judgement of adequacy is recorded in the patient record.

Termination of Accreditation

The process by which a laboratory's accreditation is ended and all regulatory agencies involved with the laboratory are notified. Reasons for termination include:

- Denial of a laboratory's accreditation after an inspection.
- Initiation of termination by the laboratory itself when it no longer wishes to participate in the CAP's laboratory accreditation programs. The laboratory is responsible for notifying CAP staff of its intention to discontinue coverage.
- Failure to return reapplication materials within a specified time frame. The termination will occur after reminder options have been exhausted. Letters will be sent to the laboratory and the regional commissioner stating that the laboratory has been terminated because completed reapplication materials were not returned to CAP.
- Merger of two or more laboratories, which results in the accreditation of a single laboratory. The laboratories that are no longer effective (eg, discontinued CLIA number) will be terminated, and the surviving laboratory's record will be updated to reflect all changes due to the merger.
- Failure to meet the standards set forth in the CAP's accreditation *Standards*.

Terms of Accreditation

Administrative obligations of a CAP-accredited laboratory.

Test

A qualitative, semiquantitative, quantitative, or semiquantitative procedure for detecting the presence of, or measuring of an analyte.

Test Complexity

Test categorization, as defined by CLIA (42CFR493.17). Tests are divided into waived, moderately complex, and highly complex categories, based on the scientific and technical knowledge, training and experience, and interpretation and judgment required to perform the test; and the degree of difficulty in the handling of reagents and materials, operational steps, calibration, and maintenance.

Testing Personnel

Individuals responsible for performing laboratory assays and reporting laboratory results.

Unsatisfactory Proficiency Testing (PT) Performance

Failure to attain at least 80% for a regulated analyte/subspecialty/specialty (ABO, Rh, and Compatibility Testing requires 100%) for a testing event. Clerical errors or data omissions are considered PT failures. For non-regulated analytes, satisfactory performance will vary based on the number of challenges. (Refer to the CAP's PT/External Quality Assurance Toolbox available through e-LAB Solutions Suite for more information.)

Unsuccessful Proficiency Testing (PT) Performance

Failure to attain at least 80% for a regulated analyte/subspecialty/specialty for 2 consecutive or 2 out of 3 testing events. (ABO, Rh, and Compatibility testing requires 100%). Unsuccessful PT performance and unsuccessful PT participation are synonymous. For non-regulated analytes, satisfactory performance will vary based on the number of challenges. Refer to the CAP's PT/External Quality Assurance Toolbox available through e-LAB Solutions Suite for more information.

Virtual Inspection

CAP model for remotely assessing laboratory compliance that utilizes video conferencing, digital file transfer, and live streaming to perform an interactive review of laboratory policies and procedures, records, and processes.

Visitor

An individual entering the laboratory who is not considered personnel.

Volunteer Inspector

A person who conducts inspections for the CAP's laboratory accreditation programs without monetary compensation. All laboratories enrolled in the CAP's laboratory accreditation programs are expected to provide a volunteer inspector team once every two years to conduct an inspection of another similar laboratory, if asked.

Waived

A category of tests defined as "simple laboratory examinations and procedures which have an insignificant risk of an erroneous result." Laboratories performing waived tests are subject to minimal regulatory requirements.

For laboratories subject to US regulations, these tests are assigned to the waived category by the US Food and Drug Administration (FDA).

Appendix E: CAP Accreditation Program Website Tools

The table includes a list of resources available on cap.org. The fastest way to locate these resources is to use the **search** option using the path indicated in the **Location** column below. Resources marked with an asterisk (*) require e-LAB Solutions Suite log in and access to an accredited laboratory. The link to access e-LAB Solutions Suite is on the CAP Home Page.

Tool	Location	Description
Accreditation Checklist Download*	e-LAB Solutions Suite: Search – Accreditation Checklists -OR- Go to: Accreditation Resources - Accreditation Checklists	Online tool to download checklists, with options to select: <ul style="list-style-type: none"> • Checklist module • Checklist edition • Checklist Type: <ul style="list-style-type: none"> ○ Master (displays all requirements with references and inspector instructions) ○ Custom (displays applicable requirements based on lab test menu) ○ Changes only (displays changes from previous to current edition) • Checklist format (PDF, Word/XML, or Excel)
Accredited Laboratory and Biorepository Directory	CAP Home: Go to: Laboratory Improvement – Accreditation – Find a CAP Accredited Laboratory	Searchable database of CAP-accredited laboratories or biorepositories
Biorepository Resources*	e-LAB Solutions Suite: Go to: Accreditation Resources – Quality Management	Quality management resources for biorepositories
CAP Accreditation Programs Policy Manual*	e-LAB Solutions Suite: Search – CAP Accreditation Programs Policy Manual -OR- Go to: Accreditation Resources – Accreditation Manuals/Retention Guidelines – CAP Accreditation Programs Policy Manual	CAP Accreditation Program administrative policies approved by the CAP’s Council on Accreditation

CAP Accreditation Standards*	e-LAB Solutions Suite: Go to: Accreditation Resources – Accreditation Manuals/Retention Guidelines	The principles of the CAP accreditation programs: <ul style="list-style-type: none"> • Laboratory Accreditation Program (LAP) • Forensic Drug Testing Program (FDT) • Reproductive Laboratory Accreditation Program (RLAP) • Biorepository Accreditation Program (BAP)
CAP Cancer Protocols Templates	CAP Home: Search - Cancer Protocols	Guidelines for collecting the essential data elements for complete reporting of malignancies and optimal patient care
CAP Laboratory Director Education, Information and Resources*	e-LAB Solutions Suite: Search – CAP Laboratory Director Education, Information & Resources -OR- Go to: Accreditation Resources – CAP Laboratory Director Education, Information & Resources	Tools to educate laboratory directors on director responsibilities
CAP Evidence-Based Guidelines	CAP Home: Search – CAP Guidelines	Evidence-based guidelines and consensus recommendations developed by the CAP Pathology and Laboratory Quality Center, along with its professional partners, intended to improve diagnostic and clinical decision making
CAP Personnel Requirements by Test Complexity*	e-LAB Solutions Suite: Search – CAP Personnel Requirements by Test Complexity -OR- Go to: Accreditation Resources – Application/Reapplication Process	Listing of CAP personnel qualifications for all CLIA-defined roles based on the complexity of tests performed
Checklist Edition Amendments and Corrections*	e-LAB Solutions Suite: Search – Checklist Edition Amendments and Corrections -OR- Go to: Accreditation Resources – Checklist Edition	Listing of errors or changes in checklist interpretation in a checklist edition after publication (not all editions have these updates)

Checklist Edition Deleted, Merged, and Moved Table*	e-LAB Solutions Suite: Search – Checklist Edition Deleted, Merged, and Moved Table -OR- Go to: Accreditation Resources – Checklist Edition	Listing of requirements that have been deleted, merged with another requirement, or moved to a different requirement number
Checklist Requirement Questions & Answers*	e-LAB Solutions Suite: Search – Checklist Requirement Q & A -OR- Go to: Accreditation Resources – Checklist Requirement Q&A	Answers to commonly asked checklist requirement questions
Deficiency Response*	e-LAB Solutions Suite: Go to: Deficiency Response	Dashboard used to upload and monitor deficiency responses
Deficiency Response Instructions*	e-LAB Solutions Suite: Search – Self and Post-inspection Toolbox -OR- Go to: Accreditation Resources – Self and Post-inspection Toolbox	Instructions for responding to CAP inspection deficiencies
eAlerts	CAP Home: Search: - eAlerts	Links to important notifications sent to laboratories about changes to the CAP's accreditation programs
Fast Focus on Compliance	CAP Home: Search – Fast Focus on Compliance	Mini-training vignettes for inspectors that use real world examples to provide practical approaches to handle new and perplexing topics
Focus on Compliance Webinars – Library of Past Webinars*	e-LAB Solutions Suite: Search– Focus on Compliance -OR- Go to: Accreditation Resources – Focus on Compliance	Archived webinar materials including: <ul style="list-style-type: none"> • Presentations • Toolkits • Questions & Answers
Focus on Compliance Webinars – Registration	CAP Home: Search – Focus on Compliance	Registration information for the complimentary series of accreditation educational webinars <ul style="list-style-type: none"> • Designed for laboratory directors, managers, and technologists • Provides expert knowledge and regulatory compliance insight

Individualized Quality Control Plan (IQCP) Toolbox*	e-LAB Solutions Suite: Search – Focus on Compliance -OR- Go to: Accreditation Resources – IQCP Toolbox	Web page includes the following tools: <ul style="list-style-type: none"> • IQCP frequently asked questions • IQCP Eligibility Flow Chart • IQCP List form and instructions • IQCP Quality Assessment – example form Jointly developed microbiology tools for antimicrobial susceptibility testing, identification systems, and media <ul style="list-style-type: none"> • Inspector tip sheet • IQCP Webinar
Inspection Resources – including Virtual and Modified Inspections*	e-LAB Solutions Suite: Search – Inspector Training & Tools -OR- Go to: Accreditation Resources – Inspector Training and Tools	Tools for performing virtual inspection and understanding the modified inspection process
Inspection Summation Report (ISR)*	e-LAB Solutions Suite: Search – Inspection Summation Report	Web page that allows laboratories to generate reports with deficiency information from current and previous CAP inspections
Inspector Guides and Tip Sheets*	e-LAB Solutions Suite: Search – Inspector Training and Tools -OR- Go to: Accreditation Resources – Inspector Training and Tools	Team leader and team member guides
Inspector Training Modules	CAP Home: Search – Inspector Training -OR- Go to: Education Main Page– Inspector Training	Online Inspector Training modules for: <ul style="list-style-type: none"> • Team leaders • Team members • Performing virtual inspections
Laboratories Outside the USA	CAP Home: Search – Laboratories Outside the USA -OR- Go to: Laboratory Improvement – Laboratories Outside the USA	Important information for international laboratories to consider when applying for CAP accreditation

Laboratory Accreditation Manual *	e-LAB Solutions Suite: Search– Laboratory Accreditation Manual -OR- Go to: Accreditation Resources – Accreditation Manuals/Retention Guidelines	Resource for laboratories and inspectors on the inspection and accreditation processes
Laboratory Inspection Preparation Course*	e-LAB Solutions Suite: Search – Laboratory Inspection Preparation -OR- Go to: Accreditation Resources – Laboratory Inspection Preparation Course	Short videos on a variety of accreditation topics designed to help prepare for CAP inspection for new and experienced laboratory leadership
Limited Services Crosswalk*	e-LAB Solutions Suite: Search – Limited Services Crosswalk -OR- Go to: Accreditation Resources – Accreditation Checklists – Limited Services Crosswalk	Tool that cross-references requirements found in the LSV checklist with the same requirements found in other checklists
Navigating the Virtual Inspection*	e-LAB Solutions Suite: Go to: Accreditation Resources – Laboratory Inspection Preparation Course	Tips on using the SharePoint software tool to share and review documents online during virtual inspections
Organization Profile*	e-LAB Solutions Suite: Go to: Organizational Profile	Tool to view and update laboratory data such as: <ul style="list-style-type: none"> • Demographics • General information on laboratory operation • Regulatory relationships (eg, CLIA number, state licensure) • Personnel roles • Laboratory sections/departments and activities performed in each
Performance Analytics Dashboard*	e-LAB Solutions Suite: Search – Dashboard -OR- Go to: Launch Dashboard	Web-based reporting solution, free to CAP-accredited laboratories, that is updated daily to: <ul style="list-style-type: none"> • Provide a comprehensive data view for proficiency testing and accreditation performance • Allow laboratories to benchmark individual performance against peers and CAP-wide performance

<p>Proficiency Testing (PT)/External Quality Assurance Toolbox *</p>	<p>e-LAB Solutions Suite: Search – PT Toolbox -OR- Go to: Accreditation Resources – Proficiency Testing (PT)/External Quality Assurance (EQA) Toolbox</p>	<p>PT resources including:</p> <ul style="list-style-type: none"> • PT compliance frequently asked questions • PT troubleshooting guides • PT result failure investigation forms • Alternative performance assessment guide
<p>Proficiency Testing Compliance Notice (PTCN)*</p>	<p>e-LAB Solutions Suite: Search – PT Compliance Notice -OR- Go to: Accreditation Resources– Proficiency Testing (PT)/External Quality Assurance (EQA) Toolbox</p>	<p>Instructions for actions to take if a PT compliance notice is received for:</p> <ul style="list-style-type: none"> • Missing PT/Non-enrollment • Non-participation in PT • Unacceptable PT performance <p>PT/EQA failure types and codes</p>
<p>Quality Management (QM)*</p>	<p>e-LAB Solutions Suite: Search – Quality Management -OR- Go to: Accreditation Resources– Quality Management</p>	<p>Quality management tools for establishing and monitoring quality indicators and educational content on quality management systems and root cause analysis</p>
<p>Retention of Laboratory Records and Materials*</p>	<p>e-LAB Solutions Suite: Search – Retention of Laboratory Records and Materials -OR- Go to: Accreditation Resources – Accreditation Manuals/Retention Guidelines</p>	<p>CAP guidelines for the retention of laboratory records and materials</p>
<p>Root Cause Analysis Toolkit*</p>	<p>e-LAB Solutions Suite: Search – Root Cause Analysis -OR- Go to: Accreditation Resources – Quality Management</p>	<p>Spreadsheet for performing a root cause analysis that helps to:</p> <ul style="list-style-type: none"> • Define a problem • Map current processes • Find the root cause • Develop a solution • Implement a solution • Assess effectiveness <p>RCA completed example and check sheet</p>
<p>Self-Inspection Tools*</p>	<p>e-LAB Solutions Suite: Search – Self and Post-inspection Toolbox -OR- Go to: Accreditation Resources - Self & Post-inspection Toolbox</p>	<p>Tips for performing a self-inspection and self-inspection forms</p>

CAP accreditation: Share the good news!

It's time to let everyone know about your team's hard work. CAP accreditation means your laboratory has met the highest standards for patient care, and that's a distinction well worth sharing. The CAP Communications team will help you spread the news with:

Share the good news in the following ways:

- **Via a news release and/or newsletter article:** Templates for both can be obtained by emailing media@cap.org. Complete and send to your Communications, Public Relations/Media, and/or Marketing departments for help with distribution.
 - The **news release** can be distributed externally to your community newspapers or a newswire service for a wider, more national reach. This template is available in select languages¹. Please contact media@cap.org to request a copy in the desired language(s).
 - The **newsletter article** can be placed in all your internal publications and posted on your website.
- **Via social media:** Publicize your accreditation via your institution's Facebook, Twitter, or other social media channels. Email media@cap.org for suggested social media memes and quotes from the CAP Council on Accreditation chair.

Download these helpful resources:

- **the CAP accreditation mark with usage guidelines:** Laboratory professionals are an integral part of patient care. Make your dedication & contribution to the patient care team more visible within your organization and showcase this important achievement & value to patients and the community. To download the accreditation mark, along with the usage guidelines, please visit [e-LAB Solutions Suite](#) (login required). *We'd love to see your laboratory use this CAP accreditation mark and ask that the CAP master brand logo is not used.*

We are excited to help you publicize your achievement in advancing laboratory medicine. If you have any questions, feel free to email us at media@cap.org or you can contact Catherine Dolf, Senior Manager, Media Relations directly at cdolf@cap.org for assistance.

- **A photo of your laboratory team:** A picture is worth a thousand words! Just snap a photo of the laboratory team and invite your CEO to be a part of the picture, too. The photo can accompany your news release, newsletter article, or both!
 - The CAP would also like the photo, so we can let others know about your achievement! Please send the photo, along with the names of your laboratory director and CEO (if applicable) to: media@cap.org.
 - Once a month, we will feature a CAP-accredited laboratory and photo on cap.org.

Discover other ways to achieve laboratory excellence with the CAP's Laboratory Quality Solutions programs.

- Verify the accuracy and reliability of your entire testing process through [proficiency testing](#).
- Reduce risk and improve patient outcomes through [quality improvement](#).
- Achieve diagnostic confidence and ensure the best patient care with [protocols and guidelines](#).

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¹ Arabic, Simplified Chinese, German, Japanese, Korean, Portuguese (Brazil), Spanish (Central/South America),



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