



COLLEGE of AMERICAN  
PATHOLOGISTS

Laboratory Quality Solutions



# Laboratory Accreditation Manual

Patient Safety | Compliance | Consistency | Confidence | Accuracy | Quality

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cap.org

## How to Contact the CAP

The information below identifies laboratory accreditation resources at the College of American Pathologists. Please contact the appropriate person by phone, mail, or fax.

- **By phone:** The CAP's main telephone number is **800-323-4040 or 847-832-7000**. CAP Accreditation business hours are 8:00 AM–5:00 PM Central Time, Monday through Friday, excluding holidays.
  - **By mail:** Mail accreditation materials to:  
CAP Accreditation Programs  
College of American Pathologists  
325 Waukegan Road  
Northfield, IL 60093
  - **By fax:** The Accreditation Program's main fax number is 847-832-8171.
  - **By email:** Contact the College of American Pathologists at [cap.org](http://cap.org).
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**Call CAP at 800-323-4040** or 847-832-7000 for questions about

- Accreditation program brochures
- Application/reapplication
- Director changes
- Inspector assignments
- Inspection dates
- Inspection materials or packets
- Laboratory demographic changes
- Laboratory test menu
- New laboratories
- Ownership changes
- Self-evaluation
- Status of accreditation

**Call CAP Accreditation Technical Specialists at 800-323-4040** or 847-832-7000 ext. 6065 or email to [accred@cap.org](mailto:accred@cap.org) for questions about

- Interpretation of checklist items
- Responding to deficiencies
- Technical review of deficiencies

**Call the Investigations Analyst at 866-236-7212** or 847-832-7533 for information about

- CMS validation inspections
- Complaints about laboratories

**Call the Regulatory Affairs Analyst at 800-323-4040 ext. 7492** or 847-832-7492 for information about

- CMS reporting issues
- State reporting issues

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# INTRODUCTION

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## Purpose of this Manual

The Laboratory Accreditation Manual is intended to provide laboratories and inspectors a basic overview on the CAP's accreditation programs and accreditation processes.

## Overview of Accreditation Programs

The College of American Pathologists (CAP) directs multiple accreditation programs. 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, 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 in 53 countries.

The accreditation programs are based on rigorous accreditation standards that are translated into detailed checklist requirements. CAP inspection teams use the checklists as a guide to assess the laboratory's overall management and operation. Inspectors examine preanalytic, analytic, and postanalytic aspects of quality management (QM) in the laboratory. These include the performance and monitoring of general quality control (QC); test methodologies and specifications; reagents, controls, and media; equipment; specimen handling, test reporting and internal performance assessment; and external proficiency testing. In addition, personnel requirements, safety, document management, and other administrative practices are included in the inspection process.

The programs are internationally recognized and are the only ones that utilize teams of practicing laboratory professionals as inspectors. Designed to go well beyond regulatory compliance, the program helps laboratories achieve the highest standards of excellence and positively impact patient care.

## Accreditation Program Organization

The Council on Accreditation (CoA) sets the strategic direction for the CAP's accreditation programs, in accordance with the CAP's vision, and monitors its overall effectiveness in ensuring that participating laboratories meet regulatory and CAP requirements. The CoA also provides oversight to the Commission on Laboratory Accreditation (CLA), a group of qualified pathologists appointed with the following charges:

- Advance the CAP's accreditation programs as the prime exemplar for the inspection and accreditation of clinical laboratories and biorepositories
- Administer the programs through the principles of peer review and education
- Further the goal of laboratory improvement in order that quality laboratory services are provided to patients and clients
- Ensure that the programs continue to meet the scientific, service, and regulatory needs of participants
- Enhance the recognition of the pathologist laboratory director's role in clinical decision making and consultation.

The CLA oversees and coordinates the activities of five CLA committees in the development, maintenance, and implementation of accreditation checklists and standards, the inspection processes, inter-inspection assessment tools, complaint investigations, and program education. The CLA also ensures that committee priorities and activities are aligned with the overall goals and strategies supporting the CAP's Accreditation programs. The CLA uses the expertise of numerous CAP scientific resource committees to keep the programs and their requirements abreast of new developments in laboratory medicine.

The Accreditation Committee, another arm of the CoA, is responsible for ensuring objectivity and consistency in CAP accreditation decisions. The Accreditation Committee is responsible for all accreditation status decisions, including accreditation suspension and probation, based on the recommendations from the reviewing commissioners, technical specialists, and other LAP committees.

### Commissioners

Regional commissioners are responsible for the accreditation activities of a specified group of laboratories. This includes the timely assignment of inspectors, review of inspection findings, and presentation of accreditation issues to the Accreditation Committee. Following an on-site inspection, the regional commissioner, in conjunction with CAP technical staff, reviews the inspection findings and the laboratory's corrective action, and contributes to any follow-up necessary to reach an accreditation decision.

State and division commissioners assist the regional commissioners. State and division commissioners are responsible for validating proposed inspector matches for the laboratories in their geographic regions. They are assisted by CAP staff to ensure that inspections are timely and in accordance with accreditation program policy. They are responsible for providing feedback and mentoring to volunteer inspectors.



## Inspectors and CAP Staff

The inspectors who conduct the on-site laboratory inspections are the lifeblood of the accreditation programs. Typically, the inspection team leader is a board-certified pathologist who has received training and has participated in several inspections as a team member. Inspection team members are other pathologists, doctoral scientists, supervisory-level medical technologists, pathology residents and fellows, and other individuals who have been trained in CAP inspection requirements and have expertise in the area of the laboratory that they inspect.

The CAP accreditation program staff at the CAP headquarters in Northfield, Illinois, comprises technical and administrative personnel who carry out the policies and procedures of the CLA and who 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 this manual, three other documents are fundamental to the inspection process: 1) the *Standards for Laboratory Accreditation* (the *Standards*), 2) the *Accreditation Checklists*, and 3) the 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 information and records it on the ISR; this information is the basis for the regional commissioner's accreditation recommendation. In addition to verifying compliance with accreditation requirements, the inspection team may share ideas for laboratory improvement. 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 four 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 CLA and 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 on-site authority for the interpretation of these standards.

Standard I relates to the qualifications, responsibilities, and role of the **director**. It discusses which responsibilities may be delegated, as well as the role of a consulting pathologist.

Standard II concerns 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. On-site inspection by an external team and an interim self-inspection are the cornerstones of the inspection requirement. Participating laboratories also provide 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. The checklists serve as instruments to guide the conduct of the inspection. The checklists are revised periodically and include approximately 2,900 requirements. Detailed information on the checklists is included in the Accreditation Checklists section and in Appendix A: Accreditation Checklist Usage Summary.

## ACCREDITATION PROGRAM TYPES

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The CAP's Accreditation Programs cover the entire spectrum of laboratory disciplines using the most scientifically rigorous checklist requirements. There are five unique programs tailored to the needs of specific types of laboratories.

The CAP's accreditation programs offer:

- Help towards continuous compliance
- Confidence in the accuracy of clinical reports
- Improved risk management
- Access to best practices
- The right to display the CAP Accreditation Mark

Facilities that choose any of the CAP accreditation programs also receive access to a range of educational opportunities, proven products and services, and health care professionals that help laboratories to excel.

### Laboratory Accreditation Program

The Laboratory Accreditation Program (LAP) was established in 1961, and the 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 on-site inspection every two years by an inspection team made up of practicing professionals.

The LAP is a CMS-approved accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) and is also recognized by the Joint Commission. In addition, the LAP is accepted by the United Network for Organ Sharing and the National Marrow Donor Program for histocompatibility testing.

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 on this option.

### **Reproductive Laboratory Accreditation Program**

The CAP developed the Reproductive Laboratory Accreditation Program (RLAP) in 1993 in collaboration with the American Society of Reproductive Medicine (ASRM) to meet the unique needs of reproductive laboratories. 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 on-site inspection every two years by an inspection team made up of practicing professionals. They are inspected with the Reproductive Laboratory Medicine, Laboratory General, Director Assessment, and All Common Checklists, as well as additional discipline-specific checklists if additional clinical testing is performed.

The RLAP is a CMS-approved accrediting organization for andrology and other tests regulated by CLIA 88 and is also recognized by The Joint Commission. In addition, the Society of Assisted Reproductive Technology (SART) recognizes RLAP accreditation of embryology laboratories for SART membership.

### **Forensic Drug Testing Program**

The CAP Forensic Drug Testing Accreditation Program (FDT) was established in 1988 and is available for laboratories performing confirmatory drug testing on urine, oral fluid, hair, and blood for nonmedical purposes, such as workplace drug testing. The program also accepts laboratories that perform urine screen-only testing by nonwaived methods.

Laboratories in FDT have an on-site 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.

## **Biorepository Accreditation Program**

The CAP's Biorepository Accreditation Program (BAP) is the newest program introduced in 2011 and is designed to improve the quality and consistency of facilities that collect, process, store, and distribute biospecimens for research.

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

Facilities in the BAP have an on-site inspection every three years by an inspection team made up of practicing professionals. They are inspected with Biorepository and General Checklists.

## **CAP 15189™ Accreditation Program**

The CAP 15189 Accreditation Program was created in 2008 to assist laboratories in maintaining compliance with all ISO 15189 requirements. Laboratories must first be accredited through the CAP's Laboratory Accreditation Program to qualify to the CAP 15189 program. This program complements the LAP by optimizing processes to improve patient care, strengthen deployment of quality standards, mitigate risk, and control costs.

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 program also provides readiness and advisory services and online education courses on quality management systems.

Information on the CAP 15189 program is available on [www.cap.org](http://www.cap.org) under Laboratory Improvement, Accreditation, CAP 15189 Accreditation Program.

# COMMISSION PHILOSOPHIES

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## Peer Review

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

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 accreditation program and the CAP, 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. Provide recommendations for improvement if possible.
- 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 Post-inspection for the Laboratory - Challenging a Deficiency in this manual.

## Thoroughness

The CAP inspection process is approved by the Centers for Medicare and Medicaid Services (CMS) and must meet all federal regulatory requirements. Additionally, participating laboratories expect a thorough, detailed, and fair inspection. All pertinent items in the customized checklist must be inspected. Since laboratories must be inspection-ready at all times, as part of providing

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

## **Judgment**

The Commission relies upon the inspector's judgment more than any other attribute in the assessment of a laboratory. This attribute is, however, the most difficult to standardize. There will be occasions when a conscientious inspector will have difficulty deciding whether a laboratory is in compliance with a checklist requirement. Many of these decisions involve assessment of partial compliance with the checklist requirement. Therefore, the inspector must describe the observations as completely as possible in the Inspector's Summation Report. This description should include details of the sampling that was 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 out-of-compliance 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). 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 in compliance before it was inspected. The regional commissioner will review disputed items and determine if the deficiency can be removed from the inspection record.

## **Harassment**

Employees of laboratories inspected by the CAP are entitled to a workplace environment that is free from sexual or other unlawful harassment. Prohibited harassment includes any comments, gestures, innuendos, or physical contact that create an intimidating, offensive, or hostile environment. Also prohibited are behaviors that harass an employee based on race, gender, disability, age, religion, national origin, or other legally protected category.

Inspectors on a CAP team, whether the team leader or a team member, must never display conduct that can reasonably be construed as harassment. Team leaders must ensure that the behavior of team members is consistent with this position; they must intervene actively if inappropriate conduct is observed.

Employees of laboratories should report inappropriate conduct on the part of 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.

## **Solicitation**

Inspectors must not in any way solicit the institution, the laboratory, or its employees 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

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. They should not be discussed in any context other than the inspection itself. Moreover, they 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 [www.cap.org](http://www.cap.org) by logging into the CAP e-LAB Solutions Suite and clicking on the “CAP Accreditation Resources” link.

The CAP further protects the CAP-accredited laboratory by requiring all CAP inspectors to attest on the inspection report that they will keep any 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 concerning 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 C.F.R. Parts 160 and 164, in accordance with HIPAA and its implementing regulations (see 45 C.F.R. § 164.514(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.

The inspection team does not make the accreditation decision, and the subject laboratory may challenge any deficiency citation. Further, the CLA 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 unannounced 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. However, the laboratory should not contact the inspector, even if a conflict of interest should be apparent. Instead, 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 determination. All state or regional commissioners have discretion to recommend reassignment if there appears to be a valid conflict of interest. A laboratory may notify CAP headquarters of perceived conflicts when the inspection assignment is made. However, the CAP may determine at any time that the perceived conflict of interest is not valid and the laboratory may not be reassigned to a new inspection team. The laboratory should not contact the assigned inspector.



# APPLYING TO CAP ACCREDITATION PROGRAMS

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## Application Request Form

Laboratories seeking accreditation by the CAP must submit an Application Request form along with a nonrefundable application fee. Once the application request is processed, the accreditation application, master checklists, and many more resources are available online via eLAB Solutions Suite™. Paper application materials will also be sent but the CAP encourages laboratories to use the online application/reapplication system.

A new applicant to the accreditation program has up to six months to complete and return the application materials. The application materials for the Biorepository Accreditation Program are not yet available through e-LAB Solutions Suite™.

Laboratories with separate CLIA numbers seeking CAP accreditation must be accredited separately, even if 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 PT products. Laboratories operating under separate CLIA certificates 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 provided in the application.

## Proficiency Testing (PT) Prerequisite

- Each separately accredited laboratory must periodically assess the accuracy of each patient-reportable test that is performed under its own CAP number.
- For analytes that require external proficiency testing (PT), each laboratory must enroll and participate in a CAP-accepted PT program. (See glossary for the definition of CAP-accepted PT program.) PT enrollment requirements may be found in the Master Activity Menu with PT Options, which is available through e-LAB Solutions Suite or the Analyte/Procedure Index of the CAP Surveys catalog.

- 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 if available. Other acceptable alternative performance assessment procedures are listed in the Accreditation Checklists and in the Inspecting the Laboratory Sections – All Common section of this manual.

For international laboratories seeking CAP accreditation, enrollment in a CAP-accepted PT program is required for a minimum of six months prior to requesting an Accreditation Application.

### **Application Forms and Supplemental Materials – New Laboratories**

Before the first on-site inspection, each laboratory must submit the following application materials. (The Biorepository Accreditation Program application instructions follow):

- Requested general laboratory information, including demographics, personnel, contacts, licensure and certification, affiliated laboratories (for laboratories that qualify to be inspected together), and terms of accreditation.
- Laboratory section (department) information forms and associated tests and activities for each section of the laboratory.
  - The laboratory will need to create a new laboratory section for each section including: section name, responsible personnel, number of technical full-time employees (FTEs), and an estimated annual test volume. (Refer to Appendix B: Guidance in Determining Test Volume.) An address must be provided for any section located at an address different from the physical location address of the main laboratory. Specific test sites must be listed for Point-of-Care Testing sections.
  - The laboratory must provide all tests and activities performed in each section.
- The following supplemental materials must be submitted with the application:
  - Most recent accreditation inspection report (if laboratory was previously accredited by another agency)
  - Laboratory Director Questionnaire
  - Organizational chart for the laboratory (not the institution), including names and titles
  - Laboratory director's current curriculum vitae (without the Social Security number). Laboratories that designate a consulting pathologist must also provide a CV for that pathologist.
  - Current CLIA certificate (or CLIP certificate for United States Department of Defense laboratories) and state licensure certificate, if applicable
  - Instrumentation list
  - Laboratory Personnel Evaluation Roster (signed and dated by director)
  - Security Clearance form, if applicable

Individuals listed in the roles of laboratory director, staff pathologists, administrative manager, accreditation contact, quality assurance contact, proficiency testing contact, section director and section supervisors should go to **MyProfile** on [www.cap.org](http://www.cap.org) to maintain their personal profile information (eg, email address, phone number).

Laboratories must review all applicable checklist requirements to prepare for on-site inspection prior to returning the application materials to the CAP. Refer to the sections on the Accreditation Checklist, Appendix A: Accreditation Checklist Usage Summary, and Preparing for Inspection: Laboratory for more information on using the checklists and tips to prepare for inspection.

**Note:** Laboratories applying for the Forensic Drug testing (FDT) Accreditation Program must also submit the following “litigation packet” information:

- A copy of the laboratory’s 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.
- A recent (past 30 days) example of a positive THC-COOH data pack in a litigation format. This should include:
  - 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 blocked out)
  - Copies of specimen and aliquot internal COC documents

### **Biorepository Accreditation Program**

Before the first on-site inspection, each biorepository must submit the following application materials:

- Requested general biorepository information, including demographics, personnel, contacts, and affiliated biorepositories.
- Laboratory section (department) Information forms and associated activities for each section of the biorepository. The following information must be supplied: section name, responsible personnel, and number of full-time employees (FTEs). For each biorepository section, the biorepository should complete an activity menu that includes all of the activities performed in that section of the laboratory. These pages may be copied if testing is done in more than one section.
- Supplemental materials, as follows: the director’s curriculum vitae; an organizational chart including both names and titles; a floor plan; and travel and lodging information forms.

Biorepositories must review all applicable checklist requirements to prepare for on-site inspection prior to returning the application materials to the CAP. Refer to the sections on the Accreditation Checklists, Appendix A: Accreditation Checklist Usage Summary, and Preparing for Inspection: Laboratory for more information on using the checklists and tips to prepare for inspection.

### **Laboratory Disciplines**

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. Discipline is a CAP-defined

term used to describe testing or services grouped within a major category of clinical laboratory science.

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 on-site inspection. Laboratories that add disciplines and/or analytes after the inspection must notify the CAP either electronically via e-LAB Solutions Suite or in writing; in some cases, additional inspections for added disciplines may be required. (Refer to the Non-routine Inspections section of this manual.)

### **Activity Menu**

The laboratory provides information about its scope of testing and lists all reportable assays and applicable method/scope codes through its activity menu. The information provided is critical and is used for the following purposes:

- Customize checklists
- Determine disciplines for which accreditation is granted
- Verify and monitor proficiency testing enrollment
- Determine whether inspectors with specialty training are required
- Determine the laboratory's annual fee

Inaccuracies in providing activities may result in additional fees associated with the need for an additional (non-routine) inspection.

### **Reapplication Process**

For previously accredited laboratories, the CAP provides reapplication materials that are prepopulated with the laboratory's data. The laboratory must verify and update the information in the Accreditation Application and Laboratory Section Information pages. Please note, laboratories should make any demographic, personnel or activity menu changes real time through e-Lab Solutions Suite™ and not wait until the reapplication process has initiated to submit all of these changes.

The following supplemental information must be provided at the time of reapplication:

- Organizational chart
- Director CV
- Instrument list
- CLIA certificate (CLIP certificate for US Department of Defense laboratories)
- Laboratory personnel roster
- Travel and lodging information
- Security clearance form, if applicable

Individuals in key roles should maintain their personnel profile information (eg, email address, phone number) at **MyProfile** on [www.cap.org](http://www.cap.org).

### **AABB Coordinated Inspection**

Laboratories wanting a CAP/AABB coordinated inspection of their transfusion medicine service must indicate that request 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. Refer to the Preparing for the Inspection-Inspector AABB Coordinated Inspection sections in this manual for more information.

### **Submitting the Application/Reapplication**

Laboratories currently have two options for completing and returning application materials. The CAP plans to transition to a new electronic format for applications/reapplications in the future and eliminate the paper application. The CAP encourages laboratories to use the CAP's current online application/reapplication system.

1. Complete the application/reapplication online at [www.cap.org](http://www.cap.org) through e-LABs Solutions Suite. All supplemental materials can be uploaded through the online system, or
2. Complete the paper application/reapplication and return forms and supplemental materials to:

CAP ACCREDITATION PROGRAMS  
COLLEGE OF AMERICAN PATHOLOGISTS  
325 WAUKEGAN ROAD  
NORTHFIELD, IL 60093-2750 USA

## OTHER TYPES OF LABORATORIES AND INSPECTION OPTIONS

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### Special Function Laboratories

- Special function laboratories are those which are administered independently of main clinical laboratories and have different CAP numbers and CLIA numbers (if applicable). They generally employ fewer personnel and are dedicated to the performance of a restricted group of clinical procedures. Examples of special function laboratories include, but are not limited to, blood gas laboratories and oncology clinic laboratories.
- If the special function laboratory is within 15 miles or 30 minutes driving distance from the main clinical laboratory, the same inspection team is assigned to perform concurrent inspections. At least four checklists are used for inspection of any special function laboratory—the Laboratory General Checklist, the Director Assessment Checklist, the All Common Checklist and the checklist(s) appropriate to the specific function(s).
- Compliance with the Director Assessment Checklist is evaluated by a peer of the laboratory director, usually the pathologist leader of the overall team.
- Special function laboratories may request their own summation conference.
- The accreditation process and decision for the special function laboratory is independent of the main laboratory.
- The responsible hospital administrator and a representative member of the medical staff are asked about the performance of every special function laboratory.

### Affiliated Laboratories

- 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 an individual CAP number and CLIA number (if applicable). Each site has separate inspection fees, application materials, checklists, and a separate certificate of accreditation.



- Examples of affiliated laboratories include: (a) two or more merged hospitals that provide some services at each site (one often designated as full service and the other as a core laboratory); (b) a large commercial laboratory that has branches in different geographic locations; or (c) remote limited service or special function laboratories.
- Affiliated laboratories that are within 15 miles or 30 minutes driving distance may be assigned to the same inspection team.

### **Satellite Laboratories**

- Satellite laboratories are usually small branch laboratories that are affiliated with, but not physically located at the same address as the central laboratory. They also have their own CAP numbers and CLIA numbers (if applicable).
- In most cases, the services that are provided correspond with the Limited Service Laboratory Checklist.
- Separate fees, application materials, and checklists are required.
- The inspection can occur concurrently with the main laboratory inspection if the satellite laboratory is within 15 miles or 30 minutes driving distance from the main laboratory. The inspection team leader needs to consider the location of the laboratories in order to allow sufficient time for transportation and inspection.

### **Staff-inspected Laboratories**

- This program is in keeping with the CAP's philosophy of peer review by using CAP-employed medical technologists to review laboratories that are often performing limited testing. These typically include affiliated and/or satellite laboratories that are located more than 15 miles or 30 minutes from the main laboratory.
- Hospitals with 100 beds or fewer that perform basic testing (such as that seen in a core laboratory) may also be inspected by the CAP-employed medical technologists. On-site anatomic pathology services must be limited to frozen sections, specimen accessioning, and/or FNA adequacy assessment to qualify for this type of inspection.

### **Limited Service Laboratories**

- The Limited Service Laboratory Checklist (LSV) is provided as a convenience when inspecting a laboratory or a laboratory section whose scope of services is confined to the most commonly performed tests. It relieves the inspector and the laboratory of the burden of completing multiple checklists during the on-site inspection.
- If a site qualifies as a limited service laboratory, and it is a free-standing entity with its own CAP number and CLIA number (if applicable), the Laboratory General, Director Assessment and All Common Checklists are used along with the Limited Service Laboratory Checklist for inspection.
- On the other hand, if the limited service laboratory is administratively and medically part of a central laboratory at the same site and shares the same CAP and CLIA number, then the Laboratory General and Director Assessment Checklists are used for both the central laboratory sections and the limited service laboratory. In such cases, the limited service laboratory is viewed as a multifunctional section of the central laboratory.
- The CAP Master Activity Menu is divided into a basic list and an extended list of reportable assays. Use of the Limited Service Laboratory Checklist is determined by the activities performed by the laboratory. Laboratories performing activities limited to the basic list of

assays may qualify for the Limited Service checklist. Laboratories performing activities from the extended list must use the applicable discipline-specific checklist(s).

- The Limited Service Laboratory Checklist may not be used alone if anatomic pathology, cytopathology, flow cytometry, molecular pathology, histocompatibility, cytogenetics, or point-of-care testing are performed. The inspector must also use the appropriate discipline-specific checklist(s) for these areas.
- If the limited service laboratory performs testing in other laboratory disciplines that can use the Limited Service Checklist (eg, chemistry, hematology), but there are section-specific requirements that are not specifically represented in the LSV Checklist (eg, pretransfusion testing, blood storage, coagulation factor assays, chromatography, electrophoresis, microbiology cultures/sensitivities, molecular microbiology, maternal alpha-fetoprotein testing, sweat testing for cystic fibrosis), the section-specific checklist must be used.
- The laboratory's application determines the appropriateness of the LSV Checklist.

### **System Inspection Option**

Laboratory directors may have *multiple* laboratories under the same ownership and administration inspected by *one* team of inspectors. This is called the 'system inspection option'. A system is composed of laboratories with highly integrated services meeting specific eligibility requirements. Laboratories desiring to participate in the CAP's System Inspection option should contact the CAP at 800-323-4040.

### **System Inspection Eligibility Criteria**

A system is defined as two or more full-service laboratories that identify themselves as a system and have common administration and ownership. All laboratories must be within three hours travel time (ground transportation) of a system-defined central location. The system option is available to laboratories participating in the Laboratory Accreditation Programs. The degree of integration within the system is a major determinant in a system meeting eligibility requirements and thereby qualifying for the system option.

Each individual laboratory within the system must meet at least seven of the following nine eligibility criteria:

- Operate on the same set of administrative policies and procedures
- Report directly to a central management team
- 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
- Be located within a three-hour driving distance from the central location (this element is required for all systems)

Approximately four to six months prior to the laboratory's anniversary date, an inspection specialist conducts a pre-inspection conference call to determine the system's level of integration of services. An on-site pre-inspection visit is scheduled for any group that is new to the CAP's System Inspection option. The information obtained by the inspection specialist is shared with the team leader and team coordinator to assist with inspection planning and the team building process.

### **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 on-site 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 Tools section below) sent by the CAP inspection specialist and a team building spreadsheet tool. The team leader shares the plans with the 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 is and is not to 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 on-site inspection of each laboratory using the relevant portions of the Anatomic Pathology and/or Cytopathology Checklists.

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. These must be inspected by member(s) of the CAP system inspection team. For questions on preparing for the inspection or at the time of the on-site inspection, call 800-323-4040 ext. 6065 to consult with a CAP technical specialist.

### **System Inspection Inspector Tools**

One of the goals of a system inspection is continuity in the inspection process. Therefore, the inspector who inspects a particular discipline should be the one inspecting this 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.

Supplements to the Systems Inspector's Inspection Packet include the following:

1. **Assessment of System Integration form** –This form is completed by the system administration and/or management team at reapplication time. The information will be included in the inspector packet and the criteria can be 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** – The team leader uses the Excel spreadsheet template to build the team and ensure adequate inspectors are used, as well as ensuring any specialty inspector needs are met. The spreadsheet is customized for the system being inspected.
3. **System Pre-Inspection Information form** – The form is completed by the system administration and/or management team before the pre-inspection call/visit. The inspection specialist reviews the information in the form with the system administration and management team and makes any necessary revisions. The completed form is forwarded to the team leader to assist in team building.

### **System Summation Conferences and the Global Summation**

A 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.)

During the last day of the system inspection, a global summation conference is held. The global summation conference is not intended to be a reiteration of all the deficiencies and recommendations cited during the system inspection, but is instead a discussion of how the system can further integrate. The inspection team leader should work with the inspection specialist to prepare a brief presentation for the system personnel being inspected. The global summation conference presentation should include system-wide deficiencies and opportunities for improvement. It is also common for the inspection team to discuss areas of excellence and strengths noted during the system inspection.

## 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
- Inspection Supplemental Information (inspection blackout dates and hours of operation)
- Accreditation Unit Activity Menu report
- Checklist Selection report
- Accreditation Checklists (customized)

The laboratory's inspection team also receives materials from the packet, including the checklists that have been customized according to the laboratory's Accreditation Unit Activity Menu. Laboratories should carefully review the activity/test information to ensure that it is current. The laboratory must update its activity menu information if there are changes prior to the inspection because changes may impact the customized checklists. Laboratories can submit test menu changes by logging into [www.cap.org](http://www.cap.org) through e-LAB Solutions Suite.

The cover letter included in the packet contains the possible dates for inspection and whether the inspection will be announced or unannounced.

Laboratories seeking **initial CAP accreditation** will typically be inspected within 90 days of receiving the 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. The team leader may contact the laboratory to discuss logistics for an unannounced inspection, but may not inform the laboratory of the inspection date.

### 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 [www.cap.org](http://www.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 policies, procedures and other compliance documents.
- Refer to the **Checklist Changes only** version of the checklists available on [www.cap.org](http://www.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 of the 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 on-site 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 Accreditation Unit Activity Menu report to confirm that the laboratory is either enrolled in CAP-accepted proficiency testing or performs alternative assessment for each activity/test . Ensure that proficiency testing and alternative 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 of more IQCP is used in the laboratory. Have the form available to present to the inspection team. Ensure that related documents supporting the IQCP (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 studies. Store on-site documents and records in a central location so that they are easily accessible during the inspection. Ensure that relevant staff knows 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 knows where to find specific documents needed for the inspection.
- Participate in educational activities offered by CAP to gain a better understanding of accreditation requirements (refer to Appendix E, CAP Accreditation Tools and Resources, for the location on [www.cap.org](http://www.cap.org))
  - **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 [www.cap.org](http://www.cap.org).
  - **Fast Focus on Compliance:** On-line modules developed to provide information on a variety of challenging topics in a bite-sized learning format.



## On-site Inspection Plan

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

| Plan Elements                               | Example Tasks   |
|---|---|
| One-hour security notification              | <ul style="list-style-type: none"> <li>• Ensure that a responsible person will be available to receive the one-hour security notification call from the inspection team</li> <li>• Define what activities need to occur when the call is received (eg, notification tree)</li> </ul>  |
| Designated central contact                  | <ul style="list-style-type: none"> <li>• Designate one or more individual as the central contact to coordinate events throughout the day</li> <li>• Greet the inspection team and make introductions</li> <li>• Arrange for a short laboratory tour at the beginning of the inspection</li> </ul>   |
| List of key personnel                       | <ul style="list-style-type: none"> <li>• Identify a list of key personnel with their contact information for each area of the laboratory who have knowledge of policies, procedures, and location of key documents (eg, QC, proficiency testing, instrument and equipment maintenance and function checks)</li> <li>• Include backup personnel in case a contact is not available on the day of inspection</li> </ul> |
| Interviews with team leader                 | <ul style="list-style-type: none"> <li>• Identify representatives from medical staff and administration who will be available for an interview with the team leader</li> <li>• Include backups in case the designated representative is not available on the day of inspection</li> </ul>   |
| Communication                               | <ul style="list-style-type: none"> <li>• Communicate with all parties within and outside of the laboratory that may be involved in the inspection process</li> <li>• Schedule interviews with representatives from the medical staff and administration</li> </ul>  |
| Meeting rooms and workspace                 | <ul style="list-style-type: none"> <li>• 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</li> <li>• Identify locations for introductions and for the summation conference</li> </ul>  |
| Transportation to test sites and facilities | <ul style="list-style-type: none"> <li>• Establish a mechanism to escort team members to testing sites</li> <li>• Provide transportation for off-site locations, if needed</li> </ul>   |

|                              |   |
|------------------------------|---|
| Staffing needs               | <ul style="list-style-type: none"> <li>• Assess workload and staffing to determine if modifications are needed to prevent disruption of patient care</li> </ul>   |
| Inspection team needs        | <ul style="list-style-type: none"> <li>• Arrange for refreshments (water/coffee) and lunch for the inspection team or provide information on locations for dining located near the laboratory</li> <li>• Provide personal protective equipment</li> <li>• Make office supplies available in the team work area (eg, pads of paper, pens, sticky notes/flags)</li> <li>• Provide telephone access</li> </ul> |
| Records                      | <ul style="list-style-type: none"> <li>• Provide centralized records to be available throughout the course of the inspection for policies, procedures, and other records</li> <li>• Ensure that personnel files are readily available</li> <li>• Arrange for off-site records needed for the inspection to be delivered to the laboratory</li> </ul>  |
| Conclusion of the inspection | <ul style="list-style-type: none"> <li>• Provide copying services prior to the summation conference</li> <li>• Provide facilities for inspectors to securely dispose of inspection materials</li> </ul>   |

## 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 CAP 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 Commission Philosophies section.)

### Team Leader Qualifications and Responsibilities

Team leaders should be:

- A peer of the laboratory/biorepository director, with similar status, type of practice, and hospital or laboratory/biorepository size
- Preferably a board-certified pathologist\* and a CAP Fellow
- Affiliated currently or recently with a CAP-accredited laboratory/biorepository
- 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/biorepository 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 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 Other Types of Laboratories and Inspection Options section for information on Staff-Inspected Laboratories.)

Inspection team leaders are responsible for:

- Assembling an inspection team of appropriate size and experience for the laboratory or laboratories being inspected
- 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 unannounced 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 envelop to return the packet to the CAP within 24 hours after the inspection is complete
  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. List(s) of qualified specialty inspectors, (applicable to cytogenetics, flow cytometry, histocompatibility, clinical biochemical genetics, and molecular pathology only)
  17. 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 (not applicable to BAP)
    6. Complaint Report, if applicable
    7. State-specific Report, if applicable
    8. Inspector's Summation Report (ISR) forms (Part A and "extra copy" pages)
    9. Laboratory organization chart
    10. Laboratory director's CV
    11. Inspector's Summation Report from the previous on-site inspection
    12. 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 (Blue Folder)
    - Instructions for Responding to Deficiencies
    - Deficiency Response Signature Page
    - Deficiency Response Sheet

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

## 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

A listing of approved specialty inspectors is included in the inspection packet if the inspection involves one or more of these checklists. The team leader must choose an inspector from the approved list. Potential team members not on the approved list may apply to be a specialty inspector on [www.cap.org](http://www.cap.org) by logging in to My Profile, selecting Skill Sets/Language Fluency in the Inspector tab, and completing the requested information for educational qualifications and experience. 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](mailto: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:

- Medical technologists/clinical laboratory scientists
- Cytotechnologists
- Histotechnologists
- Laboratory/biorepository supervisors and managers
- Doctoral scientists
- Pathology residents and fellows
- Pathologists

Inspectors must not:

- Inspect a laboratory or facility for which he or she 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 or biorepository that the inspector inspects

Inspection team members must prepare several weeks prior to the inspection in order 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 and a post-test. 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 on-line training options are available on [www.cap.org](http://www.cap.org) that emphasize the knowledge and skills required to perform an inspection, including:

- Team Leader Inspection Training
- Team Member Inspection Training
- Biorepository Accreditation Inspector Training.

Both team leaders and team members need to complete the appropriate training and online post-test prior to their first inspection. Thereafter, participants are encouraged to review the content that is most relevant to their needs as the training courses are updated annually.

Inspectors must pass the on-line post-test in order to fulfill the training requirement. Inspectors have a total of three opportunities to take and pass the post-test and then claim credit (CME/CE). CME/SAM credit can be applied to the American Board of Pathology (ABP) Self-Assessment Module (SAM) requirements. The participant **may not claim credit** if he or she does not pass the post-test.

To enroll and participate in on-line training, go to [www.cap.org](http://www.cap.org), click on the Laboratory Improvement tab, then Accreditation. Under Inspector Training and Resources, click on View Training Options and Resources.

### **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](http://cap.org).)

**Fast Focus on Compliance:** On-line 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](http://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 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. The inspection date must be mutually agreeable to all laboratory directors.
- Ensure that the **inspection occurs no more than 90 calendar days before the laboratory's anniversary date for routine inspections**. A mutually acceptable date is preferable; however, the inspection is scheduled at the convenience of the inspector.
- 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](mailto:accred@cap.org).
- Send a courtesy letter to the laboratory/biorepository director(s) indicating:
  - The inspection date
  - 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])

### **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](mailto: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.

NOTE: For unannounced inspections, the team leader may contact individuals from the laboratory being inspected to discuss logistics, but **must never** inform the laboratory personnel of the inspection date.

## 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-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

**Commission on Laboratory 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.

## 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, providing contact information and defining 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 to 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 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 separately accredited laboratory must enroll and participate in a CAP-accepted proficiency testing (PT) program for all required analytes to assess the accuracy of testing performed. In some countries, proficiency testing may be referred to as an external quality assessment program.

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 eLab Solutions™ Suite customer portal on the CAP website (cap.org)
- CAP Surveys catalog - Analyte/Procedure Index section (available on cap.org)

The CAP Accreditation Program does not typically require PT enrollment for calculated analytes. However, there are a few exceptions where PT enrollment is required (ie, Hemoglobin estimated, Hematocrit calculated, and INR calculated, non-waived).

Alternative performance assessment (APA) is required twice a year for all tests not covered by a CAP-accepted PT program. The laboratory director must define such alternative assessment procedures. The criteria for APA must be in accord 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 or other provider not required by the CAP
- Split sample analysis with another laboratory
- Split samples with an established in-house method, assayed material, and regional pools
- Clinical validation by chart review, or other suitable and documented means

### CAP-Accepted Proficiency Testing Programs

The CAP Accreditation Program has defined criteria for CAP-accepted PT programs and for each analyte. Each PT provider maintains its own list of accepted analytes. Not all analytes within a PT provider program are necessarily accepted. CAP accreditation participants must verify analyte acceptance with their PT provider.

NOTE: International laboratories must enroll in the CAP Proficiency Testing Surveys Program for a minimum of six months prior to initiating the CAP application process. Laboratories may use acceptable alternatives when the CAP is unable to deliver PT due to oversubscribed programs, stability issues, or customs denial, contingent on CAP approval.

### **Proficiency Testing Enrollment for Multiple Matrices**

PT enrollment is available in both serum/plasma and whole blood matrices for some tests. Laboratories may choose to enroll only in the PT program for the laboratory's primary sample matrix. APA would be required for the other matrix. Laboratories may of course enroll in separate PT programs for both matrices.

Urine and body fluids have unique matrices, usually with different calibrators, reagents, reference ranges and/or clinical decision-making values than those for serum, plasma, or whole blood. The laboratory must enroll in a PT program specific for such a sample type if a CAP-accepted PT program is available. Otherwise, APA is required.

### **Proficiency Testing Handling**

Among the requirements of the Clinical Laboratory Improvement Amendments (CLIA) regulations (section 493.801) is that the laboratory must test PT samples in the same manner as it tests patient specimens. 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 one time).
- 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:

- Laboratories may not engage in any inter-laboratory communications pertaining to the results of PT samples until after the deadline for submission of data to the PT provider.
- 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 (ie, one that has a different CLIA/CAP number).

A laboratory must only report proficiency testing performed in its own laboratory. It may not refer PT specimens to another laboratory and report those results. Here are examples of accidental 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. (The laboratory should have reported the preliminary result to the PT provider.)
- 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 lab sent abnormal blood smears from the PT to the main laboratory in error. (The laboratory should have submitted a PT result 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 Centers for Medicare & Medicaid Services (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 Program may also impose sanctions including loss of accreditation.

The sole exemption to the “no referral” rule is for laboratories that send slides to another facility for immunohistochemistry (IHC) staining, but perform the interpretation in-house. In that case, the IHC staining (and only the staining) of the PT slides may be referred to the usual outside facility.



## PROFICIENCY TESTING: FAILURES AND MONITORING

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### Proficiency Testing (PT) Failures

Laboratories must review the reports from the PT provider for each PT event to evaluate the results, investigate each unacceptable PT result, take appropriate corrective action, and retain all records for the event.

When investigating PT failures or biases, the following actions may be taken:

- Check reporting forms and records of sample preparation and testing for nonanalytic (eg, clerical) and analytic errors
- Review QC performance, instrument calibration, and reagent performance prior to, during, and after the time of PT performance
- Verify that the PT material was processed in the correct instrument mode and reported in the correct units
- Investigate consistent biases or trends (as defined in the lab'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 have records of investigation of each unacceptable PT result. Depending on the cause of the failure, some 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 due to arrive and when results are due
- Retrain testing personnel in the proper procedures for sample preparation, testing, and reporting

## **Proficiency Testing Monitoring**

The CAP monitors three different 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's 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 is included below. For help or more information on proficiency testing enrollment or assistance with troubleshooting PT failures, accreditation participants may:

- Refer to the Proficiency Testing/External Quality Assurance Toolbox available through the eLab Solutions™ Suite customer portal on the CAP website (cap.org)
- Contact the CAP at 800-323-4040 or 847-832-7000

For ideas on troubleshooting analytical issues, participants may also wish to 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) – Non-enrollment**

The CAP will also send a proficiency testing compliance notice (PTCN) if a laboratory is not enrolled in PT for a required analyte that is listed on its Laboratory-Specific Activity Menu. Nonparticipation is the same as receiving a PT score of zero. There is a direct relationship with the enrollment requirements and the activities on a 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
- Delete the related activity 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 alternative performance assessment 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, 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 Program

did not receive PT scores for that analyte. It may be due to a failure to submit results to the PT provider (eg, test discontinued and not removed from the Laboratory-Specific Activity Menu, results not transmitted properly, or PT kit not received) or submission of results 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 for the testing event and is considered unsatisfactory performance.

All Non-participation PTCNs require a response to the CAP to include:

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

\*If PT was performed, but results were not reported, the laboratory may “score” 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 alternative assessment. If other means of alternative assessment 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
- Investigation of whether patient results were affected
- Specific corrective action taken to prevent recurrence of the problem
- Evidence of alternative assessment (if appropriate)

Some PTCN’s do not require a response to the CAP (eg, first time PT failures for most analytes or subspecialties). Investigate the reason for each PT failure. The inspector will review and evaluate records of the investigation and corrective action during the on-site inspection.

For subsequent PT failures for the same analyte or subspecialties, the laboratory must complete the PTCN response form, including the cause 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 review PTCN responses and 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.

A laboratory that has repeat critical performance for a non-regulated analyte/test may also be directed to cease testing for an extended period of time (may differ than 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 acceptable performance on reinstatement PT.

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 on-site 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 2,900 requirements in 21 different checklists organized around specific laboratory disciplines and/or important management operations. Appendix A: CAP Checklist Usage describes each of the checklists.

The checklists are revised periodically (usually once a year) based on input from CAP's practicing experts, such as its scientific resource committees, inspectors, and participants. The edition of the checklists chosen for an on-site inspection is the edition sent at the time of application/reapplication completion, even if a newer edition has been published. The checklist edition used for the on-site inspection 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 Commission on Laboratory Accreditation and by laboratories that are preparing for such inspections. Except as permitted by section 107 of the Copyright Act, 17 U.S.C section 107, any other use 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.

## Checklist Components

The Checklists define the accreditation program requirements. Additional language is often added to explain a requirement, or to streamline the inspection process. This section describes the different elements that make up the checklist:

- **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 requirement numbers in each checklist.
- **Introductory Text:** 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 may be 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-accreditation participants 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 add a NOTE, Evidence of Compliance, and/or References.

### Example Requirement

1 ↘ GEN.23584      2 ↘ Interim Self-Inspection      3 ↘ Phase II

4 → **The laboratory has conducted a thorough interim self-inspection and has corrected all deficiencies.**

5 → *NOTE: CAP-accredited laboratories are required to complete an interim self-inspection at the start of the second year of the laboratory's two-year accreditation cycle. It is an important aspect of continuing education, laboratory improvement, and continuous compliance. Laboratories must retain records of the CAP self-inspection, as well as the corrective action for deficiencies, as part of the quality management program. The laboratory director's signature on the CAP's Self-Inspection Verification form alone is not sufficient to meet this requirement.*

6 → **Evidence of Compliance:**  
 ✓ **Written evidence of self-inspection findings with records of corrective action**

7 → **REFERENCES**  
 1) Clinical and Laboratory Standards Institute. *Assessments: Laboratory Internal Audit Program; Approved Guideline*. CLSI document QMS15-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2013.

1. **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).
2. **Subject Header:** Key words that identify the content of the requirement.
3. **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 0, I, and II deficiencies:

| PHASE           | DESCRIPTION  |
|-----------------|--|
| <b>Phase II</b> | <ul style="list-style-type: none"> <li>• Requirements for items that may seriously impact the quality of services, endanger patients, clients, or personnel, or impact regulatory compliance</li> <li>• Citations require a written response of compliance and supporting documentation prior to accreditation</li> </ul>                            |
| <b>Phase I</b>  | <ul style="list-style-type: none"> <li>• Requirements for items that may compromise the quality of services, but not endanger patients, clients, or personnel</li> <li>• Citations require a written response to the CAP indicating corrective actions, but do not require supporting documentation unless specially requested by the CAP</li> </ul> |
| <b>Phase 0</b>  | <ul style="list-style-type: none"> <li>• Items placed in the checklist for administrative purposes (data collection) only</li> <li>• They are not accreditation requirements</li> <li>• Phase 0 observations require no formal response to the CAP</li> </ul>  |

4. **Declarative Statement:** One or more sentences that define elements required for compliance.
5. **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.
6. **Evidence of Compliance:** List of suggested ways to demonstrate compliance with the requirement (eg, policies, procedures, records, reports).
7. **References:** Resources, such as peer-reviewed journals, regulations, professional guidelines, and text books that may be helpful. .

### Checklist Customization

No two laboratory sections or departments are the same. The CAP customizes participants' checklists for their on-site inspections. Customized checklists link activities (eg, tests, scopes of service, methods) reported by each section of the laboratory to the applicable checklist requirements.

To ensure proper customization of a checklist, participants must:

- Carefully complete application materials for the activity menu **and**
- Update the CAP when activity menu changes occur.



Information on completing the activity menu or changing the activity menu can be found in the sections on Applying for Accreditation and Maintaining Accreditation.

### Downloading Checklists from cap.org

To stay abreast of changes to the checklist, the CAP encourages participants to download and review checklists at any time from the eLab Solutions™ Suite customer portal on the CAP website (cap.org). The website versions contain elements that are not found in the 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 either the current, published checklist version or checklists that will be used during on-site or self-inspections
- 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   |
|---------------------|---|--|
| <b>Master</b>       | <ul style="list-style-type: none"> <li>• Contains all requirements in the specified checklist</li> <li>• Useful when starting new types of testing or services</li> </ul>   | <ul style="list-style-type: none"> <li>• Access via cap.org (log-in required)</li> <li>• Also available for purchase by non-participants in CAP accreditation</li> </ul>   |
| <b>Custom</b>       | <ul style="list-style-type: none"> <li>• Based upon each section unit/department's activity menu, this type includes only those requirements that pertain to the testing or services offered</li> <li>• Focuses attention on applicable requirements</li> </ul> | <ul style="list-style-type: none"> <li>• Mailed to accreditation program participants prior to the on-site inspection and to perform an interim self-inspection</li> <li>• Included in the inspection packet mailed to the inspection team leader</li> <li>• Access via cap.org (log-in required)</li> </ul> |
| <b>Changes Only</b> | <ul style="list-style-type: none"> <li>• Contains only those requirements that have been changed, added, or deleted since the previous edition</li> <li>• Quickly identifies changes to requirements in a track changes format</li> </ul>                       | <ul style="list-style-type: none"> <li>• Access via cap.org (log-in required)</li> </ul>   |

## 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. It shows what has been changed, added, or deleted since the previous edition in a track changes format (log-in required).
- **Focus on Compliance Webinar Series:** The annual “Checklists Update” webinar provides information on the principal changes to each edition. It may be accessed by logging into the eLab Solutions™ Suite customer portal on the CAP website at cap.org and going to CAP Accreditation Resources – Educational Resources.

## 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](mailto:accred@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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## General Principles: How to Inspect

**Preparing to Inspect:** Refer to the “PREPARING FOR THE INSPECTION-INSPECTOR” section for detailed lists of what is included in the Inspector’s Inspection Packets.

**Requirements in the Laboratory General Checklist apply to every laboratory section, but only one copy is provided to the inspection team. During the inspection of each section, each inspector should verify compliance with safety and the physical facilities and report the findings to the inspector assigned to complete the Laboratory General Checklist.**

If the intent of any checklist requirement is not clear, inspectors may contact CAP staff for clarification prior to or during the inspection by email, [accred@cap.org](mailto:accred@cap.org), or phone at 800-323-4040 ext. 6065 during the hours between 8:00 AM-5:00 CST.

The laboratory’s activity menu and instrumentation list help the inspector understand the type and scope of testing within each laboratory section. The inspection checklists are customized to the laboratory’s Activity Menu. If testing is noted which is not included in the activity menu, inspectors should contact CAP staff to obtain additional checklist sections or requirements that may be needed (Refer to “Inspecting Additional Activities, Disciplines, and Laboratories”).

### Day of Inspection:

- One hour prior to arrival, the team leader is to contact the laboratory using the one-hour security notice phone number provided in the inspector packet cover letter.
- The team should plan sufficient time to conduct a thorough inspection.

- Inspections usually begin at 8AM.

### Arrival at the Inspection Site:

When the inspection team arrives, they should:

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

### Inspection Techniques

- “Following a specimen” through the laboratory is an effective technique to address the preanalytic, analytic, and postanalytic aspects of laboratory testing. This process is generally followed by review of the laboratory’s documentation. Not only must the laboratory’s paperwork be in order, its personnel’s knowledge of the lab’s processes should be assessed. Effective inspection techniques include:
- The “teach me” approach is where the inspector selects an analyte or instrument and laboratory staff “teaches” the inspector about the procedure, process or instrument operation
- The **R-O-A-D** technique provides a structured way for inspectors to conduct an on-site evaluation of a laboratory’s performance. **R-O-A-D** icons are placed at the group level within the checklists. The icons flag specific instructions to the inspector:
  - Read/review documentation
  - Observe procedures/techniques
  - Ask probing questions
  - Discover the path of a process

### Samples of R-O-A-D 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 a. This will allow you to:

- Obtain information in a person’s own words
- Improve your understanding of the 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 requirements 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 will want to review all relevant documents including:

- Procedure manuals
- Quality control (QC) records
- Instrument maintenance records
- Test method validation and verification studies
- As the inspector examines procedures and records
- Calibration, calibration verification, and method comparison records
- List of deficiencies from the previous on-site inspection. Be sure that all deficiencies have been appropriately addressed. Pay close attention to recurring deficiencies!
- The PT Performance <100% Report (if applicable) in inspector’s packet (This report lists by analyte, all PT scores below 100% during any of the last six testing periods)  
When reviewing the PT Performance<100% Report, inspectors should:
- Confirm that the laboratory has conducted an investigation of the QC and maintenance records 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 (COM.01600)
- For each unacceptable PT event, review the records for the subsequent event
- Confirm that testing personnel follow the policies and procedures as written. Look for inappropriate actions such as duplicate testing of PT samples
- Confirm that testing personnel follow 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

- Assess whether the Activity Menu reflects the laboratory’s current testing. Look for tests in the laboratory’s procedures manual that seem to be missing from its Activities Menu

**How Much to Look at:** The review of records, forms and documents is intended to cover the full two-year period since the previous on-site inspection. The inspector should:

- Consult the laboratory’s 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 on-site 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 on-site inspection
  - Records in the preanalytic (order entry and specimen collection, processing and transport), analytic (procedures, QC, PT, instrument setup, and maintenance), and postanalytic categories (reports, reference ranges, and critical value notification); if problems are discovered (**D**iscover), review similar records for additional analytes. Discovery is a technique to further evaluate areas of concern. “Follow the specimen” and “teach me” are two examples of discovery.

**How to Obtain Information:** Inspection team members should:

- Spend more time in the laboratory observing the testing process and ask questions of bench technologist and supervisors rather than in a room reading documents.
- Give the laboratory time to retrieve needed records while continuing with the inspection process
- 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 ...?” is more effective than reading the checklist requirement out loud.

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.

### **How to Inspect Using the Checklist(s)**

Each discipline has its own checklist (such as Hematology (HEM)), but applicable requirements are in the All Common (COM) and the Laboratory General Checklist (GEN) as well. Inspectors should focus on groups of requirements using the R•O•A•D instructions (refer to Inspection Techniques, above).

The Evidence of Compliance (EOC) section of a checklist requirement lists suggested ways to show compliance. 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 assessments **AND**
- Records of these assessments

## Inspection Team Members Meeting With Direct Health Care Providers

During the course of the inspection, some team members are expected to visit actual patient care areas. Examples include:

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

Meeting with direct health care providers and observing the tests and procedures they perform can both help inspectors determine checklist compliance with checklist requirements and judge 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

## 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 (TLC).** This checklist:

- Evaluates the qualifications of the laboratory director and the effectiveness of the director in implementing the *Standards for Laboratory Accreditation*
- Includes requirements to evaluate the overall performance characteristics of the laboratory. Assists the team leader to recognize and document systemic problems with the laboratory's QM program
- Includes instructions on how to conduct interviews with the laboratory director, hospital administrator, and chief of the medical staff.
- Focuses upon those aspects of the laboratory that are at the core of quality: the laboratory director's responsibilities, the QM plan, and the laboratory's relations with the institutional medical staff and administration.

***The following information refers to the meetings with the laboratory director, hospital administrator, and representative of the medical staff. These meetings are conducted by the team leader and will provide some of the information needed to complete the inspection with the TLC Checklist. The interviews that occur at these meetings are essential parts 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 the Part A of the ISR. Deficiencies, if found, are to be cited on the TLC Deficiency page of the ISR, Part B.



## 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 15–20 minutes for the meeting. If the director is not present for the on-site inspection, the inspector should try to conduct this interview by telephone. On-site conversations with technical staff, administration, and the CMO may be used to validate the director's involvement.

The interview is an opportunity to:

- Evaluate the director's activities as listed in the TLC Checklist and the *Standards for Laboratory Accreditation*.
- Ask whether the director has any goals for the inspection, such as problems that the inspection might serve to resolve (eg, workspace issues, staffing shortages).

## 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 15–20 minute discussion and should have an understanding of 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 (ie, 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 director the authority to fulfill the 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
- Expressed 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.**

### **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 staffs, 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 15-20 minute discussion and should have an understanding of the laboratory's operations beforehand.

The interview is an opportunity to:

- Evaluate the effectiveness of the scope, quality, and timelines of the laboratory services 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 in problems.
- Judge the medical staff perception of the effectiveness of the laboratory director and other pathologists, and determine whether the laboratory director has sufficient authority to fulfill the needs of the medical staff and their patients.

### **Inspecting Additional Activities, Disciplines, and Laboratories**

If, during the inspection process, it is discovered that testing is being performed that does not appear on the laboratory's Activity Menu, the team leader or team member is expected to:

- Contact the CAP immediately (this applies only to testing being performed under the same CLIA number of the laboratory that is being inspected)
- 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 office will immediately:

- Determine whether the 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 whether the activity/discipline in question has been inspected. (Refer to the ISR section below).

## **Additional Laboratories Not Reported at Application/Reapplication**

Laboratories that perform testing under a different CLIA number or special function 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**. The inspector should advise the director to submit a formal application to CAP headquarters. The CAP will schedule an inspection at a later date.

## **What To Avoid When Inspecting**

Each member of the CAP inspection team must avoid the following topics inspecting a laboratory:

- Financials- Discussion of the laboratory's financial statement
- 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)

## **Citing Deficiencies and Recommendations**

**When to Cite a Deficiency:** Inspectors must cite deficiencies when the intent of a checklist requirement is not being met. 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 temperature on the weekend without corrective actions is evident, then a deficiency must be cited. When serious deficiencies are identified or any question from Part A (Refer to the Inspector's Summation Report (ISR) section below) of the ISR is answered "NO", the appropriate checklist requirement should be cited relating to the issue along with the TLC checklist requirement for the laboratory director responsibility.

When serious deficiencies or systemic issues across the laboratory are identified, the inspection team members must bring them to the attention of the team leader, who will determine whether

a deficiency needs to be cited from the Director Assessment Checklist for the related director responsibility. Examples of serious or system issues include:

- QM plan 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 director not being effectively “carried out”

### **Deficiencies Corrected On Site**

Some deficiencies may be corrected while the inspectors are still on site. **Correction on site is a relatively rare occurrence** and would include 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 Part B deficiency form (ISR pink sheet) how the deficiency was corrected.

Other more extensive deficiencies cannot be corrected on site. Examples include:

- Lack of a quality management plan
- 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 any impacts to patient care (eg, when expired reagents are found to be in use or when incorrect result calculations are identified)
- Recurring deficiencies

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

## How to Cite Deficiencies

Laboratory practices must meet the intent of the checklist requirement. 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.

When citing deficiencies, inspectors must notify the individual serving as the laboratory contact of the deficiency prior to the inspection summation conference in order to provide the laboratory an opportunity for questions or discussion. Deficiencies are recorded on the "Deficiencies" **pink** page of the ISR. Inspectors must:

- 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 differing interpretations of a checklist item occur, the inspector and the respective laboratory representative are encouraged to **call the CAP's technical support line at 800-323-4040 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.

## When to Give a Recommendation

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 later to do so 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”

### How to Offer Recommendations

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

- Write the checklist number and checklist requirement phrase, 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

### Completing the Inspector’s Summation Report (ISR)

The Inspector’s Summation Report (ISR) is used to record the findings of an on-site 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 of the role of the 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.
- **Part B – Deficiency Summary-** includes deficiency forms (pink pages), recommendation forms (yellow pages) recorded by the inspection team, and attestation statements signed by the laboratory director. Comments should be as detailed as needed to support and supplement the cited deficiencies in this section:
  - A copy of the Part B section must be left with the laboratory/biorepository director immediately after the inspection.
  - The Team Leader provides explanatory comments in the ISR Part A regarding unexpected testing encountered, as well as inappropriate checklist 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, all members are to be listed on the reverse side of the form.

**Team Leader Review of the Inspector’s Summation Report (ISR):** The Team Leader will:

- Copy and use blank ISR deficiency pages and recommendation pages as needed (eg, when the number of deficiency citations or recommendations do not fit on a single sheet)
- Ensure that the appropriate supervisors are aware of the deficiencies being cited
  - If, following such discussion, appropriate records have been provided to show that the laboratory was actually in compliance, the deficiency is not be cited. 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 on site, the corrected deficiency still counts as a deficiency. On the ISR inspectors should write “corrected on-site” and describe how the laboratory corrected the deficiency.

**NOTE: If serious deficiencies or systemic issues are identified or any question form 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 TLC Checklist requirement(s) related to laboratory director responsibility.**

Technical specialists at the CAP headquarters are available to assist with questions concerning checklist interpretation during the course of the inspection at 800-323-4040, between 8:00 AM-5:00 PM Central Time.

### **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 members’ questions
- Ensure consistency in recording similar findings (eg, deficiency versus recommendation)
- Identify serious deficiency 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



- 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 Part B deficiency (pink) or recommendation (yellow) form is missing or has been left blank or unsigned. All deficiency and recommendation pages should be accounted for by comparing the completed pages to the list that appears on the pink inspector Summation Report (ISR) Page Index.

## The Summation Conference

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

### Process and Format of the Summation Conference

The summation conference should be scheduled for a time when personnel involved in the inspection can attend, such as the end of the work day. 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.

Beside the laboratory director, attendees should include:

- Key laboratory personnel
- The hospital administrator
- The chief of the medical staff, if applicable

Instructions of each team member, noting inspection assignments. This may be done by the team leader or by each team member as they present their report.

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

- The College of American Pathologist Laboratory Accreditation Program seeks to improve the 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.
- All Phase I deficiencies require a written response. Phase II deficiencies require a response, a plan of corrective action, and supporting documentation that demonstrates implementation.

- “Corrected on Site” deficiencies do not require a response but are counted as deficiencies.

### **Presentation of Deficiencies**

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:

- Discuss recommendations for improvement, as time permits
- 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

Talking points for the team leader at 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.
- Deficiency responses, documentation of corrective action, and documentation of the 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.
- 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 director for supporting the CAP accreditation program.
- The copy of the handwritten Inspection Report Form that you receive today is your official report from the CPA. 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 TLC 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 Page.**
- Arrange for the laboratory/biorepository checklists and other documents that were used during the inspection and any remaining inspection material to be discarded confidentially (eg, immediately shredded).
- Ensure that the inspector Comments section of Part A of the ISR includes:
  - The team leader's opinion of the quality of the laboratory
  - 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 Part B has been photocopied and left with the laboratory director.
- Provide the envelope that contains the response forms and instructions to the laboratory director or designee.
- If after the on-site inspection the team discovers that they forgot to cite a deficiency, the team leader must contact the CAP followed by a letter to the CAP for further instructions.

## Biorepository Inspection

For the inspection of a Biorepository (BAP) facility inspectors are to use the Laboratory General (BAP) and Biorepository Checklists to review:

- Policies and procedures
- The quality management plan
- QC records
- Instrument and equipment maintenance records
- Specimen processing records
- Specimen handling processes, including storage, preservation, and disposition of specimens
- The biorepository's information systems, informed consent and institutional review board practices
- The institution's safe work practices, personnel records, physical facilities and an assessment of the biorepository director

For Biorepository Accreditation Program inspections, the requirements for the assessment of the biorepository director are included in the Laboratory General Checklist. The Team Leader may choose to interview a member of the administration and researchers (users of the biorepository's services) if available, but this step is not required.

**Currently, the Biorepository Accreditation Program does not have specific proficiency testing requirement; however, QC and quality assurance measures are required for all procedures.**

## AFTER THE INSPECTION: INSPECTION TEAM

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### Returning pink and yellow pages of ISR to the CAP:

All deficiency (pink) and recommendations (yellow) ISR pages (including any that might not have been used 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 prepaid mailing envelope and returned to the CAP within two business days of the inspection. The mailer can be used in the 48 contiguous states. Materials from inspections outside the contiguous 48 states (eg, overseas countries, Alaska, and Hawaii) should be returned to the CAP in the prepaid envelope after returning home:

- For laboratories located in the US, the ISR must be returned within two business days of the inspection date
- For international inspections, the ISR must be returned within two days after returning to the US
- For non-routine inspections or an initial inspection of a Florida laboratory, the ISR must be returned within 24 hours

### Process for Returning the ISR:

The ISR can be returned from anywhere in the US. A United Parcel Service (UPS) prepaid label is provided. 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, or
- Taken to any UPS authorized shipping location. To locate the nearest UPS location or to arrange for a special pickup, either the UPS website can be searched or 1-800-PICK=UPS (800-742-5877) can be called.

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 at a later date.

## **Claim for Inspection Reimbursement**

Return of the completed Inspector's Summation Report should not be delayed while waiting for the collection of expense information since 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 represents essential feedback to the CAP and makes program and process improvement possible. Team leaders should complete the Team Leader Evaluation questionnaire and each member of the inspection team should complete a Team Member Evaluation questionnaire.

After the inspection, discard all other inspection packet materials, including the unused checklists. Shred all laboratory-specific information before discarding it in order to maintain confidentiality.

## AFTER THE INSPECTION: LABORATORY

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### Responding to Deficiencies

Before the on-site inspection, the laboratory will receive a Laboratory Inspection Packet that contains the following:

- Set of instructions for completing responses to any deficiencies cited during the inspection
- Blank deficiency response form
- Deficiency response signature page to be signed by the laboratory director and returned with the responses (only one signature page required)

Additional copies of the signature page and deficiency response sheets are available on [cap.org](http://cap.org). They may be downloaded by logging into the e-LAB Solutions Suite on [cap.org](http://cap.org) and are found under the section CAP Accreditation – CAP Accreditation Resources – Accreditation Forms and Instructions.

At the conclusion of the on-site inspection, the inspection team will give the following to the laboratory:

- A blue envelope containing an additional set of deficiency response instructions and blank forms A copy of the Inspector’s Summation Report (ISR) with the deficiencies and recommendations listed

**This copy of the ISR serves as the laboratory’s sole reference for responding to deficiencies. The CAP will provide no additional printed summary. The laboratory must submit appropriate responses to the CAP within 30 calendar days of the inspection.** Failure to respond may result in denial or revocation of accreditation. Approximately one week after the inspection, laboratories may print a typed replica of the inspection report findings by logging into [www.cap.org](http://www.cap.org) behind eLab Solutions Suite (ELSS) - Accreditation-Inspection Summation.

**Phase II** deficiencies require a written response and supporting documentation to demonstrate that the laboratory is now in compliance. Responses should explain why each document was submitted. Deficiencies noted as “corrected-on-site” require no response unless specifically requested by the CAP.

**Phase I** deficiencies require a written response that describes the corrective action taken. Supporting documentation of deficiency correction is not required.

**Phase 0** items require no response.

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 will be changed to a deficiency, 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.)**

Some examples of supporting documents for Phase II deficiencies:

- New or revised policies or procedures with evidence of the 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

Each deficiency requires its own deficiency response form with supporting documentation attached to each form. Helpful hints in completing the response:

- List the checklist requirement number on each supporting document and underline or highlight details of the response, where appropriate
- Make all documentation single-sided
- Avoid using staples, page protectors, or binders (paper clips are preferred)
- Retain a copy of all submitted documentation

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 on the deficiency response form. This can be accomplished by selecting the check-off box, “Challenging this Deficiency” located at the bottom of the Deficiency Response form. Provide an explanation for the challenge. In the “Response” box of the deficiency form; include documentation 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.** Current practice must not be modified if challenging a deficiency. Acceptance of a challenge and subsequent deficiency removal is at the discretion of the regional commissioner. If the challenge is not accepted, additional documentation showing correction of the deficiency may be required, and the deficiency will appear in the listing of deficiencies routinely included in the accreditation packet. Deficiencies that have been approved for removal by the regional 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 On Site**

**Deficiencies corrected -onsite during the inspection will remain in the record as deficiencies.** The CAP reserves the right to request documentation from the laboratory concerning how a deficiency was corrected on site; 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 is to ensure that:**

- Responses for each deficiency using the Deficiency Response Form are submitted to the CAP within 30 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 full compliant at the time of the inspection.
- The Laboratory Director Signature Page is signed
- 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 letter is emailed or faxed to the laboratory director, requesting that documentation be sent to the CAP within 10 days.

The laboratory's regional commissioner will also review the responses. The regional 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)
- Adds 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**

The CAP's accreditation programs have established criteria for expedited processing by the CAP staff and the regional 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.

It is often difficult for laboratories with large numbers of to correct them within 30 days. The regional commissioners may:

- Communicate with the director and the state commissioner to determine whether correction is probable
- 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

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 "Probation Categories" below).

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

- The certificate of accreditation certificate and the accreditation communication sent from the CAP 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 continuing education
- Final list of deficiencies
- Press release (including instructions on how to use the CAP accreditation mark)

**Accreditation is initially valid for two years from the date of the first 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.

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

### **Post-inspection Critique**

Upon receipt of the Inspector's Summation Report from the team leader, 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 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 either 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 or 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. The laboratory using its CAP accreditation to meet regulatory standards must officially cease all testing in all sections affected.

## **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 it 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 express mail. 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. Request 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 [www.cap.org](http://www.cap.org).

## MAINTAINING ACCREDITATION

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### Terms of Accreditation Form

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

#### A CAP-accredited laboratory is obligated to:

- 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 federal, state, local, or foreign);
  - The subject of a validation inspection; or
  - The subject of adverse media attention.

Note: This applies both to laboratories accredited by the CAP and those that have applied for accreditation.

- Promptly notify the CAP when actions by laboratory personnel appear to violate federal, state, 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. The laboratory's quality management plan must incorporate corrective and preventive actions
- Provide a trained inspection team comparable in size and scope to that required for its own inspection, if requested by the CAP, at least once during the two-year accreditation period.
- Participate annually in a CAP-accepted PT program, if applicable; and, if subject to US

- CLIA regulations, meet the PT requirements in subpart H of the US CLIA regulations.
- Promptly notify the CAP (and, if subject to US CLIA regulations, notify the US Department of Health and Human Services (HHS)) in writing 30 days prior to any changes in the following: directorship, location, ownership, insolvency, or bankruptcy.
  - Promptly notify the CAP when there is a change in the laboratory's test menu. That notification must happen before the testing begins or before the laboratory permanently or temporarily discontinues some or all testing.
  - Authorize the CAP to release its inspection and PT data and other information required by law to the appropriate regulatory or oversight agencies, such as the CMS, Department of Veterans' Affairs, Department of Defense, Joint Commission, HFAP (AOA), UNOS, or state/provincial agencies.
  - If the laboratory is subject to US CLIA regulations:
    - Make available on a reasonable basis the laboratory's annual PT results upon request of any person;
    - Allow HHS or its agent to perform a validation or complaint inspection at any time during the laboratory's hours of operation and permit HHS 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.
  - Perform a self-inspection and submit a completed Self-Inspection Deficiency Summary Form in the interim year. (Refer to the Self-Inspection section below.)
  - 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 and printed from cap.org.
  - Submit only documentation and other materials to 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 (see 45 C.F.R. § 164.514(b)), unless the laboratory must submit PHI to CAP in order to respond to a deficiency or patient complaint.
  - 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.

## Maintaining CAP Accreditation Information

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

**Changes in test menu can affect checklist usage or the selected requirements included in the laboratory's customized checklist. It is imperative that the laboratory notify the CAP as soon as its test menu changes.** Submit test menu changes by logging onto cap.org, e-LAB Solutions Suite™. Changes are submitted through the Data Management link.

## Proficiency Testing Participation

Ongoing enrollment and successful participation in proficiency testing is required for maintaining accreditation. Refer to Proficiency Testing sections, for additional information.



## Self-inspection

At the beginning of the second year of the two-year accreditation cycle, laboratories complete a **mandatory self-inspection**, using the checklists sent to the laboratory for this purpose (Biorepositories follow a three-year accreditation cycle). The laboratory must perform the self-inspection and return the Self-Inspection Deficiency Summary form signed by the 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 days of the self-inspection, similar to the correction of deficiencies cited by an on-site 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 denial 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**. (Biorepositories are inspected every three years.) Laboratories will receive a reapplication to confirm their information and the new checklists to be used in the inspection.

## 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 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 intersect with the laboratory. The Joint Commission validates the CAP inspection process by sending an observer along with a CAP inspection team in a small sampling of inspections each year.



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

The CAP Laboratory Accreditation Program has 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.
- The CMS validates the CAP inspection process by sending surveyors to a representative sampling of accredited laboratories, unannounced, within 90 days after completion of CAP inspections. Some validation inspections are conducted simultaneously with CAP inspections.

- **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**

- Department of Defense (DoD)
- Veterans Administration (VA)
- Society for Reproductive Assisted Technology (SART)
- United Network for Organ Sharing (UNOS)
- National Marrow Donor Program (NMDP)

### **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. In addition to the items listed below, laboratories may also refer to Appendix E, CAP Accreditation Tools and Resources.

#### **e-LAB Solutions Suite™**

e-LAB Solutions Suite is the CAP's online portal to manage accreditation and proficiency testing. The portal provides helpful, convenient, and easy-to-use tools to:

- Manage laboratory online access, user permissions, and individual profiles
- Manage laboratory accreditation document, including customized accreditation checklist and changes to test menu/activities
- Complete the application or reapplication
- Enter, review, and approve proficiency testing (PT) results with the interactive online forms
- Connect to CAP Learning tools, assessments, and modules
- Access the Performance Analytics Dashboard

- View and print copies of evaluations, participant summary reports, kit instructions, and result forms
- Access analyte scorecards, the customized PT shipping calendar, and other analytical tools
- Access user guides and PT Exception Investigation Checklist tools
- Receive automated reporting email notifications with e-LAB Solutions Connect™ (eg, proficiency testing data receipt)

#### Performance Analytics Dashboard

The Performance Analytics Dashboard tool assists laboratories to manage risk and compliance proactively. Updated daily, the dashboard gives laboratories a single comprehensive view of all CAP proficiency testing results and accreditation information. This complimentary tool delivers key insights to help identify and mitigate risk while benchmarking laboratory performance. This tool is available to all CAP customers through e-LAB Solutions Suite™.

#### 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 or information to assist with interpreting requirements. eAlerts are communicated by email and posted on the CAP website under Laboratory Improvement, News and Updates.

#### Updating Profiles – My Profile

Personal demographic information is now maintained through the My Profile on the cap.org log in section. Individual users (ie, 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.

#### LAP Policies

The complete listing of all current Laboratory Accreditation Policies is available at [www.cap.org](http://www.cap.org), under CAP Accreditation Resources, Accreditation Standards and Manuals.

## NON-ROUTINE INSPECTIONS

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Any on-site inspection performed in addition to the laboratory's regular on-site inspection is "non-routine". The laboratory is notified about some non-routine inspections, and some are unannounced. The following reasons may require a non-routine inspection.

- 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
- A complaint about the laboratory
- 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
- For new laboratories in the state of Florida, to confirm compliance after the start of patient testing

The laboratory is ordinarily responsible for the cost of the non-routine inspection.

## COMPLAINTS AND INVESTIGATIONS

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### Complaints

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 CAP Accreditation* and/or checklist requirements in a CAP-accredited laboratory or in a laboratory seeking CAP accreditation is regarded as a “complaint”.

#### 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, or an unannounced, on-site inspection of the laboratory. The CAP only investigates complaints related to Standards for CAP Accreditation and/or accreditation checklist requirements. The CAP does not investigate complaints such as billing fraud, 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.

Once information gathering is complete, the Complaints and Investigations Committee will consider the evidence to determine whether the basis for the complaint has been substantiated. The Committee determines what remedial actions, if any, need to be taken. The CAP’s Accreditation Committee will determine whether the facility will continue to be accredited, be 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 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 by mail from the CMS surveyor and is asked to submit responses to CMS following the instructions provided. Laboratories must also submit to CAP a copy of the responses with the plan of correction for the deficiencies cited by CMS including documentation that demonstrates corrective action.

# INTERNATIONAL LABORATORY ACCREDITATION

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## Special Notes on International Accreditation

The College of American Pathologists accredits clinical laboratories both in the US and in other countries. The drive to improve quality of laboratory medicine and ultimately ensuring better patient care is the same, no matter the country. International laboratories with CLIA certificates must comply with their domestic regulations and US regulations. Because of differing government or regulatory requirements, and other factors such as geographic distance, accreditation for international laboratories adds special considerations.

## Requirements for International Laboratories

**Proficiency Testing:** international laboratories seeking CAP accreditation are required to enroll in CAP-accepted proficiency testing programs for a minimum of six (6) months prior to requesting the Accreditation Application. This helps the laboratory establish internal processes that align with the CAP's accreditation requirements. Each separately accredited laboratory must be enrolled in CAP proficiency testing under its own CAP number.

**Laboratory Director:** the laboratory seeking accreditation must have a qualified laboratory director. Typically, the laboratory director must have a MD, DO, PhD, or equivalent education and experience as determined by the CAP. If the laboratory is subject to CLIA regulations, and the laboratory director was educated outside of the US, the laboratory must have records showing that the credentials of the laboratory director are equivalent to those required in the CLIA regulations. The equivalency evaluation must be performed by a nationally recognized organization, such as the National Association Credential Evaluation Services, Inc. (NACES) (<http://www.naces.org>) and the Association of International Credential Evaluators, Inc. (AICE) (<http://www.aice-eval.org>).

**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 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

nationally recognized organization, such as the National Association Credential Evaluation Services, Inc. (NACES) (<http://www.naces.org>) or the Association of International Credential Evaluators, Inc. (AICE) (<http://www.aice-eval.org>). Laboratories not subject to US regulations may authenticate educational achievement according to prevailing governmental rules.

Scope of Disciplines: all disciplines performed by a laboratory in the same location must be listed in the application. The CAP does not accredit portions of laboratories.

Test Volume: 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 section of the application entitled CMS-Reported Test Volumes.

Limitations on Offering of Accreditation: the CAP may be unable to offer accreditation to laboratories in some geographic locations due to country-specific risks such as US trade sanctions or a serious risk to inspector safety.

Documentation: the following documents must be made available in English:

- Laboratory organization structure
- Instrument list
- Quality assurance/improvement programs
- Quality control programs
- Sample procedure for each laboratory discipline

If deficiencies are cited during an on-site inspection, deficiency responses must be submitted to the CAP in English. Supporting documentation to a deficiency may be in a language other than English, providing that the titles, major headings, and key elements demonstrating compliance are all in English.

### **Resources for International Laboratories**

More information and other resources are available online. To access this information, go [www.cap.org](http://www.cap.org). Under the Laboratory Improvement heading, select International Laboratories. In the International Laboratories screen, select the Laboratory Accreditation link.

### **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 date must be mutually agreeable to all laboratory directors if more than laboratory is to be inspected in conjunction with the main clinical laboratory.



- 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 three-month 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.

### **Inspection Teams**

Most often, the team leader for inspection of an international laboratory will be 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. An experienced inspection mentor should assess new inspection team leaders and team members for their inspection techniques.

For international (non-US) inspections, regional team member assignments will be made from the same country or from a country within the closest proximity to the laboratory being inspected. Exceptions may be made with the approval of the chair of the Council on Accreditation, the chair of the Commission on Laboratory Accreditation, or the CAP vice president for the CAP Accreditation Programs. Requests for exceptions should be submitted as early as possible so that the inspector assignment is not impacted if the request is not granted.

### **Inspection Team Travel**

Inspectors originating in the US may travel business class for all flight legs to countries outside of North America. For flights within the US or within destination country, the inspector must travel economy class.

Inspectors originating outside of the US with total flight times exceeding five (5) (excluding layovers) hours may travel business class. Inspectors with flights of five hours or less must travel economy class.

Note: All inspectors inspecting international US Department of Defense contract laboratories must travel economy class (per the US Department of Defense contract with the CAP). The CAP Travel Desk will book premium upgradable economy class airfare. This allows those inspectors who choose to personally upgrade their tickets to do so.

## **Inspection Report**

To control costs to the participating laboratories, international inspections are often grouped in tours. 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 Inspection Summation report (ISR) to the CAP within two days of the inspector's return to the US.

Alternatively, the inspection team leader may return the inspection packet prior to return to the US by UPS. (Refer to AFTER THE INSPECTION: INSPECTION TEAM for shipping instructions.)

## Appendix A: Accreditation Checklist Usage Summary

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*This appendix includes a complete listing of the accreditation checklists along with a brief description and notes relating to the usage of each checklist. 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](http://cap.org). For questions about checklist usage, contact the CAP at 800-323-4040.*

### **All Common Checklist (COM)**

- Proficiency testing
- Procedure manuals
- Specimen collection and handling
- Quality management
- Reporting of results
- Reagents
- Instruments and equipment
- Test method validation/verification
- Reference intervals
- 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. It is not used for inspections of facilities enrolled in the Biorepository Accreditation Program.

### **Anatomic Pathology Checklist (ANP)**

- Surgical pathology
- Intraoperative consultation
- Fine-needle aspiration (FNA)
- Histology
- Immunohistochemistry and immunofluorescence microscopy
- In situ hybridization (ISH)
- Digital image analysis
- Circulating tumor cell analysis
- Flow Cytometry Data Interpretation
- Autopsy pathology
- Electronic microscopy
- In 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
- Information technology systems
- Inventory management systems

- Storage
- Source and Sponsor facility
- Informed consent and institutional review board
- Distribution policies and agreements

NOTE: The BAP Checklist is for facilities enrolled in the Biorepository Accreditation Program only. Additional requirements for Biorepository inspection are found in the Laboratory General Checklist.

***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
- Hemoglobin separation
- Methods, such as TLC, GC, HPLC, MS, RIA, and electrophoresis

***Clinical Biochemical Genetics Checklist (CBG)***

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

***Cytogenetics Checklist (CYG)***

- Cytogenetic studies for constitutional and neoplastic disorders
- In situ hybridization (ISH)
- Cytogenomic microarray analysis

***Cytopathology Checklist (CYP)***

- All gynecologic and nongynecologic cytopathology, including fine-needle aspirates
- Cytology processing and staining
- Cytology screening, manual and automated

***Director Assessment Checklist (TLC)***

- Laboratory director qualifications
- Laboratory director responsibilities

NOTE: One copy of the Director Assessment Checklist is provided to the team leader for each laboratory inspected. It is not used for inspections of facilities enrolled in the Biorepository Accreditation Program.

***Flow Cytometry Checklist (FLO)***

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

### ***Forensic Drug Testing Checklist (FDT)***

- Nonmedical drug testing
- Screening and confirmatory testing for hair, oral fluid, urine, and serum specimens
- 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 malaria and other parasites
- Body fluid cell counts (automated and manual) and differentials
- Semen analysis
- Routine coagulation assays
- Specialized coagulation assays, including factor assays, mixing studies, D-dimer, and platelet function assays

### ***Histocompatibility Checklist (HSC)***

- HLA testing by serologic, molecular, flow cytometry, ELISA, and solid phase methods
- Class I and II antigen typing
- HLA antibody screening, identification, and crossmatching
- DNA typing, including generic, high resolution, and DNA sequence-based typing
- Donor-recipient histocompatibility, including renal, stem cell, and nonrenal transplants
- Stem 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
- Microbial antigen/antibody testing
- ABO/Rh and antibody screening (not-transfusion-related)
- Syphilis serology
- Western blot

### ***Laboratory General Checklist (GEN)***

- Quality management
- Specimen collection
- Chain-of-custody specimen collection and handling
- Direct-to-consumer testing

- Result reporting
- Quality of water
- Laboratory computer services
- Telepathology and remote data assessment
- Whole slide imaging
- Personnel
- Physical facilities
- Laboratory safety
- California laboratory licensure

NOTE: A Laboratory General Checklist is provided for inspections of all laboratories and biorepositories. It contains a separate section that applies only to biorepositories enrolled in the Biorepository Accreditation Program.

***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
- 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 immune system profiles and microbial antigen/antibody testing, non-transfusion-related immunohematology testing, and syphilis serology

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” labs). It is made up of a limited subset of requirements from other checklists. It is **not** appropriate for single-discipline or specialized laboratories; such laboratories must use the relevant discipline-specific checklist(s).

The Limited Service Checklist does **not** cover the following services:

- Hematology — bone marrow evaluation, blood film examination for malaria, and abnormal hemoglobin detection (except the sickling test)
- Coagulation — factor assays, mixing studies, and platelet function testing
- Chemistry — toxicology (other than drug of abuse screening and serum or whole blood alcohol), spectrophotometry, electrophoresis, chromatography, AFP, RIA, and sweat testing for cystic fibrosis
- Microbiology — cultures beyond initial plating, mycology other than KOH or wet preps, mycobacteriology, parasitology other than pinworm preparations, virology, and molecular microbiology, including DNA testing using amplified and non-amplified methods.
- Transfusion medicine — any testing other than ABO/Rh and antibody screening (non-transfusion), and direct antiglobulin testing

- Separate discipline-specific checklists are required for: 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 malaria and other parasites
- Molecular microbiology, including FDA-cleared/approved method, modified methods, and laboratory-developed methods
- Microbial identification, using methods including MALDI-TOF MS, GC, HPLC, 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, hematology, inherited disease, pharmacogenomics, HLA typing, relationship testing, and forensic identity applications
- Molecular assay validation
- Methods, such as electrophoresis, PCR, arrays, in situ hybridization, and sequencing
- Next-generation sequencing, including noninvasive screening of maternal plasma to detect fetal aneuploidy
- Stem cell engraftment monitoring

***Point-of-Care Testing Checklist (POC)***

- Kit tests or hand-carried instruments (or otherwise transported to the patient location)
- Waived and moderate-complexity testing
- POC blood gas analysis
- D-dimer studies
- 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 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



- Antisperm antibody testing
- Sperm processing for therapeutic insemination
- Embryology procedures
- Embryo and gamete cryopreservation
- Reproductive 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
- Hematopoietic progenitor cell services
- 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

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Test volumes must be reported separately for each laboratory section and are sub-divided into the following categories:

**CMS-reported** — Include test volumes for all high- and moderate-complexity testing performed in each section as reported to the CMS annually. Do not include calculated results (eg, A/G ratio, MCH, base excess, anion gap, iron saturation, INR), quality control tests, quality assurance, proficiency testing assays and tests routinely sent out to a referral laboratory.

Note: International laboratories (including Canada) that have a CLIA certificate are to report only the test volume for moderate- and high-complexity testing performed on patient specimens received from the US in the CMS reporting area.

**CMS-nonreported** — Include test volumes for waived testing and other tests or procedures to be inspected that are recognized by the CMS (eg, autopsy and employee drug testing) for each section. These totals are needed for on-site inspection planning.

Note: Laboratories that do not have a CLIA license must report **ALL** test volumes in the “CMS-nonreported” category.

Specialty information:

| Specialty          | Instruction  |
|--------------------|--|
| Chemistry          | For panel testing, count each noncalculated analyte individually (eg, a Lipid Panel consisting of a total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides equals four tests).  |
| Cytogenetics       | Determine the number of tests by the number of specimens processed on each patient (eg, count a bone marrow and a venous blood specimen received on the same patient as two tests). Count each special stain ordered and reported as a separate test.  |
| Cytology           | For manual gynecologic and nongynecologic cytology, count each slide (not each case) as one test for both Pap smears and nongynecologic cytology. Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted 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     | For panel testing, count each measured individual analyte (eg, a Lymphocyte Subset panel consisting of T cells, B cells, and NK cells equals three tests)  |
| Hematology         | Count each <i>measured</i> analyte of a complete blood count that is ordered and reported separately. Count white blood cell differentials as one test.  |
| Histocompatibility | Count each HLA typing, each HLA antibody screen, and each HLA crossmatch as one test. For example, count a B-cell crossmatch, a T-cell   |

|                       |  |
|-----------------------|--|
|                       | crossmatch, and an auto-crossmatch between the same donor and recipient pair as three tests. Count each disease-associated antigen result (such as HLA-B27) as one test.   |
| Histopathology        | Count each gross examination as a test. Count each block as a test (including blocked frozen sections). Count each special stain. Count each preliminary and final report as a test. Laboratories performing grossing and/or interpretation must report their test volume. Processing and staining are not tests and must not be counted in the test volume. Count autopsy services in the “CMS-nonreported” category.”  |
| Immunohematology      | Count each ABO, Rh, antibody screen, crossmatch, direct antiglobulin test and antibody identification as separate tests.   |
| Immunology            | Testing for allergens are to be counted as one test per individual allergen.   |
| Microbiology          | Count susceptibility testing as one test for each group of antibiotics used to determine sensitivity for one organism. Count cultures as one per test request from each specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each Gram stain or acid-fast bacteria (AFB) smear requested from the primary source is counted as one. For example, if the order for a sputum specimen includes a routine bacteriology culture, Gram stain, a mycology test, an AFB smear and an acid-fast bacillus culture, this would equal five tests. For parasitology, the direct smear, the concentration technique and the review of the prepared slide are counted as one test. |
| Molecular Pathology   | For genetic tests, each test ordered and reported is counted as one test. For Next Generation Sequencing, every test ordered (eg, a gene panel, exome or genome) is counted as one test with one report.   |
| Point-of-Care Testing | Point-of-Care (POC) testing should be counted according to the specialty of the test. For example, if a prothrombin time is done as part of POC testing it is to be counted the same as if it were done in a coagulation department. Similarly, a macroscopic (dipstick) urinalysis test done as part of POC should follow the urinalysis criteria listed below. Count nonwaived POC tests as CMS-reported and waived POC tests as CMS-nonreported.  |
| Urinalysis            | Count macroscopic and microscopic examinations as separate tests. Dipstick testing is counted 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; [www.cms.gov](http://www.cms.gov)

## Appendix C: Retention of Laboratory Records and Materials

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The College of American Pathologists (CAP) recommends the following minimum requirements for retention of laboratory records and materials. These requirements meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA). These guidelines match the CAP's most recent policy as of September 2016; they are also available on [www.cap.org](http://www.cap.org). 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 or other needs. Some state regulations and other 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 state or federal laws should be reviewed carefully when individual laboratories develop their record retention policies.

| MATERIAL/RECORD  | PERIOD OF RETENTION         |
|--|-----------------------------|
| <b><i>General Laboratory</i></b>                         |                             |
| Accession log  | 2 years                     |
| Maintenance/instrument maintenance records               | 2 years                     |
| Quality control records                                  | 2 years                     |
| <b><i>Surgical Pathology (including bone marrow)</i></b> |                             |
| Wet tissue   | 2 weeks after final report  |
| Paraffin blocks  | 10 years                    |
| Slides   | 10 years                    |
| Reports  | 10 years                    |
| <b><i>Cytology</i></b>                                   |                             |
| Slides (negative-unsatisfactory)                         | 5 years                     |
| Slides (suspicious-positive)                             | 5 years                     |
| Fine-needle aspiration slides                            | 10 years                    |
| Reports  | 10 years                    |
| <b><i>Non-Forensic Autopsy</i></b>                       |                             |
| Wet tissue   | 3 months after final report |
| Paraffin blocks  | 10 years                    |
| Slides   | 10 years                    |
| Reports  | 10 years                    |

**MATERIAL/RECORD****PERIOD OF RETENTION*****Forensic Autopsy***

|   |              |
|---|--------------|
| Wet stock tissue                                | 1 year       |
| Paraffin blocks                                 | 10 years     |
| Reports   | Indefinitely |
| Slides  | 10 years     |
| Gross photographs/images                        | Indefinitely |
| Accession log                                   | Indefinitely |
| Body fluids and tissues for toxicology          | 1 year       |
| Representative sample suitable for DNA analysis | Indefinitely |

***Clinical Pathology***

|   |           |
|---|-----------|
| Patient test records  | 2 years   |
| Serum/heparinized or EDTA plasma/CSF/<br>body fluids (except urine) | 48 hours  |
| Urine   | 24 hours* |
| Peripheral blood smears/body fluid smears                           | 7 days    |
| Permanently stained slides—microbiology<br>(Gram, trichrome, etc)   | 7 days    |

*\*Exceptions may be made at the discretion of the laboratory director.*

***Cytogenetics***

|   |   |
|---|---|
| Permanently stained slides                          | 3 years   |
| Fluorochrome-stained slides                         | At the discretion of the<br>laboratory director |
| Wet specimen/tissue                                 | Until adequate metaphase<br>cells are obtained  |
| Fixed-cell pellet                                   | 2 weeks after final report                      |
| Final reports                                       | 20 years  |
| Diagnostic images (digitized, prints, or negatives) | 20 years  |

***Flow Cytometry***

|                                |          |
|--------------------------------|----------|
| Gated dot plots and histograms | 10 years |
|--------------------------------|----------|

**MATERIAL/RECORD****PERIOD OF RETENTION*****Blood Bank***

|  |                         |
|--|-------------------------|
| Donor and recipient records  | 10 years                |
| Patient records  | 10 years                |
| Records of employee signatures,<br>initials, and identification codes  | 10 years                |
| Quality control records  | 5 years                 |
| Records of indefinitely deferred donors,<br>permanently deferred donors, or donors<br>placed under surveillance for the recipients<br>protection (eg, those donors that are<br>hepatitis B core positive once, donors<br>implicated in a hepatitis positive recipient) | Indefinitely            |
| Specimens from blood donors<br>units and recipients  | 7 days post-transfusion |

## Appendix D: Glossary of Terms

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Additional definitions are found in the Accreditation Checklists.

### **Accreditation**

The determination by the CAP that a laboratory or biorepository has successfully met the *Standards for Laboratory Accreditation* of the College of American Pathologists' Laboratory Accreditation Programs.

### **Accreditation Checklist**

A detailed series of requirements designed to evaluate whether the laboratory or biorepository meets the standards set forth in the CAP's *Standards for Laboratory Accreditation*. Each checklist is discipline-specific and 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. Biorepositories follow a three-year accreditation cycle.

### **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 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; however during the review process, a need has been identified for an interim follow-up assessment to monitor ongoing compliance.

### **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 product is available, are not appropriate for the method or patient population served by the laboratory, or participation is not required by the accreditation program.

**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 End 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, and for biorepositories, every three years).

**Application**

Forms completed by the laboratory or biorepository to initiate the accreditation process.

**Authority**

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

**CAP 15189**

- CAP 15189 is a voluntary, nonregulated accreditation to the ISO 15189:2012 Standard as published by the International Organization of Standardization.
- CAP 15189 incorporates a quality management system to include all facets of laboratory management, technical testing, and interacting departments.
- CAP 15189 is 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.
- CAP 15189 does not replace the CAP's CLIA-based Laboratory Accreditation Program, but rather complements CAP accreditation and other quality systems.

**CAP-accepted PT Programs**

Proficiency testing (PT) programs which have met the CAP's criteria. Acceptance is by individual analyte.

**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.

**CLA**

See *Commission on Laboratory Accreditation*.

**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 and management of disease. A clinical laboratory usually has one CLIA number, is located in one building or campus under the leadership of a single 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 Medicaid and Medicare 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.

**Commission on Laboratory Accreditation (CLA)**

The operational group that conducts the laboratory accreditation programs of the College of American Pathologists. The commission is composed of a chair, vice chair, CLA committee chairs, representative regional commissioners, and other appointees. Each regional commissioner is responsible for the laboratories in a specific geographic area or of a particular class. Committee chairs are responsible for specific activities such as continuous compliance, education, or the inspection process.

**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.

**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 for and oversees the work of the Commission on Laboratory Accreditation.

**Credentialing**

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

**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).

**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**

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. 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).

**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 Team Leader**

The individual responsible for assembling and leading a team of inspectors.

**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, specialty inspector lists and Inspector's Summation Report forms, etc.

**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 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 on-site inspection that contains the laboratory -specific activity menu, checklists, deficiency response sheets, and instructions on how and when to respond to deficiencies.

**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-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.

### **Limited Service Laboratory**

A clinical laboratory whose scope of offered services is limited to commonly performed laboratory tests or procedures (irrespective of workload).

### **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 on-site inspection. Non-routine inspections may be performed for a variety of reasons, including (without limitation) a change of 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 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**

1) Set of basic principles or guidelines that direct or restrict the facility's plans, actions, and decisions; 2) Statement that tells what should or should not be done.

**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**

1) Specified way to carry out an activity of a process (also referred to by ISO as "work instructions"); 2) Set of steps performed that tells "how to do it" to achieve a specified outcome, including decisions to be made.

## **Process**

1) Set of interrelated or interacting activities that transforms inputs into outputs; 2) Series of events, stages, or phases that takes place over time that tells "what happens" or "how it works."

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

The determination of laboratory testing performance by means of interlaboratory comparisons, in which a PT program periodically sends multiple specimens to members of a group of laboratories for analysis and/or identification. The program then compares each laboratory's results with those of other laboratories in the group and/or with an assigned value. Proficiency testing serves the purposes of education, laboratory improvement, and regulation.

## **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 assure 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.

**Reapplication**

The form completed by a currently accredited laboratory to enable continued participation in the CAP's laboratory accreditation programs. The form must be completed prior to the next routine inspection.

**Referring Laboratory**

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

**Referral Laboratory**

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

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

Unsatisfactory PT performance for a CLIA-regulated analyte/test/subspecialty in three consecutive, three out of four events, or two sets of "two out of three" (a failure in one event may be included in more than one set) over six 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.

**Root Cause Analysis**

A process for identifying the basic or causal factors that underlie variation in performance. A root cause analysis focuses primarily on systems and processes, not individual performance. It progresses from special causes related to a particular incident to common causes embedded within organizational processes and may identify improvements in processes or systems that decrease the likelihood of such events in the future.

**RLAP**

See *Reproductive Laboratory Accreditation Program*.

**Section Director**

The individual who is responsible for the medical, 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 on-site inspections.

**Special Function Laboratory**

Any laboratory separately accredited from the main laboratory, but which provides services that fall within the general definition of clinical laboratory services. Examples include: blood gas studies performed by the respiratory therapy department; special hematology procedures provided by the pediatrics department.

**Staff Inspector/Inspection Specialist**

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

**Standards**

The *Standards for Laboratory Accreditation* as published by the CAP Council on Accreditation. The *Standards* are the core principles of the CAP's laboratory 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 sections(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 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 the pathologist views 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. 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 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 *Standards for Laboratory Accreditation*.

### **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 the concentration 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 nonregulated 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 nonregulated 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.

### **Visitor**

An individual in 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 labs 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 lab, if asked.

### **Waived**

A category of tests defined by Clinical Laboratory Improvement Amendments of 1988 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.

| Tool  | Location   | Description  |
|---|--|--|
| Accreditation Checklist Download *  | Log into e-LAB Solution Suite – Accreditation Checklists   | Online checklist download tool <ul style="list-style-type: none"> <li>• Select from different versions:               <ul style="list-style-type: none"> <li>○ Master (displays all requirements)</li> <li>○ Custom (displays applicable requirements based on lab test menu)</li> <li>○ Changes only (displays changes from previous to current edition)</li> </ul> </li> <li>• Choose the desired format:               <ul style="list-style-type: none"> <li>○ PDF</li> <li>○ Word/XML</li> <li>○ Excel</li> </ul> </li> </ul> |
| 2017 Checklist Edition Changes: Deleted, Merged, and Moved Requirements * | Log into e-LAB Solution Suite – CAP Accreditation Resources – Accreditation Standards and Manuals                    | Table to quickly identify changes in requirement numbers from one edition to another   |
| <a href="#">Accredited Laboratory Directory</a>                           | CAP Home – Laboratory Improvement – Accreditation – Accredited Laboratory Directory                                  | Searchable database of CAP-accredited laboratories or biorepositories  |
| <a href="#">Focus on Compliance Webinars</a>                              | CAP Home – Laboratory Improvement – Accreditation – Accreditation Learning – Focus on Compliance Webinars – View All | Registration information for the complimentary series of accreditation educational webinars <ul style="list-style-type: none"> <li>• For laboratory directors, managers, and technologists</li> <li>• Provides expert knowledge and regulatory compliance insight</li> </ul>   |
| Focus on Compliance Webinars – Archive *                                  | Log into e-LAB Solution Suite – CAP Accreditation Resources – Educational Resources – Learn More                     | Archived webinar materials including: <ul style="list-style-type: none"> <li>• Presentations and tool kits</li> <li>• Question/Answers</li> </ul>  |



| Tool   | Location  | Description  |
|--|---|--|
| <a href="#">Inspector Training</a>                                   | CAP Home – Laboratory Improvement – Accreditation – Accreditation Learning – Inspector Training - View Courses                    | Online Inspector Training modules for: <ul style="list-style-type: none"> <li>• Team leaders</li> <li>• Team members</li> <li>• Biorepository inspectors</li> </ul>  |
| <a href="#">Fast Focus on Compliance</a>                             | CAP Home – Laboratory Improvement – Accreditation – Accreditation Learning – Inspector Training - View Courses                    | Mini-training vignettes for inspectors: <ul style="list-style-type: none"> <li>• Use real world examples</li> <li>• Provide practical approaches to handle new and perplexing topics</li> </ul>  |
| <a href="#">eAlerts</a>  | CAP Home – Laboratory Improvement – News and Updates  | Links to important notifications sent to laboratories about changes to the CAP's accreditation programs  |
| <a href="#">Laboratory Personnel Evaluation Roster</a>               | CAP Home – Laboratory Improvement – Accreditation – Regulatory Information – Personnel Evaluation Form Requirements               | Web page includes the CAP's personnel roster form and additional tools, including: <ul style="list-style-type: none"> <li>• Instructions for completing the personnel roster</li> <li>• Listing of CAP Personnel Requirements by Test Complexity</li> <li>• Personnel frequently asked questions</li> </ul>  |
| <a href="#">Individualized Quality Control Plan (IQCP) Resources</a> | CAP Home – Laboratory Improvement – Accreditation – Regulatory Information – Individualized Quality Control Plan (IQCP) Resources | Web page includes the following tools: <ul style="list-style-type: none"> <li>• IQCP frequently asked questions</li> <li>• IQCP Eligibility Flow Chart</li> <li>• IQCP List form and instructions</li> <li>• Annual Assessment of IQCP - example form</li> <li>• Jointly developed Microbiology tools for AST, ID systems, and media</li> <li>• Inspector tip sheet</li> </ul> |

| Tool   | Location  | Description  |
|--|---|--|
| Laboratories with California Laboratory Licensure Frequently Asked Questions * | Log into e-LAB Solution Suite – CAP Accreditation Resources – Accreditation Guidance Documents                                    | Answers to frequently asked questions about the new Laboratory General Checklist requirements for laboratories that have a California clinical laboratory license  |
| Laboratory Accreditation Manual, 2018 Edition *                                | Log into e-LAB Solution Suite – CAP Accreditation Resources – Accreditation Standards and Manuals                                 | Resource for laboratories and inspectors on the inspection and accreditation processes   |
| PT/External Quality Assurance Tool Box *                                       | Log into e-LAB Solution Suite – CAP Accreditation Resources – Accreditation Forms and Instructions                                | Proficiency testing (PT) resources including: <ul style="list-style-type: none"> <li>• PT compliance frequently asked questions</li> <li>• PT troubleshooting guides</li> <li>• PT compliance notice forms and instructions</li> </ul>   |
| Minimum Guidelines for the Retention of Laboratory Records and Materials *     | Log into e-LAB Solution Suite – CAP Accreditation Resources – Accreditation Guidance Documents                                    | Document contains CAP recommendations for retention of laboratory records and materials  |
| Laboratory Accreditation Forms *   | Log into e-LAB Solution Suite – CAP Accreditation Resources – Accreditation Forms and Instructions                                | The following forms can be downloaded: <ul style="list-style-type: none"> <li>• Test menu changes</li> <li>• Notification for changes to laboratory director, laboratory name, location, and ownership</li> <li>• Personnel roster</li> <li>• Deficiency response</li> <li>• Self-inspection</li> <li>• IQCP</li> <li>• HIPAA: Business Associate Agreement</li> </ul> |
| <a href="#">Guide to CAP Accreditation for International Participants</a>      | CAP Home – Laboratory Improvement – Accreditation – Regulatory Information – Individualized Quality Control Plan (IQCP) Resources | Contains important information for international laboratories that are considering applying to the CAP for accreditation   |

| Tool   | Location  | Description  |
|--|---|--|
| <a href="#">CAP Cancer Protocols and Templates</a> | CAP Home – Protocols and Guidelines – Cancer Protocols  | Guidelines for collecting the essential data elements for complete reporting of malignant tumors and optimal patient care  |
| <a href="#">CAP Guidelines</a>                     | CAP Home – Protocols and Guidelines – Current CAP Guidelines  | Evidenced-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 Accreditation Programs Policy Manual           | CAP Home – Laboratory Improvement – CAP Accreditation Resources – Accreditation Standards and Manuals | CAP Accreditation Program administrative policies approved by the CAP's Council on Accreditation   |

**Call the Lead Inspection Analyst at 800-323-4040 ext. 7380** or 847-832-7380 for information about

- Inspector demographic changes
- Reimbursement for inspection
- Specialty inspector lists

**Call the Systems Staff Coordinator at 800-323-4040 ext. 7279** or 847-832-7279 for information about

- Systems inspections

**Call the Checklist Operations Specialist at 800-323-4040 ext. 7545** or 847-832-7545 for

- Historical checklists
- Paper copies of checklists

**Call the Staff Inspector Coordinator at 800-323-4040 ext. 7279** or 847-832-7279 for

- Staff inspector information

**Call a Proficiency Testing Compliance Group Representative at 800-323-4040 ext. 6052** or 847-832-7000 ext. 6052 for questions regarding

- Proficiency testing enrollment, participation, or performance compliance notices
- CAP-accepted proficiency testing programs

**Call the Education Division at 800-323-4040** for questions about

- Education programs for laboratories and/or inspectors
- Continuing education (CME/ CE) certificates
- Registering for accreditation related education programs

**Call the Inspection Assignment Specialist at 800-323-4040** or 847-832-7000 for questions about

- Inspector assignment



## Let Them Know You've Earned the Mark

The CAP certification mark recognizes your organization for achieving CAP accreditation, something you share with more than 7,500 laboratories worldwide. The mark is a way to display to peers, patients, and the public that you've attained CAP accreditation through the most respected and recognized laboratory accreditation program in the world.

Proudly display your CAP certification mark on your website, advertisements, laboratory reports, and in your patient areas to communicate your CAP accreditation status. We know you're proud, and we're proud, too.

To access and download your CAP certification mark, please log in to your e-LAB Solutions™ account, or contact the CAP Customer Contact Center.

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